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Recommended Citation

Krafft, J., Ong, C. W., Davis, C. H., Petersen, J. M., Levin, M. E., & Twohig, M. P. (In press). An open trial of group acceptance and commitment therapy (ACT) with an adjunctive mobile app for generalized anxiety disorder (GAD). *Cognitive and Behavioral Practice*.

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An open trial of group acceptance and commitment therapy (ACT) with an adjunctive mobile app for generalized anxiety disorder (GAD)

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Abstract

Generalized anxiety disorder (GAD) is a common and debilitating condition. Effective treatments exist, but they are time- and resource-intensive. This study tested the initial efficacy and acceptability of a novel treatment protocol designed to increase efficiency: acceptance and commitment therapy (ACT) taught in groups and through an adjunctive mobile app. Participants were 21 individuals with GAD who received six weeks of 2-hour group ACT sessions as well as access to an adjunctive ACT mobile app. Significant improvements occurred in worry, anxiety, social functioning, and depression as well as relevant processes (psychological inflexibility, anxiety-related cognitive fusion). In-the-moment improvements were also observed in symptoms and ACT processes immediately after completing mobile app sessions. Treatment was perceived as credible and acceptable overall. However, rates of reliable and clinically significant change were low, and app usage did not correlate with change in worry. Overall, this study suggests that an efficient, brief ACT group intervention combined with a mobile app may lead to improvements in GAD but may not be sufficient for clinically significant change. A detailed overview of the treatment is included, and guidance for clinicians interested in implementing this protocol is discussed.

Keywords: worry; technology; mindfulness; group therapy; psychological flexibility

Introduction

Generalized anxiety disorder (GAD) is a debilitating anxiety disorder characterized by persistent tension and worry related to a wide range of topics (American Psychiatric Association, 2013). Global studies indicate 1.8% annual prevalence in adults around the world, with a 3.7% lifetime prevalence (Ruscio et al., 2017). GAD is highly impairing and commonly comorbid with other mental health difficulties, particularly depression and other anxiety disorders (Ruscio et al., 2017). Impairment in GAD spans across a wide range of domains, but GAD has a stronger correlation between symptoms and disrupted social functioning when compared to other anxiety disorders (McKnight et al., 2016).

There are effective treatments for GAD, particularly cognitive behavioral therapy (CBT; Cuijpers et al., 2014). However, the median number of CBT therapy sessions for individuals with GAD is twelve (Cuijpers et al., 2014), and effective GAD treatment in typical practice may require 15 to 25 sessions (Hoyer & Gloster, 2009), representing a significant investment of resources. Promising approaches for streamlining the treatment of GAD include group formats, the integration of adjunctive technology, and acceptance-based treatment, also called acceptance and commitment therapy (ACT) or acceptance-based behavior therapy (ABBT; Hayes-Skelton, Roemer, & Orsillo, 2013; Roemer, Orsillo, & Salters-Pedneault, 2008). The aims of the present study are to examine the preliminary feasibility and effectiveness of combining group ACT with an adjunctive mobile application as a brief and cost-effective potential treatment for GAD.

ACT is a modern approach to CBT, aiming to improve quality of life by increasing psychological flexibility and reducing experiential avoidance. Psychological flexibility is the ability to engage with values-based action and remain in the present moment while accepting whatever internal experiences arise, contrasted with psychological inflexibility (a process in

which a rigid, literal, and avoidant relationship with internal experiences dominates over behavior; S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006). GAD symptoms are highly correlated with psychological inflexibility (Bluett et al., 2014).

There is significant preliminary evidence for ACT and ABBT as treatments for GAD. In a randomized controlled trial (RCT) of ABBT for GAD, 63.3 to 80% of participants experienced clinically significant change and ABBT improved outcomes to an equivalent degree compared to an applied relaxation intervention (Hayes-Skelton, Orsillo, et al., 2013). In another recent RCT of ACT for GAD, ACT resulted in equivalent improvement relative to cognitive therapy and Rational-Emotive Behavior Therapy (Stefan et al., 2019). In that trial, 79.2% of participants fell below the GAD clinical cut-off after receiving ACT (Stefan et al., 2019). ABBT has also been shown to work through its hypothesized mechanisms: changes in emotional acceptance and valued behavior (S. A. Hayes et al., 2010).

Despite the treatment options for GAD, treatment remains expensive and long (Cuijpers et al., 2014; Newman, 2000). Thus, it is necessary to consider how to make treatment more efficient. One method to reduce time and costs may be to utilize group treatment formats (Fogarty et al., 2019). Preliminary research supports the use of group ACT as a treatment for GAD. In an RCT of group ACT for GAD, an ACT group and CBT group for GAD had largely equivalent results, although the ACT group experienced a greater decrease in worrying symptoms from baseline to posttreatment (Avdagic et al., 2014). The majority (78.9%) of participants reported significant changes in worry and improvements in quality of life (Avdagic et al., 2014). In an Iranian trial, participants in female outpatient groups for GAD reported significantly reduced metacognitions and anxiety as compared to a waitlist (Fathi et al., 2017). Thus, group ACT shows potential as a cost-effective alternative for GAD treatment.

Another method to reduce treatment costs may be to include technology such as mobile applications. Early research demonstrates promise of using mobile apps adjunctive to treatment; one small meta-analysis found that mobile technology use was associated with better treatment outcomes ($d = .34$) and had a significant added benefit to in-person treatment ($d = .27$; Lindhiem, Bennett, Rosen, & Silk, 2015). Because mobile apps are available at any time, it is possible that they adjunctively encourage generalization through more frequent practice of therapy skills (Levin et al., 2017). Greater generalization could potentially even result in a reduced number of sessions needed for effective treatment. Adjunctive apps also make it easier for clients to refer back to skills learned and practice them, enhancing maintenance of treatment gains. However, there is a dearth of research available on the use of ACT mobile apps to treat GAD, and on adjunctive mobile apps to augment ACT more broadly. Thus, an adjunctive app with ACT as a treatment for GAD merits investigation.

Present study

In the present study, we tested ACT in a six-session group therapy format for individuals with GAD incorporating the use of a mobile app with ACT skills as an additional support for participants between sessions. We used an adapted version of the ACT Daily app, which has been found to be beneficial in previous studies (*citation removed for review*). We predicted that group ACT would lead to improvement in worry, anxiety, comorbid depression, functioning, and well-being. We also predicted that group ACT would lead to improvement in relevant processes of change, namely psychological inflexibility, anxiety-related fusion, mindfulness, and progress towards values. Lastly, we predicted that combining a mobile app with group ACT would be credible, acceptable, and satisfactory to participants. Despite its small sample, the present study has significant implications for streamlining treatments for GAD in the future.

Methods

Participants

This trial was preregistered as XXXX (*removed for review*) at ClinicalTrials.gov. We received approval for this study from the local Institutional Review Board and all participants provided informed consent. We recruited individuals in the community seeking treatment for worry through flyers, class announcements, online announcements, and provider referrals. One participant received research participation credit; no other compensation was provided.

Interested individuals completed the Generalized Anxiety Disorder-7 Questionnaire (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) online as an initial screening to determine the presence of anxiety symptoms. We invited those who scored at or above the clinical cutoff of 10 for an in-person screening interview, which was completed by a graduate research assistant to determine study eligibility. Inclusion/exclusion criteria were as follows: (a) at least 18 years old, (b) fluent in English, (c) meeting diagnostic criteria for GAD, (d) no serious mental illness (e.g., bipolar disorder, psychosis), (e) not currently receiving other psychological treatment, and (f) interested in participating in group treatment for worry. We assessed diagnostic criteria using the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998).

In total, we enrolled 21 participants who met inclusion criteria. Participants were largely young ($M = 22.81$), female (85.71%), non-Hispanic (95.24%), and White (90.48%, see Table 1 for details). Although the study was open to community members, most participants were university students (85.71%). Comorbid diagnoses identified were social anxiety disorder (SAD; $n = 7$), major depressive disorder (MDD; $n = 5$), panic disorder ($n = 4$), agoraphobia ($n = 3$), PTSD ($n = 3$), bulimia nervosa ($n = 2$), and obsessive-compulsive disorder (OCD; $n = 1$).

Of the 21 enrolled, 3 withdrew prior to the intervention. Overall, 18 individuals participated in 4 group cohorts, with an average cohort size of 4.5 (see Figure 1).

Measures

We administered each of the following self-report measures at three timepoints: baseline (prior to beginning the first group session), posttreatment (following the sixth and final weekly group therapy session), and a one-month follow-up assessment. We administered all assessments through Qualtrics, a secure online survey platform.

Anxiety. We used two standardized measures of anxiety/worry, both with adequate psychometric properties. The Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) is a 16-item measure of pathological worry which has shown reliability and validity, and is associated with clinical anxiety disorders (Molina & Borkovec, 1994). Worry measured with the PSWQ was the pre-specified, primary outcome measure. Internal consistency in the present study was acceptable ($\alpha = 0.77$). The State-Trait Anxiety Inventory–Trait Subscale (STAI-T; Spielberger, 1983) is a reliable and valid 20-item questionnaire assessing the severity of long-standing, or trait, qualities of anxiety. Reliability was good in this sample ($\alpha = 0.82$).

Depression. Given its frequent comorbidity with anxiety disorders, we assessed levels of depression using the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), a widely-used 21-item scale of depression symptoms that has demonstrated convergent and divergent validity (Beck et al., 1996). Reliability was excellent for this sample ($\alpha = 0.91$).

Quality of life and positive mental health. To assess quality of life, we administered the Satisfaction with Social Roles and Activities 8-item short form measure of the Patient-Reported Outcomes Measurement Information System (PROMIS; Hahn et al., 2014), a reliable and valid series of brief psychometric instruments capturing a variety of aspects of psychological health. Reliability was excellent for this sample ($\alpha = 0.92$). We chose this particular PROMIS measure as a means of capturing satisfaction and engagement in various social and familial roles

pertaining to overall quality of life. Additionally, to assess levels of positive mental health, we administered the Mental Health Continuum–Short Form (MHC-SF; Lamers, Westerhof, Bohlmeijer, Ten Klooster, & Keyes, 2011). The MHC-SF is a 14-item measure of emotional, psychological, and social wellbeing that has shown good reliability and validity (Lamers et al., 2011). Internal consistency was excellent ($\alpha = 0.92$) in the present study.

Processes of change. We administered a number of additional measures to assess potential psychological processes of change. To measure psychological inflexibility/experiential avoidance, a central target of ACT interventions, we used the Acceptance and Action Questionnaire-II (AAQ-II; Bond et al., 2011). The AAQ-II has demonstrated strong reliability and validity, including with anxiety disorder samples (Fledderus et al., 2012). Internal consistency in this sample was good ($\alpha = 0.84$). Another important aim of ACT is to reduce cognitive fusion, or rigid attachment to thoughts and feelings as “true” or believable. Thus, we administered the Believability of Anxious Feelings and Thoughts Questionnaire (BAFT; Herzberg et al., 2012), a 16-item measure of anxiety-related cognitive fusion which has shown reliability and validity in both nonclinical and clinically-anxious samples (Herzberg et al., 2012). Internal consistency was good ($\alpha = 0.88$). We additionally assessed mindfulness, another core process in ACT, using the Mindful Attention Awareness Scale (K. W. Brown & Ryan, 2003). The MAAS is a 15-item measure of mindful attention which has shown reliability and validity, and internal consistency in this trial was good ($\alpha = 0.84$). To assess progress towards one’s personal values, also targeted in ACT, we administered the Valuing Questionnaire–Progress subscale (VQ; Smout, Davies, Burns, & Christie, 2014), which has demonstrated reliability and validity. In this study, reliability was good ($\alpha = 0.85$).

Treatment expectancy and satisfaction. To assess perceived credibility/expectancy of our ACT group intervention for worry, we administered the 6-item Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000) after the first session. The CEQ has shown reliability and validity, and the construct of expectancy has additionally been associated with improved clinical outcomes (Smeets et al., 2008). The CEQ is typically standardized and used for comparisons or to control for the effects of treatment credibility. However, in this study it was used descriptively to assess perceptions of treatment credibility. Scores on item 5 were transformed from a 1-9 scale to a 0-100% scale in order to calculate an average expectancy. Reliability of both CEQ subscales was acceptable (Credibility $\alpha = 0.73$; Expectancy $\alpha = 0.71$).

At the end of treatment, we assessed satisfaction with the intervention using an adapted, 7-item version of the Treatment Evaluation Inventory–Short Form (Kelley et al., 1989). This version has been used in previous studies (Twohig et al., 2018), and scores over 21 indicate a treatment is more acceptable than not. Internal consistency was marginal ($\alpha = 0.69$). As our intervention was a previously untested design, we developed a series of novel satisfaction questions administered at posttreatment. These included items such as “Overall, I found the group helpful,” and “Overall, I found the mobile app helpful,” and were rated on a five-point scale from 1 (“strongly disagree”) to 5 (“strongly agree”).

Mobile app assessments. In addition to the above measures, we integrated a series of brief assessments into the adjunctive mobile app based on prior studies (*citation removed*). Seven brief questions were administered to participants each time they opened the app, each assessing a single construct. Three assessed psychological symptoms (anxiety, worry, and depression) and four assessed ACT processes (experiential avoidance, cognitive fusion, inattention, and disconnection from values). The assessments began with the phrase “How much are you...?”

followed by each individual item: “Feeling nervous, anxious, or on edge” (i.e., anxiety); “Worrying too much about different things” (i.e., worrying); “Feeling down, depressed, or hopeless” (i.e., depression); “Fighting your feelings” (i.e., experiential avoidance); “Stuck in thoughts” (i.e., cognitive fusion); “Running on autopilot” (i.e., lacking mindful awareness); and “Disconnected from values” (i.e., lacking connection with values). The ACT process questions were used to direct participants to a skill to facilitate the process they found most challenging at that moment. The same series of questions were provided to participants immediately after completing each skill training session, which allows for examining immediate, in-the-moment effects from using the app. All questions were answered using a 0-100 sliding scale. The three items assessing symptoms were selected and adapted from the GAD-7 (Spitzer et al., 2006) and Patient Health Questionnaire-9 (Kroenke et al., 2001) respectively; items were chosen that assessed the most prototypical symptoms of anxiety, worry, and depression. The four psychological flexibility items have been used in previous clinical trials evaluating ACT Daily and have been found sensitive in detecting the differential effects of distinct ACT components (*citation removed*).

Therapists

Two clinical psychology doctoral students served as cotherapists for each group. The first author served as a therapist for all “cohorts” of the group, the second author served as a cotherapist for the first three cohorts, and the third author was a cotherapist for the fourth and final cohort. All student therapists had prior experience conducting ACT for anxiety disorders and received weekly supervision from a licensed psychologist and expert in ACT for anxiety.

Therapy protocol

Participants received 6 two-hour weekly group sessions. The sessions largely followed the same format of reviewing skills practice in the past week, introducing a new topic and related ACT skills, and reviewing and encouraging use of the adjunctive mobile app. The therapy protocol drew from existing ACT therapy protocols and books, most notably a group ACT protocol for anxiety and depression in college students (Boone & Canicci, 2013), an ACT protocol for obsessive-compulsive disorder (Twohig, 2021), and a general guide to ACT (Harris, 2009). We placed an emphasis throughout treatment on experiential exercises (e.g., meditations) over didactic learning. Additionally, participants were encouraged at the end of each session to make behavioral commitments for the coming week, where they could practice skills learned in real-world situations. The full protocol is available online at *URL removed*. Due to the flexible nature of ACT, specific sessions varied from the protocol below as appropriate (e.g., spending more time fostering acceptance when avoidance was observed), and alternative metaphors or exercises with a similar function were sometimes used. Example dialogue below is a composite of some important clinical moments based on our experiences working with each cohort.

Session 1: Introduction. We reviewed group expectations and the general format of therapy. We explored personal values by soliciting from the group individual reasons for seeking help with worry (e.g., wanting to be less preoccupied when spending time with family, wanting to perform better at work). We next introduced the concept of control as the problem, utilizing metaphors such as trying to put out a fire when any efforts only seem to make it bigger:

Therapist 1 (T1): Here's how I see this...imagine that you notice a small fire in your backyard. You try to stamp it out, you throw a bucket of water on it. It keeps getting bigger. You get a hose, a fire extinguisher, throw a blanket over it...no matter what you

do, it keeps getting bigger. You're doing all the right things, but they aren't working out in the ways they should. How does that compare to your experiences with worry?

Participant 1 (P1): I can see that...sometimes stamping it out works for a bit. But a lot of the time it gets bigger no matter what I do. So how do you put it out?

T: How much effort have you put into finding a way to stamp it out? And how much has it paid off? I wonder if it's worth continuing to look for ways to put it out...

Next, we invited group members to share their own control strategies for anxiety and invited them to consider whether they were more effective in the short- or long-term.

Session 2: Acceptance. To introduce acceptance, we led an activity in which pairs of group members took turns trying to push away an index card representing anxiety, that their partner was then instructed to push back on no matter the other's efforts. We then invited group members to instead hold the index card as if it were something precious, and to imagine what it would be like to hold their anxiety in a similar way (a version of the "Butterfly Exercise;" Boone & Canicci, 2013). This exercise elicited a range of reactions, for example:

T1: What was it like holding that anxiety in this gentle, curious way?

P1: It felt really different. Like a bit of a weight off my shoulders.

P2: It just made me think even more about how much I don't want these worries. It brings me down so much.

T2: Okay, that's an interesting thing to notice. And I wonder what it would be like to try holding that thought, of "I don't want this, it's bringing me down" in a gentle way too.

We also discussed the connection between efforts to control anxious feelings and their behavioral impacts.

Session 3: Defusion. We introduced the practice of cognitive defusion by discussing the ways in which minds generate both helpful and unhelpful signals, and how it can be difficult to tell the difference, as illustrated in the Bear and the Blackberry Bush story (Wilson & Dufrene, 2009). Defusion was further demonstrated by the concept of replacing “buts” with “ands” in regard to anxious thoughts (i.e. choosing to pursue an activity “and” feeling anxious about it), as well as a meditation based on the Leaves on a Stream metaphor (S. C. Hayes et al., 2012). Debriefing the Leaves on a Stream meditation was often a critical moment to continue fostering defusion, for example:

P1: I felt like I couldn't figure out how to put my thoughts on the leaves.

T1: And that thought, “I don't know how” – did you put that one on a leaf?

Session 4: Present Moment Awareness/Self-as-Context. To illustrate the concept of present moment awareness, we used the “time machine” metaphor (Harris, 2009) to convey how minds tend to pull us into the future or past in vivid ways. We found this to be a useful point for connecting to values, for example in the following dialogue:

T1: It sounds like most of us agree that we spend most of our time with our minds in the future, then the past, and not so much in the present. If you got to choose, where would you want your mind to be most of the time?

P1: Definitely more in the present than it is right now.

T1: Why is that? What would you want to be present for?

P1: Partly to focus on things better. But also to really be there when I'm with my friends.

We additionally used the “label parade” exercise (Boone & Canicci, 2013), in which one member of a pair listens to the other describe a challenging situation, and writes “labels” on a card whenever an internal experience is mentioned, which the speaker then attaches to

themselves (e.g. “I am anxious,” “I am sad”). We discussed what it could mean to “wear” these various labels when pursuing meaningful activities instead of trying to eliminate them. Lastly, we introduced the chessboard metaphor (S. C. Hayes et al., 2012) to teach the notion of “dropping the fight” against anxious feelings, and instead assuming the perspective of one which can contain them and continue to act in meaningful ways.

Session 5: Values. We introduced the idea of personal values as distinct from specific actions or goals by means of the compass metaphor. We then explored personal values with an experiential exercise focused on noticing what it is like to choose values. We invited participants to share times when they felt especially connected to values, and notice qualities present in such instances such as vitality, flexibility, and intention. Participants often equated values with feeling good, so we worked to help distinguish values from emotions as follows:

P1: I just want to enjoy being with people again. Like going out and just having fun.

T1: It sounds like there’s two things in there—wanting to be with people, and wanting to feel a certain way. How much control do you have over each of those?

P1: I guess I have more control over being with people than whether I enjoy it or not.

T1: Is it worth it to spend time with people, even if you don’t feel good in the moment?

We also emphasized the concept of workability when perceived barriers to valued living arise, and how to use psychological flexibility to return to values when faced with anxiety.

Session 6: Committed Action. In the final session, we emphasized the importance of making continued behavioral commitments towards one’s personal values. We utilized the metaphor of tending to a garden to illustrate how persistence, flexibility, and an orientation toward long-term growth are essential to living a valued life with anxiety and worry. We invited

participants to create a personalized plans to identify possible barriers to valued goals, and strategies for overcoming them using psychological flexibility skills, for example:

T1: What might get in the way of making time for self-care?

P1: Mainly just not having enough time.

T2: This might sound weird, but I wonder if we could separate that into two parts.

There's the experience of having other commitments that take up your time, and I'm guessing there's also the thought, "I don't have time for this." Which gets in your way?

P1: Oh yeah, I guess they both do. I am busy, but just the thought stops me a lot too.

T2: So how might you get some distance from that thought when it comes up?

Adjunctive mobile app

In addition to attending six weekly group therapy sessions, we provided access for all participants to ACT Daily. Our research lab designed ACT Daily as an adjunctive tool for clients participating in face-to-face ACT to enhance retention and practice of therapeutic coping skills (*citation removed for review*). The app was slightly adapted for this study to focus on worry. At the end of the first group session, we gave participants a brief tutorial on how to access ACT Daily and use various app features. Participants were encouraged to use the app daily if possible, and at least twice weekly. Email reminders about the app were sent twice weekly.

After completing the initial questions, participants were directed to practice skills in one ACT area (defusion, acceptance, present moment, or values) based on which area they rated as most challenging. Thus, participants received tailored ACT skill coaching based on which psychological flexibility process they were struggling with the most in the moment. Previous research indicates that this tailoring feature leads to stronger effects on mental health (*citation removed*). Within each skill session, users could choose between practicing a "depth skill,"

which consisted of a more time-intensive exercise such as an audio-guided meditation, or a “quick skill,” which comprised a briefer prompt such as visualizing a simple metaphor for practicing flexibility. Overall, the app included 6 depth skills and 28 quick skills for each component, for a total of 136 possible ACT skill coaching options.

Analysis plan

Treatment credibility, expectancy, acceptability, and satisfaction are reported descriptively among all participants who provided data ($n = 17$ to $n = 18$). Adherence to group sessions and the mobile app is also reported descriptively.

All outcome analyses followed an intent-to-treat approach, including data from participants who did not adhere to study procedures or missed assessment points ($n = 21$). Missing data are accounted for using maximum likelihood estimation. Mixed-effects models with a random intercept (modeling participant-level variability on the outcome) and random slopes for participant by time (modeling participant-level differences on the slope of the outcome) were employed for all analyses of change. These analyses employ time over the full study period as the predictor, with time coded as 0 for baseline, 0.625 for the posttreatment assessment, and 1 for the final follow-up assessment as this approximates the relative durations of each part of the study. In all outcome models, the dependent variables were standardized, providing an estimate of effect size in terms of change in standard deviations on the dependent variable for the full intervention period. This is a recommended method for estimating effect size in mixed-effects models (Lorah, 2018). Hypothesized processes of change were also investigated in the same manner, testing for overall change over the study period.

Treatment effects were then examined against criteria for statistically reliable change (Jacobson & Truax, 1991). A reliable change index of 10 was calculated based on norms for the

PSWQ in GAD patients (T. A. Brown et al., 1992). Clinically significant change (Jacobson & Truax, 1991) was assessed using the clinical cutoff of 45 on the PSWQ (Behar et al., 2003).

These analyses were conducted in participants who provided follow-up data.

A series of exploratory correlations in assessment completers tested whether pre-post change on hypothesized processes of change (AAQ-II, BAFT, MAAS, and VQ Progress) was associated with change on the PSWQ from pretreatment to posttreatment.

Exploratory analyses also evaluated effects of app usage. First, correlations in assessment completers tested whether app usage correlated with change on the PSWQ from pretreatment to posttreatment. A series of exploratory models then tested the immediate pre-post effects of using the app on a series of items measuring anxiety, depression, experiential avoidance, cognitive fusion, inattention, and disconnection from values. These models were three-level mixed-effects models, with a random intercept for overall participant variability and a random intercept for the timepoint within each participant. Outcomes were standardized and a fixed effect was estimated for pre-app use (coded as 0) relative to post-app use (coded as 1) such that the regression estimates indicate change in standard deviations from pre-app use to post-app use.

Analyses used the R statistical software (R Core Team, 2018). Mixed-effects models used the `lmer()` function (Bates et al., 2015), and *p*-values for these models were calculated with the `summary()` function in the `lmerTest` package (Kuznetsova et al., 2017). *P*-values calculated in this manner have been demonstrated to have appropriate rates of Type I error (Luke, 2017).

Results

Credibility/expectancy and acceptability

The average score on treatment credibility (among those who attended the first group session, $n = 18$) was 6.76 ($SD = 1.23$), indicating that the treatment was seen as more credible

than not. The average treatment expectancy score was 58.58% (SD = 13.15), indicating that participants felt treatment would result in a 58.58% improvement in anxiety symptoms. Of those participants who completed the TEI-SF (n = 17), the average score was 28.29 (SD = 3.00), above the benchmark of 21 and indicating average scores of around a 4 (= “agree”) with the items on the TEI-SF assessing acceptability.

Novel satisfaction items (completed by n = 17 participants; measured on a scale from 1 = “strongly disagree” to 5 = “strongly agree”) also supported acceptability of the intervention. Participants on average agreed with the statements “Overall, I found the group helpful” (M = 4.59, SD = 0.51) and “Overall, I found the mobile app helpful” (M = 3.94, SD = 1.09). Findings were somewhat mixed on the utility of combining the group and app, suggesting it was viewed as useful but not essential. Specifically, participants agreed that “Combining the group and mobile app helped me to apply the skills I learned” (M = 4.06, SD = 0.75) but also slightly agreed that “The group would have been just as helpful without the app” (M = 3.53, SD = 1.13).

Adherence

Adherence to the group therapy sessions was measured in terms of attendance. Of 21 participants who completed baseline, 3 (14.29%) withdrew before the group started, 3 (14.29%) withdrew after completing the first session, and 2 (9.52%) withdrew after completing the first 3 sessions (see Figure 1 for details). Of the other 13 participants, one (7.69%) missed two sessions, and four (30.77%) missed one session. Participants overall completed 3.86 group sessions on average, while participants who did not withdraw completed 5.54 group sessions on average.

Number of mobile app sessions completed was also calculated for each participant. Daily use was recommended as a goal, which would give a benchmark of 64 uses, and biweekly use was recommended as a minimum, which would give a benchmark of 18 uses. On average in the

intent-to-treat sample, participants completed 14.5 app sessions (SD = 13.9, range: 0-51) and 8 participants (38.10%) met the benchmark of 18 uses. Participants who did not withdraw from the group sessions completed 22.00 sessions on average (SD = 12.52, range: 7-51).

Analyses of effects over time

Worry and anxiety. The primary outcome of the PSWQ decreased significantly ($\beta = -0.93, p = .005$; see Table 2 for descriptives and Table 3 for results of all outcome models). This indicates that the PSWQ decreased by approximately 0.93 standard deviations during the study. A significant decline of 0.72 SD was also found on the STAI-Trait ($\beta = -0.72, p = .015$).

Social functioning and well-being. Scores on the PROMIS SSRA significantly increased ($\beta = 0.74, p = .027$), indicating a 0.74-SD improvement during the study period on social functioning. Well-being measured with the MHC-SF also improved by 0.49 standard deviations over the study period, an effect that trended towards significance but did not meet the alpha of .05 ($\beta = -0.49, p = .086$).

Depression. As measured with the BDI-II, depression decreased significantly by approximately 0.69 standard deviations during the study period ($\beta = -0.69, p = .001$).

Processes of Change

Significant changes were seen on the AAQ-II ($\beta = -0.66, p = .02$), indicating a 0.66 SD decrease in psychological inflexibility, and BAFT ($\beta = -1.05, p < .001$), indicating a 1.05 SD decrease in anxiety-related cognitive fusion. Progress toward personal values, measured with the VQ Progress subscale, was estimated to increase by 0.48 standard deviations, but this was not a significant change ($\beta = 0.48, p = .094$). Mindful awareness measured with the MAAS also did not change significantly ($\beta = 0.19, p = .43$).

Timing of improvement

There was significant improvement on the PSWQ from pre to post ($\beta = -0.99, p = .0002$) of approximately 1 SD, but no significant change from post to follow-up ($\beta = .17, p = .30$). Therefore, gains appeared to be maintained after the group sessions ended, but no additional gains were observed in the period in which participants were solely using the mobile app.

Reliable and clinically significant change

Of 16 participants providing follow-up data, 6 (37.5%) experienced reliable change. No participants met the criterion for clinically significant change ($PSWQ < 45$).

Process analyses

Pre to posttreatment changes on the AAQ-II ($r = 0.53, p = .03$), BAFT ($r = 0.67, p = .004$), and MAAS ($r = 0.80, p = .0001$) were significantly correlated with pre-posttreatment change on the PSWQ, while changes on VQ Progress ($r = 0.28, p = .28$) were not.

App usage effects

Number of app sessions completed was not correlated with pre to posttreatment change on the PSWQ ($ps > .10$). There were significant immediate effects of app use in expected directions on all outcomes measured: anxiety ($\beta = -0.28, p < .001$), worry ($\beta = -0.30, p < .001$), depression ($\beta = -0.20, p < .001$), experiential avoidance ($\beta = -0.28, p < .001$), cognitive fusion ($\beta = -0.36, p < .001$), inattention ($\beta = -0.28, p < .001$), and disconnection from values ($\beta = -0.21, p < .001$). This indicates that each app check-in variable significantly improved on average from immediately before to immediately after completing ACT skill coaching sessions in-the-moment.

Discussion

The current study examined the acceptability and efficacy of six sessions of group ACT with an adjunctive mobile app for people diagnosed with GAD. Participants rated the full intervention package as at least moderately acceptable. Dropout rates corroborated these self-

report results as 72% of participants who started the group intervention completed all six sessions. These participants also completed more than two app sessions a week, which was the recommended minimum use, suggesting participants were on average at least minimally engaged in the app. However, most participants did not adhere to the ideal rate of daily use, and they reported the app might not have added significant incremental benefit to the group sessions.

With respect to efficacy, there was a significant decrease equivalent to 0.93 standard deviations in the primary outcome of worry over the course of treatment, which were maintained at follow-up. Furthermore, 37.5% of participants showed reliable change in worry, though no participants showed clinically significant change. These results suggest group sessions may be useful as an initial option when treatment resources are limited. As such, group ACT sessions may be more appropriately situated within a stepped care model wherein participants who do not experience sufficient gains from group therapy may then “step up” to more targeted, intensive treatments, to maximize both efficiency and impact. The significant decrease in depressive symptoms (equivalent to a 0.69 SD reduction) also supports a transdiagnostic application of ACT, as depression was not directly targeted, and this also indicates an area of potential efficiency.

Although these group sessions had limited efficacy with regard to expediting full remission of worry symptoms, other clinical trials of ACT for GAD also reported posttreatment PSWQ means outside a normative range (51.0 to 54.2; Avdagic et al., 2014; Roemer & Orsillo, 2007; Roemer et al., 2008). This could be because ACT focuses less on changing frequency of worry per se and more on improving functioning and wellbeing even in the presence of worry. Thus, while the PSWQ is an important indicator of symptom severity, it may not be the most theoretically relevant indicator of ACT efficacy. Social functioning significantly improved over

the course of the study, consistent with this aim. However, we did not observe significant changes in positive mental health. This is arguably more difficult to achieve as positive mental health entails flourishing, not just absence of pathology. While we found a nonsignificant change of 0.49 SDs from pretreatment to follow-up, our intervention did not meet this higher bar. However, limited power should also be considered as a possible explanation given the size of this effect.

Support for the efficacy of the current intervention for processes of change was mixed. Psychological inflexibility and cognitive fusion significantly decreased over time (0.66 and 1.05 SDs respectively). Though progress toward values and mindful awareness did not show any significant changes, there was an increase in progress toward values of 0.48 SDs; low power may have contributed to this effect being nonsignificant. Thus, there was stronger evidence for shifting psychological inflexibility and cognitive fusion but some evidence to support the efficacy of the intervention for progress toward values. Low power and timing of assessments also limited the ability to test the potential effects of theorized processes of change. Changes in psychological inflexibility, cognitive fusion, and mindful awareness shared significant large, contemporaneous correlations with reduction in worry, but this does not provide sufficient information to determine causality or temporal order. Change in values progress also had a small-to-medium correlation with reduction in worry, and it is possible that being underpowered contributed to this effect being nonsignificant.

With regard to efficacy of the app, we found in-the-moment effects of skills coaching on all outcomes of interest (i.e., anxiety, worry, depression) and targeted processes assessed in the app check-ins (i.e., experiential avoidance, cognitive fusion, inattention, disconnection from values), with sizes of 0.21 to 0.36 SDs, suggesting that app users experienced improvement

immediately after they used the app skill coaching sessions. However, it is unclear if these immediate effects translated to overall skill building and generalization to other contexts over the course of treatment as number of app sessions completed was not correlated with changes in worry. More intricate analyses using these proximal measurements as intermediary explanatory variables that bridge app use to long-term outcomes are needed to clarify the relevance of app use to treatment response. In addition, it is possible that this change could be explained by demand characteristics, as app exercises were directly and clearly targeted toward altering specific processes that were also assessed immediately thereafter.

Suggestions for implementation

Based on our experience with this trial, we have several suggestions for clinicians who are interested in implementing this or a similar protocol. First, although sessions are organized around one core process, it is essential to weave all six processes in as needed. We found that acceptance work needed frequent revisiting in order to ensure that participants used other skills to foster valued living rather than to attempt to control inner experiences. We discovered that it was beneficial for the cotherapists to each take a distinct role (alternating by session or halfway through a session), in which one therapist focused more on the didactic elements of introducing content (e.g., metaphors and exercises), while the other therapist focused more on noticing and responding to ACT processes in the moment.

We also found it important to encourage present-moment awareness in virtually every session, as people with GAD have a tendency to be highly fused with their worries and other thoughts, which sometimes led the group into highly cognitive, unproductive conversations, as seen in this dialogue:

P1: I feel like right now this stuff is helping me, but what if things got really hard, like they did after I got fired? Like, would this be enough? Is that how it works?

T1: I wonder if we could slow down here. Can you take a moment and notice what it feels like to ask that question, and to sit with the uncertainty of it...of not having an answer?

As with individual clients, we found that attachment to the agenda of controlling emotions varied at the group level, and assessing the group's overall attachment to a control agenda was useful. Some groups quickly recognized that control strategies had not worked well to address anxiety, while others overall believed that *some* strategies (e.g., exercise, therapy skills, medication) would work well in the long-term to reduce anxiety if they were continued consistently. In these cases, we aimed to model curiosity, often by encouraging participants to really focus on implementing the strategy they thought was most likely to help, and to report back on what they found. Typically, at the start of the next session the group was able to conclude that either these strategies did not work as well as they anticipated, or that it was not feasible to implement them in the way they hoped.

More broadly, we found that a focus on the behavioral principles at the core of ACT is essential to effectively implementing this protocol. For example, when participants engaged in interpersonal behavior that seemed ineffective (e.g., telling long fused stories), we employed differential reinforcement, emphasizing and praising their more effective contributions to the group and redirecting after their less effective contributions. We also aimed to connect these behaviors back to psychological flexibility, for instance:

T1: I've noticed this group is pretty quiet today. What's showing up for everyone?

P1: I'm just pretty tired.

P2: Yeah, me too. It's been a long week.

P3: Honestly, I feel like I don't have anything to contribute.

T1: Thanks for sharing what's going on for you. It's interesting to me that with all of the things you mentioned—feeling tired, the thought “I don't have anything to contribute”—it seems like in each case, what is stopping you from participating is some uncomfortable thoughts or feelings. Is this one of those moments where there's a choice between doing what matters to you and doing what your thoughts and feelings seem push you towards?

Similarly, we found it helpful to consider group sessions as a process of shaping (i.e., differential reinforcement of successive approximations). In any group, some participants will begin more psychologically flexible than others. If a participant is highly inflexible initially, it may be useful to reinforce responses that are even slightly more flexible. For instance, a participant who says they want to practice “staying calm” is indicating a perceived need to avoid anxiety. However, if they report that they want to try staying calm by “just noticing” their thoughts and feelings, when previously they would have actively worked to suppress these experiences, then this choice still indicates increasing flexibility, and it would be valuable to reinforce it.

Study therapists also noted several lessons learned regarding integrating an adjunctive mobile app into group treatment. Although the study therapists were researchers and thus highly motivated to test the full treatment package, we still found it difficult at times to determine how best to integrate the app in treatment (e.g., giving a rationale for app use, emphasizing app use relative to other homework assignments) and these barriers should be explored more in future research. Due to the large library of skills, participants who had used the app were not all exposed to the same metaphors or exercises, which sometimes made it difficult to lead discussion around experiences with the app, but was also beneficial at times as it created opportunities for participants to explain metaphors or exercises to the group in their own words.

We also noted potential group processes in app usage; it seemed that high or low levels of engagement could easily become normalized by other members of the group. For example, if a participant found an exercise especially helpful and shared how they applied it to their struggles in group, other participants seemed more interested in using the app.

Limitations

The lack of a control group precludes ruling out alternative explanations for the observed improvement over time, such as measurement responsiveness or regression to the mean. However, given the medium to large effect sizes observed in the current study, it is plausible the changes were attributable to the intervention. Still, other study designs are needed to verify the efficacy of this protocol for GAD. In addition, the small sample size and consequent low power likely increased the probability of Type II error. We also recruited a relatively homogeneous sample of mostly White college students who received reminders to attend group sessions that were held on campus. Our findings may not be generalizable to settings where group participants are more diverse, have multiple ongoing activities (e.g., work, childcare), do not receive reminders in already overburdened healthcare systems, or have to put substantial effort or money into traveling to the group location. Furthermore, college students may be more adept at navigating mobile apps than other populations, increasing their app usage. At the same time, because these sessions were free, there was little financial cost to missing sessions. It is possible that participants who pay for sessions and are penalized for failing to attend them will have a higher rate of adherence.

Another limitation is that several measures assessed trait-like symptoms or processes without a specified time period (i.e., PSWQ, STAI-T, PROMIS SSRA, and AAQ-II); it is possible that using state measures or asking participants to consider the most recent week or two

would have increased sensitivity to change given the brief study timeframe. In addition, the items used in the mobile app to assess ACT processes, although they have some tentative support for construct validity (*citation removed*), have not been investigated for psychometrics; as such, findings on pre-post change when using the mobile app should be considered with caution. Finally, the study was insufficiently powered to test the temporal relationship between hypothesized change processes and outcomes, which would have clarified the importance of targeting these change processes in treatment.

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Table 1. *Participant demographics at baseline*

	<i>M(SD)/%</i>
Age	22.81 (6.90)
Gender	14.29% male 85.71% female
Ethnicity	4.76% Hispanic/Latinx 95.24% non-Hispanic/Latinx
Race	4.76% Asian 90.48% White 4.76% Other
Student status	85.71% Student
Median household income	\$40,000-59,999
Therapy utilization	9.52% accessed therapy in 6 weeks before study
Medication utilization	42.86% used psychiatric medication in 6 weeks before study

Table 2. *Descriptive statistics at baseline, posttreatment and follow-up*

	Baseline (n = 21) M(SD)	Posttreatment (n = 17) M(SD)	Follow-up (n = 14) M(SD)
PSWQ	69.52 (6.08)	60.41 (7.79)	61.64 (9.82)
STAI-T	57.76 (7.34)	52.59 (6.95)	52.57 (5.58)
PROMIS SSRA	21.05 (7.24)	26.53 (5.94)	25.29 (5.72)
MHC-SF	33.29 (13.35)	41.24 (10.17)	38.71 (9.93)
BDI-II	24.90 (11.03)	18.18 (9.30)	17.29 (7.88)
AAQ-II	32.05 (7.14)	27.53 (6.15)	28.29 (4.53)
BAFT	75.38 (15.98)	53.06 (21.46)	54.79 (20.61)
MAAS	3.01 (0.76)	3.22 (0.75)	3.08 (0.65)
VQ-Progress	14.48 (5.24)	17.82 (3.88)	16.64 (3.37)

Table 3. *Change over intervention period*

	<u>Time β</u>	<u>p</u>
<u>Outcome</u>		
PSWQ	-0.93	.005
STAI-T	-0.72	.015
PROMIS SSRA	0.74	.027
MHC-SF	0.49	.086
BDI-II	-0.69	.001
<u>Process</u>		
AAQ-II	-0.66	.02
BAFT	-1.05	<.001
MAAS	0.19	.43
VQ-Progress	0.48	.094

Figure 1. Participant flow diagram

