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Evaluating a Smartphone Mindfulness Intervention's Effectiveness at Reducing Anxiety and Worry

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EVALUATING A SMARTPHONE MINDFULNESS INTERVENTION'S EFFECTIVENESS AT REDUCING ANXIETY AND WORRY

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Abstract

There are effective treatments for anxiety and worry symptoms, but there are also many barriers to receiving traditional treatments. A smartphone mindfulness intervention may circumvent many barriers to treatment. This study evaluated the efficacy of a widely used smartphone mindfulness application (app) by randomly assigning participants to either receive access to the app for 8 weeks or to wait for 4 weeks before receiving access to the app for 4 weeks. Anxiety and worry were measured at baseline, 4 weeks, and 8 weeks. It was hypothesized that access to the app for 4 weeks and 8 weeks would be associated with less anxiety relative to the waiting period, with the lowest anxiety and worry at the eight week point. Participants completed a demographic questionnaire, the Beck Anxiety Inventory (BAI), and the Penn State Worry Questionnaire (PSWQ). Participants with moderate to high scores on measures of anxiety were randomly assigned to a treatment group, and completed the measures again four and eight weeks after beginning the study. A series of mixed measure ANOVAs were conducted using an intention to treat last observed carried forward (ITT LOCF) method of analysis. In comparison to the waitlist, anxiety scores decreased significantly both after four and eight weeks of application use. In comparison to the waitlist, worry scores were significantly reduced by the eight week point, but not after only four weeks. This research indicates that this application has a statistically and clinically significant impact on anxiety symptoms in a short amount of time (four weeks), but significant reductions in worry require more time (eight weeks).

Keywords: Mindfulness, Online, Smartphone, Technology, Worry, Anxiety, Randomized Trial

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Evaluating a Smartphone Mindfulness Intervention's Effectiveness at Reducing Anxiety and Worry

Seventy-seven percent of Americans own a smartphone (Pew Research Center, 2017), potentially enabling millions of people to reduce their anxiety with a technology they already carry with them. Many people are already turning to apps that supposedly enable them to achieve "effortless change" in their mental health, "stop worrying," and "relieve stress and anxiety" in "just 3 minutes daily" (Google Play, 2017). Those bold claims are direct quotes from descriptions of some of the most frequently downloaded anxiety-related apps in the Google Play and iTunes apps stores. Can anxiety and worry really be easily defeated with a few clicks on a touch screen? One application with particularly extraordinary claims hints at the truth with a midsentence asterisk. If the reader then scrolls down half a page, she finds a footnote that displays a long disclaimer beginning with the phrase "results not clinically proven" (Google Play, 2017). Recently published meta-analyses indicate that most anxiety and worry-focused smartphone applications on the market do not have any published evidence of efficacy (Sucala et al., 2017; Van Ameringen, Turna, Khalesi, Pullia, & Patterson, 2017); nevertheless, the number of mental health applications on the market continues to increase (Sucala et al., 2017). Sucala and colleagues (2017) searched the Google Play and iTunes app stores by mixing words such as "worry" and "anxiety" with words like "cure" and "relief" and found over 5,000 related applications. The applications are abundant and are being used by millions of people right now. For this reason, it is imperative that researchers empirically evaluate these applications' efficacy at doing what they claim to do.

Anxiety and Worry

Given the large numbers of apps out there, the law of supply and demand would suggest that there are a great number of people looking for anxiety and worry relief on their smartphones. What exactly are they trying to get relief from? Fear and anxiety are cognitive-affective states tied to autonomic arousal, particularly to the sympathetic nervous system (Barlow, 2008; Nesse, Bhatnagar, & Ellis, 2016). These states are evolutionarily adaptive responses to an environmental threat, but can be maladaptive in extremes (Barlow, 2002; Lack, 2013). If a woman in the woods is suddenly confronted with a large, hungry predator, it is highly adaptive for her sympathetic nervous system to become aroused (Barlow, 2008; Lack, 2013; Nesse et al., 2016). As her sympathetic nervous system becomes aroused, her respiration increases, her heartrate increases, and her digestive system slows down as the blood that would normally flow to these organs is shunted to her muscles and skin (Nesse et al., 2016). Because of these changes, she is more prepared to successfully run from danger or fight the predator. This woman is experiencing fear. Fear is a response to a dangerous stimulus that is characterized by a marked increase in arousal and a predisposition for action (Barlow, 2002). It has been historically helpful for humans to experience autonomic arousal when their lives are in danger from physical harm (such as from predators), food scarcity, or social rejection in environments in which communities are essential to survival (Lack, 2013). As Barlow (2002) describes it, this cognitive-affective state is like the body's alarm system. An alarm system's usefulness depends on the its ability to be set off at times of genuine threat and to not go off at times when there is no substantial threat. Problems occur when an individual experiences a large number of false alarms and when the alarm system does

not turn off after a threat has passed, as this heightened level of arousal is not ideal for all situations and is best used in short spurts, not for long periods of time.

Relatedly, anxiety is cognitive-affective state in which an individual feels a sense of helplessness to predict, control, or prevent a possible future event or situation (Barlow, 2002). This state is accompanied by a physiological reaction of preparation for the anxiety-evoking situation and with the shifting of attention from external sources to internal (usually negative) self-evaluation (Barlow, 2002). While anxiety can create a similar physiological affect to fear, anxiety is future-focused, unlike present-focused fear (Barlow, 2008; Craske et al., 2009). Worry is a verbally-based thought pattern focused on potentially anxiety-producing situations that may occur in the future and potential ways to deal with those situations (Barlow, 2002; Borkovec, 1994; Craske, 1999). Much like fear, worry can be advantageous to the problem-solving process in small doses (Barlow, 2002; Davey & Tallis, 1994). Too much worry, though, can be time consuming, distressing, feel uncontrollable, and interfere with daily functioning (Borkovec, 1994). Though worry can be perceived by the worrier as an attempt to take control over and cope with an anxiety-producing future threat (Barlow, 2002), worry is a defense mechanism for avoiding the emotional core of the anxiety (Craske, 1999). Worry has a different physiological component than either fear or anxiety; sympathetic arousal is suppressed during worry, and chronic worry is characterized by muscle tension, parasympathetic activity, autonomic inflexibility, and lower heartrate variability (Borkovec, 1994). Anxiety and worry are separate, but interrelated, cognitive-emotional states that each can be adaptive, but can also be detrimental in heavy doses.

In the United States, the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM–5*) provides the standardized criteria for the diagnosis of mental health disorders (American Psychiatric Association, 2013). The DSM-5 has a section of disorders specifically called Anxiety Disorders, which includes specific phobia, social anxiety disorder (SAD), panic disorder (PD), agoraphobia, and generalized anxiety disorder (GAD) (American Psychiatric Association, 2013). Although they are all called "anxiety" disorders, these can be more thought of as being existing on a continuum between a "fear" and an "anxiety" disorder. Specific phobia, for instance, is characterized by an extreme fear of a particular object or situation, and thus is more of a fear-based disorder than an anxiety-based disorder (American Psychiatric Association, 2013). Panic Disorder is also largely fear-based, as it is characterized by unexpected panic attacks, but is also accompanied by worry about the occurrences or consequences of such panic attacks (Barlow, 2002). Agoraphobia is a disorder characterized by anxiety about and fear of places or situations in which an individual may experience panic (American Psychiatric Association, 2013). GAD's diagnostic criteria is characterized primarily by an excessive and uncontrollable worry (American Psychiatric Association, 2013). SAD is characterized by persistent fears of as well as worry and anxiety about social interactions or situations in which criticism and rejection by others is possible (American Psychiatric Association, 2013).

There are several other disorders in the DSM-5 that have an essential anxiety-related component, including obsessive-compulsive disorder (OCD) and posttraumatic stress disorder (PTSD) (American Psychiatric Association, 2013). To qualify for a post-traumatic stress disorder diagnosis, a person must experience a traumatic event and then

experience anxiety-related, intrusive symptoms and/or physiological reactions and hyperarousal after experiencing the traumatic event (American Psychiatric Association, 2013). Obsessive compulsive disorder is characterized by obsessions (unwanted and intrusive thoughts, images, or impulses) and/or compulsions (specific, repetitive, and internal or external behavior) (American Psychiatric Association, 2013). Typically a person with OCD experiences significant anxiety and distress because of the obsession and then engages in a compulsion in order to attempt to reduce the anxiety caused by the obsession (Lack, 2012).

Impact of the Anxiety-Related Disorders

Anxiety-related disorders are the most prevalent category of mental disorder (Kessler, Berglund, et al., 2005; Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012), and are especially prevalent among people of European decent (Baxter, Scott, Vos, & Whiteford, 2013). Anxiety Disorders are so widespread that the economic burden that these disorders have in the United States alone - in terms of direct cost of psychiatric treatment, unnecessary medical treatment costs, work performance costs and costs related to mortality - are estimated to be between 42 and 47 billion dollars (Kessler & Greenberg, 2002). Factoring in long term opportunity costs for all those effected adds an estimated $100 billion to that total (Kessler & Greenberg, 2002).

People diagnosed with Anxiety Disorders have significantly lower overall quality of life than people who do not (Barrera & Norton, 2009; Fehm, Beesdo, Jacobi, & Fiedler, 2008; Haller, Cramer, Lauche, Gass, & Dobos, 2014; Olatunji, Cisler, & Tolin, 2007). There are five primary areas of quality of life that have been researched in people with anxiety disorders: physical health, mental health, work situations, social relations,

home and family relations (Fehm et al., 2008; Olatunji et al., 2007). Each of the five primary domains of quality life are substantially and significantly reduced for people with anxiety disorders as a whole (Olatunji et al., 2007). While the individual anxiety disorders impact each of these domains slightly differently, they each significantly impair at least three of the above domains (Olatunji et al., 2007). Anxiety disorders also have high comorbidity with other physical and mental health disorders (Fehm et al., 2008; Graaf, Tuithof, Dorsselaer, & Have, 2012). Many physical disorders may be caused or exacerbated by anxiety (Hazlett-Stevens, Craske, Mayer, Chang, & Naliboff, 2003; Lichstein, Wilson, & Johnson, 2000; Lucchetti et al., 2013). Even after factoring for these comorbidities, individuals with Anxiety Disorders miss more days of work (Graaf et al., 2012) and have more frequent appointments with their doctors (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007).

Impact of Subclinical Anxiety and Worry

Having heightened levels of anxiety or worry can have severely negative impacts even for those who do not meet the diagnostic criteria for a psychological disorder. Subclinical levels of worry and/or anxiety symptomology are associated with headaches (Lucchetti et al., 2013), insomnia (Lichstein et al., 2000), irritable bowel syndrome (Hazlett-Stevens et al., 2003), and high prevalence of suicidal ideation (Gilmour, 2016). Heightened but subclinical anxiety and worry also results in lower life satisfaction in areas of family relations, social relations, work situations, and financial situations (Fehm et al., 2008). Those with subclinical but elevated levels of anxiety experience similar levels of distress and psychosocial impairment compared to those who meet full diagnostic criteria for an anxiety disorder (Goodwin et al., 2005; Haller et al., 2014).

Those with sub-clinical but elevated levels of anxiety are also at increased risk of developing one or more anxiety disorders (Karsten et al., 2011; Wolitzky-Taylor et al., 2014).

Cognitive Behavioral Therapy for Anxiety, Worry, and Related Disorders

The scope and impact that heightened anxiety and worry has is great, but thankfully there are effective treatments that can help to reduce those. Each type of anxiety disorder has at least one cognitive-behavioral therapeutic protocol which is considered a specific, evidence-based treatment and the gold standard in treatment for that disorder (Olatunji, Cisler, & Deacon, 2010). Hofmann and Smits's (2008) meta-analysis of randomized placebo trials for adults with anxiety disorders revealed that CBT is significantly more effective than a placebo at reducing anxiety severity for anxiety disorders as a whole (Hedges' $g = 0.73$). When they broke down the effect size for each type of disorder, they found that OCD was the most impacted by CBT (Hedges' $g = 1.31$), followed by acute stress disorder (Hedges' $g = 1.31$), then social anxiety disorder (Hedges' $g = 0.62$), posttraumatic stress disorder (Hedges' $g = 0.62$), generalized anxiety disorder (Hedges' $g = 0.51$), and panic disorder (Hedges' $g = 0.35$). They also found that the attrition rate from CBT (23%) was not significantly different from the attrition from the placebo treatment.

There are four characteristics that are common to the majority of these treatments: psychoeducation, cognitive restructuring, exposure, and problem-solving. Psychoeducation is the process through which the clinician informs the client about the problem or disorder the client is dealing with, the mechanisms that are maintaining the problem, and the process and psychological underpinnings of the treatment plan.

Cognitive restructuring is the process through which cognitive process are corrected through repeated practice of purposeful, conscious reasoning (Craske, 1999). During cognitive restructuring the client learns to question his automatic thoughts while estimating the probability, importance, and potential outcome of each thought or mental prediction coming to fruition (Beck, Emery, & Greenberg, 2005). Exposure is the process through which the client is systematically and repeatedly exposed to the situation or object which produces anxiety and remains exposed to that anxiety-provoking situation until his or her anxiety decreases naturally (Craske, 1999). Problem solving is the process through which the clients learn when and how to implement and utilize the tools they gain throughout therapy in order to maintain the gains they have made once therapy is completed. Each of these components may also increase self-efficacy, which could be an additional mechanism of treatment (Craske, 1999).

Clinician-Directed Mindfulness Meditation Interventions

Whereas cognitive behavioral therapies are some of the most established and empirically supported therapies for anxiety and worry, they are not the only form of effective treatment. One group of interventions that has been empirical supported is based on mindfulness meditation. Mindfulness is defined as purposefully, non-judgmentally, and continually cultivating active attention on the present moment (Kabat-Zinn, 1990; Kabat-Zinn, 2003). There are many forms of empirically validated mindfulness interventions, the first of which was Mindfulness Based Stress Reduction (MBSR; Kabat-Zinn, 1990). MBSR is based upon Buddhist meditation practices and was originally developed for patients with chronic illnesses. MBSR teaches both formal meditation and informal meditation. One of the formal meditations, the sitting meditation, is described as

follows (Teasdale, Segal, & Williams, 1995): A student sits quietly, focusing on something specific (usually her own breath). If she starts thinking other thoughts, she "acknowledges" and "lets go" of those thoughts as soon as she notices them, returning her attention to the present moment. Informal meditation is the application of those principles on the activities and thoughts in daily life (Teasdale et al., 1995). Informal meditation can occur during any activity, such as walking or doing dishes (Kabat-Zinn, 1990). Mindfulness meditation alone as an intervention, in comparison to MBSR, appears to result in weaker effects on measures of psychological well-being and stronger effects on measures directly tied to mindfulness, indicating that there is more to MBSR than mindfulness alone (Eberth & Sedlmeier, 2012).

Mindfulness-Based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2002) is a second empirically tested mindfulness intervention. MBCT is based on MBSR but has an additional cognitive therapy component; specifically, it teaches consumers about depression and how to notice reoccurring thought patterns (Segal et al., 2002). There are other empirically validated interventions, such as Dialectical Behavioral Therapy (Linehan, 1987) and Acceptance and Commitment Therapy (Hayes, Strosahl, & Wilson, 1999), which also have a strong mindfulness component, but do not focus on mindfulness meditation specifically.

Mindfulness meditation-based interventions have had statistically significant therapeutic effects on a number of issues and disorders. These include, but are not limited to, stress (Baer, Carmody, & Hunsinger, 2012), depression (Fjorback, Arendt, Ornbol, Fink, & Walach, 2011; Hofmann, Sawyer, Witt, & Oh, 2010; Kimbrough, Magyari, Langenberg, Chesney, & Berman, 2010; Marchand, 2012), anxiety (Arch et al., 2013;

Evans et al., 2008; Fjorback et al., 2011; Hofmann et al., 2010; Kimbrough et al., 2010; Marchand, 2012), worry (Arch et al., 2013), post-traumatic stress disorder (Kimbrough et al., 2010) and binge-eating disorder (Katterman, Kleinman, Hood, Nackers, & Corsica, 2014). These mindfulness-based interventions have shown to be more effective than waitlist and sham treatments and comparable to the efficacy of cognitive behavioral therapy for anxiety disorders (Arch et al., 2013; Goldin et al., 2016). Vøllestad, Nielson, and Nielson's (2012) meta-analysis of mindfulness- and acceptance-based interventions for anxiety disorders found that anxiety reduction from pre- to post- intervention was significant with a large effect size (Hedges' g = 1.08), as was the overall between group effect size for randomized controlled trials (Hedges' g = -0.83). For depression symptoms, there was a significant, large effect size from pre- to post- intervention (Hedges' g = 0.85) and for the overall between group for randomized controlled trials (Hedges' g = -0.72). The mean rate of attrition from these mindfulness- and acceptance-based interventions was 15.4%.

In comparison to cognitive behavioral therapies for anxiety, little is definitively known about the mechanisms through which mindfulness interventions reduce anxiety and worry. Increases in trait mindfulness appears to be an important mediator in the relationship between these interventions and changes in worry (Hayes-Skelton, Calloway, Roemer, & Orsillo, 2015; Vøllestad, Sivertsen, & Nielsen, 2011), anxiety (Goldin et al., 2016; Vøllestad et al., 2011), emotional regulation (Keng, Smoski, Robins, Ekblad, & Brantley, 2012), and fear of emotion (Keng et al., 2012). As with most of the potential mediators discussed here, research has not yet demonstrated whether changes in mindfulness precede changes in other outcomes (Vøllestad et al., 2011).

For mindfulness interventions in particular, increased executive functioning related to ability to self-regulate and self-manage is an important proposed mechanism (Bondolfi, 2005; Hart, Ivtzan, & Hart, 2013). Decentering (Safran & Segal, 1996) and reperceiving (Shapiro, Carlson, Astin, & Freedman, 2006) are interrelated and similar constructs which involve shifts in perspective about one's thoughts and emotions and have been proposed as important mechanisms of change in mindfulness interventions. Decentering, the ability to observe emotions and thoughts as events without identifying with the thoughts and emotions (Safran & Segal, 1996), appears to be an important mediator in the relationship between mindfulness interventions, such a MBSR, and reductions in anxiety (Arch et al., 2013; Bondolfi, 2005; Hayes-Skelton et al., 2015; Hoge et al., 2015).

Cognitive appraisal appears to mediate the relationship between trait mindfulness and anxiety and stress (Curtiss, Klemanski, Andrews, Ito, & Hofmann, 2017; Schmertz, Masuda, & Anderson, 2012; Weinstein, Brown, & Ryan, 2009). A study which isolated the interoceptive components and the metacognitive components of a mindfulness intervention, found that the interoceptive components alone were better than the metacognitive components alone at reducing chronic worry (Delgado-Pastor et al., 2015). Self-compassion also appears to be important mechanism in reducing worry and fear of emotion (Keng et al., 2012).

Lindsay and Creswell (2017) have recently proposed a theory through which to integrate the current findings and encourage further exploration, the Monitor and Acceptance Theory. They propose that the attention-monitoring in mindfulness improves cognitive outcomes and that attention monitoring and acceptance of affect and cognitions

combine to improve physical and mental health outcomes. This theory integrates much of the findings of the studies done to date, but needs further testing.

Administration of Mindfulness Based Treatments

Mindfulness based interventions, including MBSR and MBCT, are typically taught in a group setting and administered over an 8 week course (Santorelli, 2014). They are comprised of 8 weekly sessions of 2.5-3.5 hours each and one 7.5 hour retreat. Instructors of these interventions require clients to engage in 45 minutes in formal meditation and 5-15 minutes in informal meditation 6 days per week in addition to class time. As such, they require a significant time commitment for an entire 8 week period.

Some studies of clinician-directed mindfulness interventions have found a significant decrease in stress or anxiety in less time, either through testing after an abbreviated program or testing before the 8 week program is complete. Participants benefited as early as 4 weeks into an 8 week MBSR treatment in two separate published studies, with significant decreases in anxiety (Kimbrough et al., 2010) and in perceived stress (Sass, Berenbaum, & Abrams, 2013). Participants in an intensive clinician-directed mindfulness intervention experienced a significant decrease in psychological distress in 2.5 weeks (Sass et al., 2013).

CBT versus Mindfulness Based Treatments

As briefly mentioned above, mindfulness-based interventions and cognitive behavioral therapy have comparable efficacy at reducing anxiety and worry (Arch et al., 2013; Goldin et al., 2016). Mindfulness interventions also tend to have lower rates of attrition than cognitive behavioral therapies (Arch et al., 2013; Khoury et al., 2013; Khoury, Sharma, Rush, & Fournier, 2015). Arch and colleagues (2013) conducted a

randomized clinical trial with veterans with one or more anxiety disorder and compared MBSR to CBT at baseline, after treatment, and at a 3 month follow up. They found that participants who received CBT had better, though not statistically significant improvements in principal clinical severity rating both post-treatment and at follow-up (post treatment Cohen's d = .29, follow up Cohen's d = .56), but that those who received MBSR had lower anxious arousal, which was significant at follow up, but not directly after treatment (post treatment d = .31, follow up d = .49). They also found that for worry and depression symptomology, those who received CBT fared slightly better post treatment (d = .07 for worry, d = .08 for depression), but on both measures those who received MBSR were most improved at follow up (d = .25 for worry, d = .08 for depression).

Recent research indicates that mindfulness interventions may have many of the same mechanisms for reduction in anxiety and worry as cognitive behavioral therapy (Goldin et al., 2016; Hayes-Skelton et al., 2015). Exposure to negative emotional states may be one such mechanism (Bondolfi, 2005). Though mindfulness interventions and CBT may have some similar mechanisms and similar overall efficacy, one or the other may be more effective for a specific individual. For instance, baseline anxiety sensitivity and depression severity seem to moderate the differences between treatment outcomes of a slightly modified version MBSR and group CBT (Arch & Ayers, 2013). Arch and Ayers (2013) found that CBT was more effective at reducing anxiety disorder symptomology for those with no to mild depressive symptoms at baseline, whereas MBSR was more effective at reducing anxiety disorder symptomology for those with moderate to severe symptoms. For anxiety sensitivity, the relationship was non-linear so

that those with very high or very low anxiety sensitivity responded better to CBT than MBSR, and those with anxiety sensitivity close the mean of the sample responded better to MBSR than CBT.

As previously mentioned, mindfulness-based interventions are typically administered in a group setting and involve meeting face to face for 2-4 hours per week for 8 weeks in addition to a full day retreat near the end of treatment (Santorelli, 2014). This treatment course is the same regardless of diagnosis type or severity of symptoms. In contrast, treatment length varies in cognitive behavioral therapy depending upon the type of anxiety disorder. In standard cognitive behavioral therapy, sessions typically last between one and two hours, there are between one and two session per week, and treatment typically lasts between 10 and 20 weeks. For generalized anxiety disorder, treatment is typically administered in one hour sessions and can last anywhere between 10 and 20 sessions (Craske & Barlow, 2006b). For social anxiety treatment typically consists of once weekly sessions for 12 to 16 weeks (Herbert, Rheingold, Gaudiano, & Myers, 2004; Hope, Heimberg, & Turk, 2006). For panic disorder with agoraphobia treatment typical consists of once weekly sessions for 12 weeks (Craske & Barlow, 2006a). The primary treatment method for obsessive-compulsive disorder, exposure and response prevention, typically takes between 17 and 20 sessions to complete (Foa, Yadin, & Lichner, 2012). There are intensive protocols of cognitive behavioral therapy for anxiety disorders that involve longer session length or shorter length between sessions in which the length of treatment may last between 3 and 6 weeks (Craske & Barlow, 2006a; Storch et al., 2008). As with MBSR, CBT treatments require at-home practice of the

skills learned in session (Craske & Barlow, 2006a, 2006b; Foa et al., 2012; Hope et al., 2006).

Barriers to Treatment of Anxiety Disorders

Although there are these quite effective treatments for people who experience distressing levels of anxiety and worry, the majority of people with a diagnosable disorder do not receive treatment (Goodwin, Koenen, Hellman, Guardino, & Struening, 2002; Roness, Mykletun, & Dahl, 2005). Those that do receive treatment wait between 1 and 16 years on average (depending on the specific disorder) before seeking and receiving services (Goodwin et al., 2002; Iza et al., 2013; Wang et al., 2007; Wang et al., 2005). Even then, many of those who do receive services do not receive evidence-based services (Marques et al., 2010).

There are many barriers that may keep such an individual from effective treatment. Some of these barriers are structural in nature (i.e. insurance, cost, or transportation related barriers) and others are attitudinal (i.e. concern for stigma or negative beliefs about help-seeking) Chartier-otis, Perreault, & Bélanger, 2010; Craske et al., 2005). One of the most commonly reported barriers overall is not knowing where to go to receive services (Chartier-otis et al., 2010; Craske et al., 2005; Fox, Blank, Rovnyak, & Barnett, 2001; Goodwin et al., 2002; Marques et al., 2010; Olfson et al., 2000; Sareen et al., 2007; Thompson, Hunt, & Issakidis, 2004). This issue has some structural and attitudinal components; in certain regions, help may not be readily available, but in the regions where help is available mental health literacy may be at the root of this barrier (Coles & Coleman, 2010).

Many individuals report that specific structural barriers have kept them from seeking and receiving services for their anxiety and worry-related issues. The most cited structural barriers are concerns about cost of treatment and whether insurance would adequately cover those costs (Chartier-otis et al., 2010; Craske et al., 2005; Fox et al., 2001; Goodwin et al., 2002; Marques et al., 2010; Mojtabai et al., 2011; Olfson et al., 2000; Sareen et al., 2007; Williams, Domanico, Marques, Leblanc, & Turkheimer, 2012). Another common barrier was the feeling it would take up too much time to receive adequate services (Marques et al., 2010; Mojtabai et al., 2011; Sareen et al., 2007; Williams et al., 2012). Some individuals reported an inability to receive services from locations they contacted or extremely long wait times for appointments as the primary reason they did not receive services (Chartier-otis et al., 2010; Craske et al., 2005; Fox et al., 2001). For a smaller percentage of individuals other additional barriers, such as difficulties with transportation, played a major role in their not seeking treatment (Fox et al., 2001; Gulliver, Griffiths, & Christensen, 2010; Mojtabai et al., 2011).

Some studies have found that attitudinal barriers are more likely to keep a person from successfully seeking treatment than structural barriers (Sareen et al., 2007; Williams et al., 2012). Some of the most prevalent attitudinal barriers are low perceived need for treatment (Edlund, Unützer, & Curran, 2006; Gulliver et al., 2010; Mojtabai, Olfson, & Mechanic, 2002; Mojtabai et al., 2011; Thompson et al., 2004), a desire to handle the issue on one's own (Goodwin et al., 2002; Gulliver et al., 2010; Marques et al., 2010; Mojtabai et al., 2011; Olfson et al., 2000; Sareen et al., 2007; Thompson et al., 2004), concern about stigma (Chartier-otis et al., 2010; Goodwin et al., 2002; Gulliver et al., 2010; Marques et al., 2010; Mojtabai et al., 2011; President's New Freedom Commission

on Mental Health, 2005; Williams et al., 2012), thinking the problem would get better on its own (Sareen et al., 2007; Thompson et al., 2004), and perceiving that treatment is ineffective (Chartier-otis et al., 2010; Marques et al., 2010; Thompson et al., 2004).

People living in certain communities and of certain demographic characteristics have even more barriers to seeking and receiving treatment than others. More structural barriers are reported among Hispanic, African American, and other minority racial and ethnic groups than their white counterparts (Mojtabai et al., 2011; Williams et al., 2012). Young people, people in rural areas, and people of minority ethnic groups may be more likely to be concerned with what others might think about their seeking treatment (Gulliver et al., 2010; Wynaden et al., 2005), indicating higher stigma and confidentiality/trust concerns in those groups. Likewise, ethnic minorities may feel more concern about a racial inequality in treatment which may inhibit them from seeking treatment (Williams et al., 2012).

These concerns for inequality of treatment are well warranted. Studies have shown that medical practitioners are influenced by personal information such as gender, race, and class when making diagnoses and treatment plans (Garb, 2013; Loring & Powell, 1988). Additionally, middle class African Americans and both white and African American working class individuals are likely to encounter an additional barrier to receiving treatment: difficulty receiving an appointment (Kugelmass, 2016). The inequality in availability based on race, gender, and class is so pronounced that a study by Kugelmass (2016) demonstrated that a white middle class female may be approximately sixteen times more likely to receive a requested weekday evening appointment than a black working class male, even if they have the exact same insurance. The white middle

class female would also be five times more likely to receive any appointment with a psychotherapist than her black, working class male counterpart (Kugelmass, 2016). While African-Americans may not be the only minority group to experience this barrier, no one has yet investigated what other groups may also be at a disadvantage.

Circumventing the Barriers through Technology

Finding ways to systemically address these barriers is important, but it is equally important to find ways to circumvent them. Self-help interventions, particularly technology- driven interventions, are one potential approach to circumvent these barriers. There has been some concern that, like traditional treatment, technology-supported mental health services would be more accessible to the wealthy than those with fewer economic resources (Anderson, Jacobs, & Rothbaum, 2004). This may be of particular concern for computer-based programs, but smartphone dependency is more common among younger, lower income, and non-white Americans and among those with lower levels of education (Pew Research Center, 2017), which are the exact demographic groups which are least likely to receive traditional mental health services (Kessler, Demler, et al., 2005). It is important to note that some self-help smartphone applications require either a onetime payment for access or a month subscription, which may be a barrier to those with fewer resources. One of the higher cost applications has a subscription fee of $13 per month (Headspace Inc, 2010). This cost would likely be a substantial barrier to some, though it would be an economic barrier to fewer people than traditional sliding scale therapy appointment costs.

In addition to alleviating many of the barriers related to cost and concern for insurance coverage, smartphone-based interventions are not hindered by transportation

concerns or lengthy wait times. While the intervention itself may be time consuming, the timing of a smartphone application is by its nature more flexible than traditional mental health care, and thus may alleviate some of the barriers related to concern treatment will take up too much time.

While many people with anxiety and worry endorse a desire to handle their mental health concerns on their own, they may perceive a smartphone app as a part of that process of self-help rather than contrary to that desire. Users of these applications may have less concern for confidentiality, because utilizing a smartphone application does not require another person to know about the issue. A smartphone app also does not permit people of certain demographics access while refusing others, so smartphone applications may be able to override some of the structural and discriminatory barriers to accessing help for mental health. While mental health smartphone applications have the potential to circumvent many barriers to receiving traditional mental health service for anxiety, they do not circumvent the sizable barriers of low perceived need for help, a belief that the problem will get better on its own, or a perception that treatment is ineffective.

The importance of whether or not technology-driven treatment can potentially reach more individuals than traditional treatment modalities is dependent on the whether or not technology-driven treatments are effective. It is important that each new modality and type of self-help intervention be validated, because even though it may have the same underlying principles as an effective clinician-based intervention, the changes made to change the modality may impact its efficacy. For instance, an online intervention based upon the well-tested, well-supported principles of cognitive behavioral therapy was found

to have no significant effects on anxiety or worry when tested on a large sample of school-aged students (Calear et al., 2016).

There is a general consensus that evaluative literature of online-, computer-, and smartphone-based treatment is lagging behind the growth of technology and demand in this area (Bennion, Hardy, Moore, & Millings, 2017; Coull & Morris, 2011; Lui, Marcus, & Barry, 2017; Sucala et al., 2017). There is evidence that guided self-help, whether in the form of an internet intervention with some clinician emails or bibliotherapy with brief phone calls, can be as effective as traditional face-to-face therapy for depression and anxiety disorders (Cuijpers, Donker, van Straten, Li, & Andersson, 2010). There is also some preliminary evidence that standalone technology-driven treatment based upon traditional therapies can be effective at increasing the quality of life (Reger & Gahm, 2009; Sucala et al., 2017), decreasing anxiety (Lui et al., 2017; Reger & Gahm, 2009; Sucala et al., 2017; Van Ameringen et al., 2017), decreasing depression (Lui et al., 2017; Reger & Gahm, 2009; Sucala et al., 2017; Van Ameringen et al., 2017), and decreasing PTSD symptomology (Van Ameringen et al., 2017). It is important to note that many, though not all, studies that do evaluate technology-driven interventions to date have methodological limitations, such as no control groups or small sample sizes.

This dearth of research may be most pronounced for one of the most widely accessible modalities: smart-phone applications. A recent meta-analysis found that 96.2% of anxiety-related smartphone applications had no available efficacy data (Sucala et al., 2017). As such, there is no single mental health smartphone application on the market to date which is definitively evidence-based (Lui et al., 2017). Thus, more research is needed in this area.

Technology-Driven Mindfulness Interventions

Technology-driven mindfulness interventions may be uniquely capable of overcoming some of the barriers to traditional treatment. Mindfulness has generated some buzz in popular culture tied to positive psychological benefits of mindfulness (Pickert, 2014). This may increase the likelihood that individuals would engage in mindfulness, whether or not they admit they have a problem for which they need help, potentially circumventing the attitudinal barrier of low perceived need for help and perhaps of some sources of stigma. Additionally, a recent study by Wahbeh, Svalina, and Oken (2014) indicated that more people would choose an internet-based mindfulness intervention than would select a one-on-one or group in person format (though the difference was only statistically significant for the latter). This indicates a considerable level of acceptability for this mode of delivery.

In the last seven years, there has been an increase in empirical studies evaluating technology-driven mindfulness interventions. While no single intervention has been researched enough to constitute being categorized as an evidence-based practice, overall the literature indicates that mindfulness can be taught via an online modality. Technology-driven mindfulness interventions can be effective at increasing state and trait mindfulness (Cavanagh et al., 2013; Cavanagh, Strauss, Forder, & Jones, 2014; Mahmood, Hopthrow, & Randsley de Moura, 2016; Spijkerman, Pots, & Bohlmeijer, 2016; van Emmerik, Berings, & Lancee, 2017) and at increasing the potential mechanism of decentering in particular (Chittaro & Vianello, 2014, 2016).

Many of the benefits derived from in-person mindfulness interventions have also been found in online mindfulness interventions. Studies have found significant decreases

in stress with large to medium effect sizes as a result of technology-driven mindfulness interventions (Cavanagh et al., 2013; Fish, Brimson, & Lynch, 2016; Jayawardene, Lohrmann, Erbe, & Torabi, 2017; Krusche, Cyhlarova, & Williams, 2013). Online mindfulness interventions have also resulted in significant increases of quality of life (Boettcher et al., 2014; van Emmerik et al., 2017), well-being (Spijkerman et al., 2016), and positive affect (Gluck & Maercker, 2011; Howells, Ivtzan, & Eiroa-orosa, 2016) in both clinical and non-clinical populations. Technology-driven mindfulness interventions have also made statistically and clinically significant reductions in anxiety (Boettcher et al., 2014; Cavanagh et al., 2013; Cavanagh et al., 2014; Spijkerman et al., 2016) and depression (Boettcher et al., 2014; Cavanagh et al., 2013; Cavanagh et al., 2014; Fish et al., 2016; Spijkerman et al., 2016) with effect sizes ranging from small to large (g = 0.22-0.97 for anxiety, and g = 0.29-0.83 for depression).

This increase in empirical literature has been dramatically outpaced by the development and proliferation of technology-driven mindfulness interventions on the marketplace. Between 2013 and 2015 there were between 200 and 600 mindfulness related apps in Google play and Apple app stores and that number continues to grow (Plaza, Demarzo, Herrera-Mercadal, & García-Campayo, 2013; Tunney, Cooney, Coyle, & Reilly, 2017). This study sought to evaluate the efficacy of one of the more popular available smartphone applications and, in doing so, to contribute to the slowly growing literature on technology-driven mindfulness.

Why *Headspace*?

At the time this was written, *Headspace* (Headspace Inc, 2010) was in the top five results in the Apple App Store for the search term “anxiety.” *Headspace* reported

approximately 18.5 million downloads as of September 2017 (M. Economides, personal communication, September 13, 2017). In a study comparing 23 mindfulness applications, *Headspace* was rated was rated the highest in all domains of the Mobile Application Rating Scale, including engagement, functionality, aesthetics, information, satisfaction, and overall (Mani, Kavanagh, Hides, & Stoyanov, 2015). Engagement is an important component to an effective mental health application (Price et al., 2014).

It is imperative that a mental health application as popular as *Headspace* be properly tested for efficacy, because if it is not effective it could be a significant waste in terms of subscription fees, time, and opportunity costs (Price et al., 2014). *Headspace* is currently recommended by reputable organizations despite the lack of research (Bennion et al., 2017), and if it is effective it could be more widely recommended as an adjunctive or standalone treatment for mental health problems. Given *Headspace*'s widespread use and high ratings, they were approached regarding the proposed research and were amenable to cooperating.

There has been some empirical evidence that *Headspace* can have an impact on mental health. Howells and colleagues (2016) found that meditating using *Headspace* for ten days resulted in a small, but statistically significant, increase in positive affect and a small, nearly significant ($p = .05$) reduction in depression. Separate studies have found that *Headspace* can reduce mind wandering (Bennike, Wieghorst, & Kirk, 2017) and increase compassion (Lim, Condon, & DeSteno, 2015). While there is some proof of concept that *Headspace* can have an impact on mental health, the question remains as to whether it can have the kind of impact on anxiety and worry that one would expect from an effective mindfulness intervention.

Purpose of Study and Hypotheses

This study sought to evaluate whether *Headspace* can reduce anxiety and worry in individuals with moderate to clinical levels of anxiety or worry. This study also sought to determine how long the app should be used to have optimal effects. Participants were randomly assigned to receive access to Headspace for 8 weeks or wait for 4 weeks before receiving access to Headspace for 4 weeks to test the following hypotheses:

Hypothesis 1 was that the four week intervention would significantly reduce anxiety in comparison to a wait-list control. Hypothesis 2 was that the eight week intervention would significantly reduce anxiety in comparison to the waitlist control. Hypothesis 3 was that the eight week intervention would significantly reduce anxiety in comparison to the 4 week intervention. Hypothesis 4 was that the four week intervention would reduce worry in comparison to a wait-list control. Hypothesis 5 was that the eight week intervention would significantly reduce worry in comparison to the waitlist control. Hypothesis 6 was that the eight week intervention would significantly reduce worry in comparison to the 4 week intervention. **Method**

Participants

An *a priori* analysis through G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) determined that 85 participants would be the appropriate sample size for this study. This was based upon the effect size found in previous per protocol clinician-directed studies, as there is no consistent effect size for online interventions. In order to control for up to approximately 50% dropout rates, 163 participants were recruited, randomly assigned, and included in analysis. Demographic information is presented on *Table 1*, *Table 2*, and *Table 3*. One-hundred and thirty one of the participants reported having a female gender

identity (80.4%), twenty-nine identified as male (17.8%), and three identified as another gender identity (1.8%), with two of those specifying that they identified as genderfluid. Regarding sexual identity, 76.7% identified as heterosexual, 13.5% identified as bisexual, 4.3% identified as pansexual, 3.1% as homosexual, and 2.5% as asexual. The mean age of the participants was 24 years old (*SD* = 9; range = 18-65). Sixty-two percent of the participants identified as White, 13.5% as biracial or multiracial, 9.9% identified as Hispanic/Latino, 8% as Asian, 4.9% as Black/African American, and 1.8% as Native American. Forty-five point four percent of the participants reporting being of Christian faith, 17.2% reported being atheist, 16.0% reported being agnostic, 8.6% reported being spiritual but not religiously affiliated, 4.9% reported being undecided, 3.7% reported having no religious or spiritual worldview, 1.2% reported being Muslim, 1.2% reported being Buddhist, 1.2% reported being Hindu, and 0.6% reported being Wiccan.

Approximately forty-percent of participants reported being single, never married; 39.3% reported being in a dating relationship; 18.4% reported being married; and 2.5% reported being divorced. Less than one percent of participants reported not having completed high school, while 25.8% reported high school being their highest level of formal education, 41.7% reported having completed some college, 6.1% reported having completed a two year degree, 12.3% reported having completing an undergraduate degree, 5.5% reported having completed some graduate work, 6.1% reported having completed a Master's degree, and 1.8% reported completing a doctorate degree. The mean reported household income was $56,000 (SD = $49,000, Range = $0-$200,000). Eighty-seven percent of participants reported the United States of America as being their

country of origin, and 93.9% reported the United States of America as being their country of residence.

The majority of the participants (57.1%) reported never having received a diagnosis for mental health disorder. The second largest number of participants (9.2%) reported having received a diagnosis of major depressive disorder and an anxiety-related disorder at some point in their life. Generalized anxiety disorder diagnosis was the next most common at 6.7%, with 4.3% having received a major depressive disorder diagnosis, 4.3% having received two or more anxiety related disorder diagnoses, 2.5% having a social anxiety disorder diagnosis, and 1.8% having an attention-deficit hyperactivity disorder diagnosis. An alcohol or substance abuse or dependency related, an adjustment disorder, or a major depressive disorder and post-traumatic stress diagnosis was each reported by 1.2% of the participants. Less than one percent of the participants reported having each of these disorders: bipolar disorder, panic disorder, post-traumatic stress disorder, autism/Asperger's syndrome, or an eating disorder. Twelve participants (7.4%) reported receiving two or more diagnoses in a combination not specified above.

Eighty percent of participants reported receiving no current mental health services, 14.1% reported currently receiving counseling, and 4.9% reported currently receiving another mental health service (i.e. couples counseling or support group). Fifty-nine percent of participants reported taking no medications and 14% reported taking a non-psychotropic medication (i.e. birth control pills, blood pressure medication). Regarding medication, 12.3% of the participants reporting taking more than one medication, with 4.3%taking sleep medication, 3.7% not knowing what medication they

take, 3.1% of participants taking a stimulant, 2.5% taking an anti-depressant, and 1.2% taking an anti-anxiety medication.

Participants were also asked about their previous experience with meditation. Of the 59 participants who responded to this question, 17 (28.8%) said that they had previous experience with mindfulness meditation. Eight of those said they had previous experience with Headspace specifically. Five reported having less than an hour of mindfulness practice, six reported having between 1 and 5 hours of mindfulness practice, two reported having between 5 and 10 hours of practice, one reported having between 11-20 previous hours of experience, one reported having between 76-100 previous hours of experience, and two reported having more than 100 hours of previous mindfulness practice.

Measures

The participants first answered a brief demographic and environmental questionnaire (see Appendix A). This assessed age, gender, racial identity, educational attainment, socio-economic status, prior mental health history, and ongoing treatments for mental health.

Participants then completed self-ratings of their levels of anxiety and worry. The Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) is a well validated anxiety measure (see Appendix B). This 21-item inventory has participants respond how often they have been bothered by certain symptoms (i.e. Indigestion) in the last month on a 4-point Likert scale that ranges from zero (not at all) to three (severely). Previous research has shown it has good test-retest reliability (r = 0.83) over 5 weeks (de Beurs, Wilson, Chambless, Goldstein, & Feske, 1997). In this study, the BAI had a good test-

retest reliability over four weeks when evaluated during the waitlist control period (r = 0.74, $p < .001$). An initial study validating the BAI found a score of 22 to be the mean BAI (Beck et al., 1988). As such, this was considered the cut off for moderately high anxiety in this study.

Worry was measured by the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) (see Appendix C). This questionnaire is rated on a 5-point Likert scale with 16 items such as "my worries overwhelm me" (1 being "not at all typical of me" and 5 being "very typical of me"). The PSWQ has a good test-retest reliability (r = 0.92) over 8-10 weeks (Molina & Borkovec, 1994), 1994) and isn't affected by social desirability (Meyer et al., 1990). In this study, the PSWQ had a good test-retest reliability over four weeks when evaluated during the waitlist control period (r = 0.77, $p < .001$). Some previous studies have used scores as low as 45 as cut off scores for clinically significant worry (Behar, Alcaine, Zuellig, & Borkovec, 2003). Others have found the mean PSWQ score in community samples to be 40 (Meyer et al., 1990). As such, 40 was utilized as a cutoff score to demonstrate moderate, subclinical worry.

The mindfulness intervention used was the Headspace app (Headspace Inc., 2010). This program has guided mindfulness audio recordings, videos, and cartoons explaining the mindfulness principles. It can be accessed by computer or through Android or iOS smartphone devices. Headspace normally costs a monthly fee, but participants received a code that allowed them full access to the program for two months. Each participant's activity in the mindfulness program was recorded by the app and this information was then made accessible to the researcher from Headspace Inc.

Procedure

Upon receiving IRB approval, participants were recruited to participate in the study. Participants were recruited from a number of sources. Recruitment occurred online using the SONA Systems portal (for current students) via online advertisements (for non-students), and paper advertisements placed (with permission) in coffee shops, public libraries, and other establishments. Participants clicked on or typed in the link to the survey in order to participate. The advertisements and first page of the survey included email addresses and phone numbers of the researchers for the participants to contact if they had any questions. All participants were required to be at least 18 years old in order to participate.

All participants read and electronically signed an informed consent form and then completed a preliminary assessment with a demographic and environmental questionnaire and the anxiety and worry questionnaires online. Those participants who had an elevated score of anxiety or worry (22 or higher on the BAI; PSWQ score of 40 or higher) were to be invited to continue in the study. Those who agreed to continue were randomly assigned to a treatment group using a random number generator. Undergraduate participants received class credit for their participation, while participants from the community received a single entry into a weekly drawing for each 10 minutes they spent meditating through the application. The winner of each drawing won a $20 gift card. Some undergraduate participants chose to switch incentive programs midway through the program if they no longer needed credits for class.

Enrolled participants received an individualized access code to the Headspace online and mobile application (Headspace Inc, 2010) when their intervention period

began. The time each participant spent using this application was automatically recorded by the Headspace program. Participants were told to use the program for 1-2 sessions per day (10-40 minutes) at least six days a week.

After completing their treatment condition, all participants received an email with a link to a follow-up measure survey containing the BAI, the PSWQ, and a questionnaire about any previous mindfulness practice. Those assigned to the 4 week intervention were wait-listed for 4 weeks before receiving the Headspace code (see Figure 1 for study participant flow). Data collection occurred over a 14 month time period.

Data Analysis

During data analysis, the researcher discovered that because of an error during the invitation process, only 831 of 857 individuals who should have invited to participate in the study actually were. Analyses showed this error was not systematic in nature, though, and should have no impact on results. Under 20% (164 total) of invited individuals agreed to continue in the study, but during data analysis it was found that one individual selected the same response to every question (including reverse coded items), so their data was excluded from final analysis. The prescreening data for the remaining 163 participants was analyzed using a series of chi-square and t-tests to determine if there were differences between the assigned groups with respect to demographic information and the initial BAI and PSWQ scores. Participants were not excluded from analysis if they had previously received mental health diagnoses, were currently receiving mental health services or medication, or had previous meditation experience. For this reason it was necessary to determine if the portion of the sample that had these preexisting factors responded to treatment differently than the rest of the sample. A series of 2 x 3 mixed

ANOVAs were conducted on anxiety and worry, with time of testing (pretest, midtest, posttest) as the within-subjects variable and with diagnosis status, mental health service status, medication use status, and previous meditation experience as the between-subjects variables.

The data was analyzed on an intention to treat (ITT) basis using the last observation carried forward (LOCF) method. Therefore, all participants who were randomly assigned to one of the two conditions were included in analysis regardless of treatment dosage (i.e. time spent using the app), and any missing values were filled in with the last observed data for that participant. This is a highly conservative method of analysis for randomized trials and is based upon the assumption that participants who fail to complete the intervention did not benefit from it. A 2 (group; 4 week intervention, 8 week intervention) x 3 (time; pretest, midtest, posttest) repeated measures analysis of variance (ANOVA) was conducted on PSWQ and BAI scores. This was followed by Bonferroni corrected post hoc analyses and pairwise comparisons as needed to evaluate each hypothesis. Finally, the mean percent change in symptoms was calculated for each of the experimental conditions and each form of analysis.

Results

Table 2 displays descriptive statistics of anxiety and worry symptoms. A series of independent t-tests were conducted to determine if there was any statistically significant differences in terms of prescreening anxiety and worry scores between those invited to continue in the intervention portion of the study and did not choose to participate in the study (not assigned) and those who did continue in the study (randomly assigned). There was a significant difference in prescreener anxiety scores between those who were not

assigned (*M*=14.12 *SD*= 11.59) and those who ultimately were randomly assigned (*M*= 17.60 *SD*= 11.83); *t*(785)= 3.39, *p* = .001. There was not a statistically significant difference in prescreener worry scores between those who were not assigned (*M*=59.00 *SD*= 11.72) and those who ultimately were randomly assigned (*M*= 61.03 *SD*= 11.83); *t*(825)= 1.94, *p* = .052. This indicates that those who chose to consent to participate in research had significantly higher anxiety scores, and somewhat higher (though not statistically significantly higher) worry scores than those who chose not to participate in the intervention.

A series of t-tests on the prescreening measure indicated that there were no statistically significant differences between the two assigned groups in regards to demographic information or initial PSWQ or BAI scores. Likewise, a series of t-tests indicated that there were no significant differences between the assigned groups in regards to incentive program selected, diagnosis status, mental health service use, or medication use.

Pre-Existing Factors

For a frequency table regarding the pre-existing factors see *Table 2* and *Table 3*.

Diagnosis Status

The anxiety scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 2), with time of testing (pretest, midtest, posttest) as the within-subjects variable and Diagnosis status (previous diagnosis, no previous diagnosis) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, *p* = .15. Mauchly's *W* was significant, *W* = .78, *p* < .001, $\chi^2(2)=39.69$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on anxiety symptoms was found, *F*(1.67, 268.02) = 12.05, *p* < .001, $\eta_p^2=$

.070. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ (p = .39), but that posttest anxiety scores (M = 14.40, SD = 11.09) were significantly lower than both pretest (M = 17.53, SD = 11.94) and midtest (M = 16.49, SD = 11.45) anxiety scores (both ps < .001). The main effect of diagnosis on anxiety symptoms was significant, $F(1, 161) = 25.43$, $p < .001$. Scores of those who had been previously diagnosed had higher anxiety scores (M = 20.60, SD = 11.20) than those who had never been diagnosed (M = 12.78, SD = 10.57). There was no significant interaction between time and diagnosis status, $F(1.67, 268.02) = .24$, $p = .75$, $\eta_p^2 = .001$.

The worry scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 3), with time of testing (pretest, midtest, posttest) as the within-subjects variable and diagnosis status (previous diagnosis, no previous diagnosis) as the between-subjects variable. Box's M test showed that the assumption of homogeneity of variance-covariance matrix was not violated, p = .23. Mauchly's W was significant, W = .85, $p < .001$, $\chi^2(2)=26.30$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on worry symptoms was found, $F(1.77, 284.15) = 9.58$, $p < .001$, $\eta_p^2 = .056$. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ (p = .59), but that posttest worry scores (M = 58.39, SD = 12.90) were significantly lower than both pretest (M = 61.00, SD = 12.69) and midtest (M = 60.20, SD = 12.74) worry scores (both ps = .001). The main effect of diagnosis on worry symptoms was significant, $F(1, 161) = 12.49$, $p = .001$. Scores of those who had been previously diagnosed had higher worry scores (M = 63.20, SD = 11.39) than those who had never been diagnosed (M = 57.09, SD = 13.11). There was no significant interaction between time and diagnosis status, $F(1.77, 284.15) = .16$, $p = .83$, $\eta_p^2 = .001$.

Mental Health Service Use

The anxiety scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 4), with time of testing (pretest, midtest, posttest) as the within-subjects variable and mental health service usage (current use of mental health services or counseling, no current use of mental health services) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .002$. Mauchly's *W* was significant, $W = .78$, $p < .001$, $\chi^2(2)=39.74$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on anxiety symptoms was found, $F(1.67, 268.02) = 6.20$, $p = .01$, $\eta_p^2 = .037$. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ ($p = 1.00$), but that posttest anxiety scores (($M = 14.40$, $SD = 11.09$) were significantly lower than both pretest ($M = 17.53$, $SD = 11.94$) and midtest ($M = 16.49$, $SD = 11.45$) anxiety scores ($p = .04$ and $p = .03$, respectively). The main effect of mental health service use on anxiety symptoms was not significant, $F(1, 161) = 2.59$, $p = .11$. There was no significant interaction between time and mental health service use, $F(1.67, 267.96) = 1.81$, $p = .17$, $\eta_p^2 = .011$.

The worry scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 5), with time of testing (pretest, midtest, posttest) as the within-subjects variable and mental health service usage (current use of mental health services or counseling, no current use of mental health services) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .46$. Mauchly's *W* was significant, $W = .85$, $p < .001$, $\chi^2(2)=26.15$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on worry symptoms was found, $F(1.77, 284.36) = 4.31$, $p = .018$, $\eta_p^2 = .026$. Bonferroni corrected post hoc tests

showed that pretests and midtests did not significantly differ (p = 1.00), but that posttest worry scores (M = 58.39, SD = 12.90) were significantly lower than both pretest (M = 61.00, SD = 12.69) and midtest (M = 60.20, SD = 12.74) worry scores (p = .04 and p = .02, respectively). The main effect of mental health service use on worry symptoms was not significant, $F(1, 161) = 2.55$, p = .11. There was no significant interaction between time and mental health service use, $F(1.77, 284.36) = .49$, p = .59, η_p^2= .003.

Medication Use

The anxiety scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 6), with time of testing (pretest, midtest, posttest) as the within-subjects variable and medication usage (current medication usage, no current medication usage) as the between-subjects variable. Box's M test showed that the assumption of homogeneity of variance-covariance matrix was not violated, p = .21. Mauchly's W was significant, W = .78, $p < .001$, $\chi^2(2)=39.76$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on anxiety symptoms was found, $F(1.67, 267.93) = 11.53$, $p < .001$, η_p^2= .067. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ (p = .42), but that posttest anxiety scores (M = 14.40, SD = 11.09) were significantly lower than both pretest (M = 17.53, SD = 11.94) and midtest (M = 16.49, SD = 11.45) anxiety scores (both ps < .001). The main effect of medication usage on anxiety symptoms was not significant, $F(1, 161) = 3.61$, p = .059. There was no significant interaction between time and medication use, F (1.67, 267.93) = .34, p = .67, η_p^2= .002.

The worry scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 7), with time of testing (pretest, midtest, posttest) as the within-subjects variable and

medication usage (current medication usage, no current medication usage) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .71$. Mauchly's *W* was significant, $W = .85$, $p < .001$, $\chi^2(2)=25.95$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. A significant main effect of time on worry symptoms was found, $F(1.77, 284.62) = 7.95$, $p = .001$, $\eta_p^2 = .047$. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ ($p = .88$), but that posttest worry scores ($M = 58.39$, $SD = 12.90$) were significantly lower than both pretest ($M = 61.00$, $SD = 12.69$) and midtest ($M = 60.20$, $SD = 12.74$) worry scores (both ps = .002). The main effect of medication usage on worry symptoms was not significant, $F(1, 161) = 2.61$, $p = .11$. There was no significant interaction between time and medication use, $F(1.77, 284.36) = 1.93$, $p = .15$, $\eta_p^2 = .012$.

Previous Mindfulness Meditation Experience

The anxiety scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 4), with time of testing (pretest, midtest, posttest) as the within-subjects variable and previous mindfulness experience (previous experience, no previous experience) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .36$. Mauchly's test of sphericity was not significant ($W = .87$, $\chi^2(2)=5.34$, $p = .07$), so sphericity is assumed. A significant main effect of time on anxiety symptoms was found, $F(2, 78) = 5.97$, $p = .004$, $\eta_p^2 = .113$. Posttest anxiety symptoms ($M = 12.39$, $SD = 10.77$) were non-significantly lower than pretest ($M = 17.49$, $SD = 11.42$) and midtest ($M = 16.17$, $SD = 12.76$) anxiety scores. The main effect of previous mindfulness experience use on anxiety symptoms was not

significant, $F(1, 39) = .99$, $p = .33$, $\eta_p^2 = .025$. There was no significant interaction between time and previous mindfulness experience, $F(2, 78) = 1.40$, $p = .25$, $\eta_p^2 = .035$.

The worry scores were analyzed in a 2 x 3 mixed factorial ANOVA (Figure 5), with time of testing (pretest, midtest, posttest) as the within-subjects variable and previous mindfulness experience (previous experience, no previous experience) as the between-subjects variable. Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .27$. Mauchly's test of sphericity was not significant ($W = .94$, $\chi^2(2) = 2.25$, $p = .33$), so sphericity is assumed. A significant main effect of time on worry symptoms was found, $F(2, 80) = 5.20$ $p = .008$, $\eta_p^2 = .115$. Posttest worry symptoms ($M = 56.47$, $SD = 11.39$) were lower than pretest ($M = 60.36$, $SD = 11.14$) and midtest ($M = 59.92$, $SD = 11.42$) worry scores. The main effect of previous mindfulness experience on worry symptoms was not significant, $F(1, 40) = .64$, $p = .43$, $\eta_p^2 = .016$ There was no significant interaction between time and previous mindfulness experience, $F(2, 80) = 1.22$, $p = .30$, $\eta_p^2 = .029$.

Summary

The analyses investigating the impact of diagnosis, mental health service usage, medication use, and previous mindfulness experience on worry and anxiety symptoms in relation to mindfulness meditation application usage showed that while anxiety and worry scores tend to be higher among the participants with mental health diagnoses, who are using mental health services or medications, it is only significantly higher for those with a mental health diagnosis. These analyses also showed that the smartphone mindfulness intervention's anxiety and worry reducing effect over time did not significantly interact with mental health diagnosis status, mental health service usage,

medication usage, or previous mindfulness experience. This indicates that including these individuals in analysis did not appear to significantly impact the comparison of the results over time, though it may have resulted in slightly higher average scores on the worry and anxiety measures.

Anxiety

The anxiety scores (BAI) of those assigned to the four week waitlist followed by a four week intervention were then analyzed in comparison to those who were assigned to the eight week intervention using the LOCF ITT method of analysis. *Table 4* displays all of the descriptive statistics for the mixed ANOVAs on anxiety and worry symptoms. *Table 5* displays each of the Mixed-ANOVA effects for anxiety symptoms. The anxiety scores were analyzed in a 2 x 3 mixed factorial ANOVA, with time of testing (pretest, midtest, posttest) as the within-subjects variable and intervention type (four week waitlist followed by four week of mindfulness intervention, eight week mindfulness smartphone intervention) as the between-subjects variable (see Figure 9). Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .53$. Mauchly's *W* was significant, $W = .79$, $p < .001$, $\chi^2(2)=37.00$, with $\varepsilon > .75$, so the Huynh-Feldt correction was utilized. The main effect of intervention type on anxiety symptoms was not significant, $F(1, 161) = .005$, $p = .95$. A significant main effect of time on anxiety symptoms was found, $F(1.69, 271) = 10.91$, $p < .001$, $\eta_p^2 = .063$. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ ($p = 1.00$), but that posttest anxiety scores ($M = 14.40$, $SD = 11.08$) were significantly lower than both pretest ($M = 17.53$, $SD = 11.94$) and midtest ($M = 16.49$, $SD = 11.44$) anxiety scores

(both *p*s < .001). There was a significant interaction between time and group, $F(1.68, 271) = 5.44$, $p = .008$, $\eta_p^2 = .033$.

To further elucidate the source of this interaction effect, a multivariate simple effects test of time within each group was conducted. For the waitlist/four week intervention group there was a significant simple effect of time, $F(2, 160) = 6.98$, $p = .001$, $\eta_p^2 = .080$. For the eight week intervention group, there was a significant simple effect of time, $F(2, 160) = 11.76$, $p < .001$, $\eta_p^2 = .128$. The relationship was probed in a series of Bonferroni corrected planned pairwise comparisons as appropriate for each hypothesis. As would be expected in hypothesis 1, there was no significant difference between pretest ($M = 16.06$, $SD = 12.76$) and midtest ($M = 17.44$, $SD = 12.57$) for the waitlist condition ($p = .60$), but there was a significant difference between pretest ($M = 18.53$, $SD = 11.30$) and midtest ($M = 15.84$, $SD = 10.63$) of the eight week intervention group ($p = .009$), with scores reducing over time (see Figure 10).

As would be expected in hypothesis 2, there was no significant difference between pretest ($M = 16.06$, $SD = 12.76$) and midtest ($M = 17.44$, $SD = 12.57$) for the waitlist condition ($p = .60$), but there was a significant difference between pretest ($M = 18.53$, $SD = 11.30$) and posttest ($M = 14.19$, $SD = 10.18$) of the eight week intervention group ($p < .001$). In reference to hypothesis 3, there was a significant difference between midtest ($M = 17.44$, $SD = 12.57$) and posttest ($M = 17.44$, $SD = 12.57$) anxiety scores for those who completed the four week waitlist before completing four weeks of the smartphone mindfulness intervention with scores reducing over time ($p = .001$). There was also a significant difference between pretest ($M = 18.53$, $SD = 11.30$) and posttest ($M = 14.19$, $SD = 10.18$) of the eight week intervention group ($p < .001$) with scores

reducing significantly over time. To further investigate this interaction in reference to hypothesis 3, a 2 x 2 mixed factorial ANOVA was conducted, with time of testing (pretest, posttest) as the within-subjects variable and intervention type (four week intervention, eight week mindfulness smartphone intervention). In this analysis, only the main effect of time was significant, $F(1, 161) = 34.41$, $p < .001$, $\eta_p^2 = .176$. The main effect of group was not statistically significant, $F(1, 161) = .03$, $p = .87$, $\eta_p^2 < .001$. Contrary to hypothesis 3, there was no significant group x time interaction effect $F(1, 161) = 1.79$, $p = .18$, $\eta_p^2 = .011$.

Worry

The worry scores of those assigned to the four week waitlist followed by a four week intervention were analyzed in comparison to those who were assigned to the eight week intervention using the LOCF ITT method of analysis. *Table 4* displays all of the descriptive statistics for the mixed ANOVAs on anxiety and worry symptoms. *Table 6* displays each of the Mixed-ANOVA effects for anxiety symptoms. The worry scores were analyzed in a 2 x 3 mixed factorial ANOVA, with time of testing (pretest, midtest, posttest) as the within-subjects variable and intervention type (four week waitlist followed by four week of mindfulness intervention, eight week mindfulness smartphone intervention) as the between-subjects variable (see Figure 11). Box's *M* test showed that the assumption of homogeneity of variance-covariance matrix was not violated, $p = .32$. Mauchly's *W* was significant ($W = .85$, $\chi^2(2)=25.34$, $p < .001$, $\varepsilon > .75$), so the Huynh-Feldt correction was utilized. A significant main effect of time worry symptoms was found, $F(1.77, 285.45) = 8.25$, $p = .001$, $\eta_p^2 = .049$. Bonferroni corrected post hoc tests showed that pretests and midtests did not significantly differ ($p = 1.00$), but that posttest worry

scores (M = 58.39, SD = 12.91) were significantly lower than both pretest (M = 61.00, SD = 12.68) and midtest (M = 60.19, SD = 12.74) worry scores (p = .002 and p = .001, respectively). The main effect of intervention type on worry symptoms was not significant, $F(1, 161) = .06$, $p = .81$. There was no significant interaction between time and group, $F(1.77, 285.45) = 1.98$, $p = .15$.

The main effect of time indicated that the intervention may have reduced worry scores. To better understand how this effect may relate to the hypotheses of this study, a series of Bonferroni corrected planned pairwise comparisons as appropriate for each hypothesis. As would be expected in hypothesis 4, there was no significant difference between pretest (M = 59.88, SD = 13.80) and midtest (M = 60.39, SD = 13.27) for the waitlist condition (p = 1.00), but contrary to hypothesis there was also no significant difference between pretest (M = 61.76, SD = 11.89) and midtest (M = 60.07, SD = 12.44) of the eight week intervention group (p = .14; see Figure 12 for a graph of means).

As predicted by hypothesis 5, there was no significant difference between pretest (M = 59.88, SD = 13.80) and midtest (M = 60.39, SD = 13.27) for the waitlist condition (p = 1.00), but there was a significant difference between pretest (M = 61.76, SD = 11.89) and posttest (M = 58.32, SD = 12.87) of the eight week intervention group ($p < .001$), with scores reducing significantly over time (see Figure 13 for a graph of means). In reference to hypothesis 3, there was a significant difference between midtest (M = 60.39, SD = 13.27) and posttest (M = 58.50, SD = 13.06) worry scores for those who completed the four week waitlist before completing four weeks of the smartphone mindfulness intervention with scores reducing over time (p = .04). There was also a significant difference between pretest (M = 61.76, SD = 11.89) and posttest (M = 58.32, SD = 12.87)

of the eight week intervention group ($p < .001$) with scores reducing significantly over time.

To further investigate hypothesis 6, a 2 x 2 mixed factorial ANOVA was conducted, with time of testing (pretest, posttest) as the within-subjects variable and intervention type (four week intervention, eight week mindfulness smartphone intervention). In this analysis, only the main effect of time was significant, $F(1, 161) = 21.27$, $p < .001$, $\eta_p^2 = .117$. The main effect of group was not statistically significant, $F(1, 161) = .10$, $p = .76$, $\eta_p^2 = .001$. Contrary to hypothesis 3, there was no significant group x time interaction effect $F(1, 161) = 1.83$, $p = .18$, $\eta_p^2 = .011$.

These results were consistent with hypothesis 5, and contrary to hypotheses 4 and 6. It may be worth noting that while the four week intervention was not superior in comparison to the four week waitlist control, there were some mixed results as to whether the four week mindfulness intervention resulted in a significant pre-post reduction in worry symptoms. Those who completed the intervention after completing the waitlist reported barely significant results ($p = .04$), and those who started with the intervention reported non-significant results ($p = .14$).

A parallel series of per protocol analyses was conducted to determine the impact of the intervention on those who use the application for at least 1 hour for every 4 weeks they were asked to use it (1 hours for the 4 week group and 2 hours for the 8 week group), with similar results to analyses using LOCF (see Appendix D).

Percent Reduction of Worry and Anxiety Symptoms

In order to provide a numerical representation of mean change in anxiety and worry symptoms for participants in the experimental groups based upon the amount of

hours of use and the amount of weeks of access, the mean percent reduction was calculated. This was done for the LOCF ITT method of analysis, the per protocol method of analysis requiring 60 minutes or more of application use per 4 week period of access, and a per protocol method of analysis requiring 240 minutes or more of application use per 4 week period of access (which was the minimum requested amount in this study). *Table 7* presents this data for both anxiety and worry symptoms.

Discussion

This study sought to evaluate a widely used smartphone mindfulness app's effectiveness at reducing anxiety and worry symptoms and to evaluate the length of use required for any such benefits. An extremely conservative intention to treat last observed carried forward method of analysis was conducted for each of the mixed ANOVAs conducted and all post hoc and pairwise comparisons were Bonferroni corrected.

As predicted in hypotheses 1 and 2, individuals assigned to use the mindfulness smartphone application reported having significantly lower anxiety symptoms at both four weeks and eight weeks in comparison to a four week waitlist control group. When compared to the four week waitlist, there was a medium sized interaction effect between group and time for the four week intervention and a large effect size for this interaction for the eight week intervention. Contrary to hypothesis 3, the difference between four weeks and eight weeks of use was not statistically significant. Those who used the application for four weeks experienced a 14-31% mean reduction in anxiety symptoms, and those who used the application for eight weeks experienced a 23-34% reduction in anxiety symptom. Because the mean reduction of anxiety in four weeks of application use is as high as 31% in some groups, the lack of significant difference between the outcomes

at four weeks and eight weeks could be related to ceiling effects. Preliminary analysis indicated that of those invited to continue in the study and use the application, those who chose to participate had higher physiological anxiety symptoms than those who did not. This may indicate that those more in need of a reduction of these types of symptoms are more likely to use it. Alternately, it may be that having those with higher anxiety symptomatology elect to participate may have provided more room to improve, and thus increased effect sizes for anxiety reduction. Overall, these results indicate that the smartphone mindfulness intervention had a clinically and statistically significant impact on users' anxiety symptoms in a short amount of time.

Contrary to hypothesis 4, in comparison to a four week waitlist control group, individuals assigned to use the mindfulness smartphone application did not report having significantly lower worry symptoms at four weeks into intervention, but did at eight weeks into the intervention (as predicted in hypothesis 5). When compared to the four week waitlist, there was a medium effect size for the interaction effect between group and time for this interaction effect for the eight week intervention. Contrary to hypothesis 6, the difference in worry symptom reduction between four weeks and eight weeks was not statistically significant. The LOCF analysis and the per protocol analysis that required a minimum of 60 minutes per 4 weeks of access to the application indicated that participants with access to the application for four weeks experienced a 2-6% mean reduction in worry symptoms. Those same analyses indicated that those with access to the application for eight weeks experienced a 5-9% reduction in worry symptoms. This indicates that more mindfulness application use time is required for the smartphone application to have a clinically significant impact on worry symptoms than anxiety. This

concept is bolstered by the fact that those who used the application for an average of one hour per week experienced about a 9% reduction in worry symptoms in a four week time period and an approximate 18% reduction in worry symptoms after eight weeks.

This smartphone mindfulness intervention resulted in more robust and timely reductions in anxiety symptoms than in worry symptoms. Most evaluations of clinician-directed mindfulness treatments do not include a measure of outcomes at 4 weeks into intervention, but only after completion of the full 8 week intervention (Evans et al., 2008; Vøllestad, et al., 2012). Eight weeks of this smartphone mindfulness intervention has nearly as large of an impact on anxiety symptoms, in terms of effect size, as clinician-directed mindfulness and acceptance-based interventions (Vøllestad, et al., 2012) and a greater impact than most other technology driven mindfulness applications (Boettcher et al., 2014; Cavanagh et al., 2013; Cavanagh et al., 2014; Spijkerman et al., 2016). Though eight weeks of this smartphone mindfulness intervention only had a medium effect size on worry, it had nearly as large of an impact on worry symptoms as clinician-directed mindfulness interventions (Vøllestad, et al., 2011). As such, the discrepancy in effect size and treatment effectiveness for anxiety and worry may not be unique to this modality of treatment, but more representative of mindfulness interventions in general.

If future replication and expansion studies indicate that the results found in this study are an accurate and generalizable assessment of Headspace's effectiveness at reducing anxiety and worry, the clinical implications would be profound. Headspace could be used as either an adjunctive or standalone treatment for those with moderate to high anxiety and worry. Health insurance companies with a vested interest in reducing the increased costs medical costs associated with heightened anxiety, could offer at-risk

client's access to Headspace, potentially decreasing their chances of needing treatment for future physical and mental health issues (Fehm et al., 2008; Hazlett-Stevens et al., 2003; Kroenke et al., 2007). Organizations with long waiting lists, such a community mental health centers or college campus counseling clinics, could provide those waiting to see a clinician with Headspace codes in order to provide initial symptom reduction when they would ordinarily be receiving none. Individuals in rural areas could have an accessible resource for mental health assistance, without having to travel to distant towns to see a clinician. More research is needed to determine if and how this intervention truly works.

The purpose of this study was to provide an initial evaluation of the effectiveness of Headspace at reducing anxiety and worry symptomology. This study did not address potential mechanisms of treatment. There are many potential mechanisms through which mindfulness interventions like Headspace may reduce anxiety and worry. Potential mechanisms include, but are not limited to, increases in trait mindfulness (Roemer, & Orsillo, 2015; Vøllestad et al., 2011), increases in executive functioning related to self-regulation and self-management (Bondolfi, 2005; Hart et al., 2013), increases in decentering of emotions (Hayes-Skelton et al., 2015; Safran & Segal, 1996), increases in self-compassion (Keng et al., 2012), and exposure to unpleasant emotional states (Bondolfi, 2005). None of these potential mechanisms of change were measured in this study. As such, it would be premature to draw conclusions as to the mechanisms of action for this intervention. Any of these potential mechanisms could have impacted the effectiveness of this treatment, as could many other factors. Previous research has indicated that an individual's expectation of a treatment's anxiety reducing outcome can

be a significant predictor of treatment response (Brown et al., 2014; Price & Anderson, 2012; Westra, Dozois, & Marcus, 2007). Likewise, initial self-efficacy and the development of self-efficacy over the course of an intervention can significantly impact an individual's treatment response to anxiety-related treatments (Brown et al., 2014). Since the potential positive psychological benefits of mindfulness has generated some buzz in popular culture, including being featured on the cover of TIME magazine (Pickert, 2014), it could be that this treatment has higher than average overall outcome expectancies. Heightened expectancy effects could, in part, explain the lack of dose effect found for anxiety symptomology in this study. Future researchers could include measures of these potential mechanisms of action and/or active controls in order to determine more accurately what, if any, aspects of this mindfulness intervention are reducing anxiety and worry and to what degree, if any, expectancy effects or other non-treatment specific factors are doing so.

This study had several limitations that researchers can address in future research. The control group used in this study was a waitlist group which does not account for a placebo effect in the way that an active control group would. Furthermore, due to time limitations, the waitlist intervention was only four weeks in duration, instead of eight weeks. After the four week waitlist control, the mean anxiety and worry scores either increased or remained fairly steady, and there is reason to believe this trend would have continued for an additional four weeks, but this cannot be known without running additional participants.

It is important to note that much of the data in this study were provided by self-report. All information about demographics, pre-existing factors, and anxiety/worry

symptomology were self-report data. As discussed in more detail by Abbott, Shirali, Haws, and Lack (2017), the accuracy of self-report measures are dependent on a participant's level of insight and degree of honesty. A participant may purposely lie in self-report measures for a number of reasons including concern that disclosing factors such a previous diagnosis may exclude them from participating in the study (Resnik & Ness, 2012). While there were no such exclusion criteria in this study, the participants did not know this. Previous studies have found that there is also considerable error in self-reporting of even concrete observable behaviors such as physical activity (Prince et al., 2008). Thus, even participants with good insight who were trying to report accurately may still have given inaccurate information about their current anxiety or worry symptoms due to cognitive biases or memory errors (Abbott et al., 2017). Notably, all data regarding each participant's minutes of Headspace application usage was provided by electronically tracking their usage through the app itself and not through self-report by the participants. This is a strength of this study's design that may not be the norm in assessments of technology-delivered interventions (Firth et al., 2017).

This was the first study of its kind to assess the Headspace application's impact on anxiety and worry symptoms and the results are promising (Headspace Inc., 2010). A clinically effective application of this kind may be able to circumvent many of the structural and attitudinal barriers to treatment. However, it is still unclear as to whether this application will be able to reach populations that would otherwise be unlikely or unable to seek or access counseling. Our sample did not have a large proportion of the individuals less likely to receive mental health services, such as males and ethnic minorities. Additionally, the participants in this study was comprised of primarily young

adults. It may be that middle age and older individuals may either feel uncomfortable with a smartphone intervention or have difficulty using it. Further research should be conducted on the comparative acceptability of this smartphone mindfulness application to in-person treatment and other forms of help-seeking. Research could also be conducted to determine the effectiveness of this application on demographic groups underrepresented in this sample.

The results of this study could provide potential application users with a picture of what kind of results to expect from regular use of the Headspace application, and how long they can expect to wait before seeing reductions in their anxiety and worry. Likewise, this study can help inform clinicians and institutions on what resources may be of use to their clients. It is important to note that a single study does not provide enough evidence to determine if a specific treatment can be considered truly an evidence-based practice. This study helps to fill the growing gap in research on smartphone application interventions, but further replications and extensions of this type of study are critically needed.

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Table 1

Descriptive Information for Demographic Variables of Participants

	M	SD	Range
Age	24	9	18-65
Household Income	$56,000	$49,000	$0-$200,000
	N		%
Gender Identity			
Female	131		80.4%
Male	29		17.8%
Other	3		1.8%
Sexual Orientation			
Heterosexual	125		76.7%
Bisexual	22		13.5%
Pansexual	7		4.3%
Homosexual	5		3.1%
Asexual	4		2.5%
Race/Ethnicity			
White	101		62%
Biracial/Multi-Racial	22		13.5%
Hispanic/Latinx	16		9.9%
Asian	13		8%
Black/African American	8		4.9%
Native American	3		1.8%
Religion/Spiritual Worldview			
Christian	74		45.4%
Atheist	28		17.2%
Agnostic	26		16.0%
Spiritual not Religious	14		8.6%
Undecided	8		4.9%
No Religious/Spiritual Worldview	6		3.7%
Muslim	2		1.2%
Buddhist	2		1.2%
Hindu	2		1.2%
Wiccan	1		0.6%

Table 2

Descriptive Information for Preexisting Factors of Participants

	N	%
Diagnosis Status		
No Diagnosis	93	57.1%
Major Depressive and Anxiety	15	9.2%
Generalized Anxiety	11	6.7%
Major Depressive	7	4.3%
Two or More Anxiety	7	4.3%
Social Anxiety	4	2.5%
Attention-Deficit Hyperactivity	3	1.8%
Alcohol/Substance Dependent	2	1.2%
Adjustment	2	1.2%
Major Depressive and PTSD	2	1.2%
Bipolar Disorder	1	.6%
PTSD	1	.6%
Asperger's	1	.6%
Panic Disorder	1	.6%
Eating disorder	1	.6%
Mental Health Service Usage		
None	131	80%
Counseling	23	14.1%
Other Mental Health Service	8	4.9%
Medication Usage		
None	96	58.9%
Non-psychotropic	23	14.1%
More than one	20	12.3%
Sleep Medication	7	4.3%
Unknown	5	3.1%
Anti-Depressant	4	2.5%
Anti-Anxiety	2	1.2%

Table 3

Descriptive Information for Previous Meditation Usage of Participants

	N	%
Previous Meditation Usage		
None	42	71.2%
Some	17	28.8%
If Some, Amount of Use:		
Less than 1 hour	5	29.4%
Between 1 and 5 hours	6	35.3%
Between 6 and 10 hours	2	11.8%
Between 11 and 20 hours	1	5.9%
Between 76-100 hours	1	5.9%
More than 100 hours	2	11.8%

Table 4

Descriptive information for the Beck Anxiety Inventory (BAI) and Penn State Worry Questionnaire (PSWQ) for each group

	Waitlist Control/ 4 Week Intervention Group			8 Week Intervention Group			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Beck Anxiety Inventory (BAI)									
Pre	66	16.06	12.76	97	18.53	11.31	163	17.53	11.94
Mid	66	17.44	12.57	97	15.85	10.63	163	16.49	11.45
Post	66	14.71	12.37	97	14.19	10.18	163	14.40	11.09
Penn State Worry Questionnaire (PSWQ)									
Pre	66	59.88	13.80	97	61.76	11.89	163	61.00	12.69
Mid	66	60.38	13.27	97	60.07	12.44	163	60.20	12.74
Post	66	58.50	13.06	97	58.32	12.87	163	58.39	12.90

Table 5

Mixed-ANOVA model effects for the Beck Anxiety Inventory (BAI) using a Last Observed Carried Forward Intention to Treat method of analysis

Analysis type	Factor	*Df*	*Df error*	*F*	*p*	η_p^2
Pre to Mid to Post (3x2)						
	Time	1.69	271	10.91	<.001	.063
	Group	1	161	.01	.95	<.001
	Time x Group	1.68	271	5.44	.008	.033
Pre to Mid (2x2)						
	Time	1	161	.88	.35	.005
	Group	1	161	.06	.80	< .001
	Time x Group	1	161	8.52	.004	.050
4 Week Waitlist to 8 week Intervention (2x2)						
	Time	1	161	4.42	.04	.027
	Group	1	161	.05	.82	<.001
	Time x Group	1	161	16.48	<.001	.093
4 Week Intervention to 8 week Intervention (2x2)						
	Time	1	161	34.41	<.001	.176
	Group	1	161	.03	.87	<.001
	Time x Group	1	161	1.79	.18	.011

Table 6

Mixed-ANOVA model effects for the Penn State Worry Questionnaire (PSWQ) using a Last Observed Carried Forward Intention to Treat method of analysis

Analysis type	Factor	*Df*	*Df error*	*F*	*p*	η_p^2
Pre to Mid to Post (3x2)						
	Time	1.77	285.45	8.25	.001	.049
	Group	1	161	.06	.81	<.001
	Time x Group	1.77	285.45	1.98	.15	.012
Pre to Mid (2x2)						
	Time	1	161	.82	.64	.005
	Group	1	161	.17	.68	.001
	Time x Group	1	161	2.77	.10	.017
4 Week Waitlist to 8 week Intervention (2x2)						
	Time	1	161	5.11	.03	.031
	Group	1	161	.002	.97	<.001
	Time x Group	1	161	9.18	.003	.054
4 Week Intervention to 8 week Intervention (2x2)						
	Time	1	161	21.27	<.001	.117
	Group	1	161	.10	.76	.001
	Time x Group	1	161	1.83	.18	.011

Table 7

Percent reduction in anxiety and worry symptoms for each experimental group condition

Measure	Group	Intervention Interval	Analysis Type					
			Last Observed Carried Forward		Per Protocol (60 minutes per 4 weeks)		Per Protocol (240 minutes per 4 weeks)	
			N	Mean %	N	Mean %	N	Mean %
Beck Anxiety Inventory								
	Eight Week Group	Pre to Mid (4 Weeks)	97	14.46%	49	20.86%	16	14.44%
		Pre to Post (8 Weeks)	97	23.42%	40	33.91%	13	32.87%
	Four Week Group	Mid to Post (4 Weeks)	66	15.65%	26	30.50%	10	23.79%
Penn State Worry Questionnaire								
	Eight Week Group	Pre to Mid (4 Weeks)	97	2.73%	50	3.53%	16	9.86%
		Pre to Post (8 Weeks)	97	5.57%	41	8.83%	13	17.72%
	Four Week Group	Mid to Post (4 Weeks)	66	3.11%	26	5.91%	9	8.58%

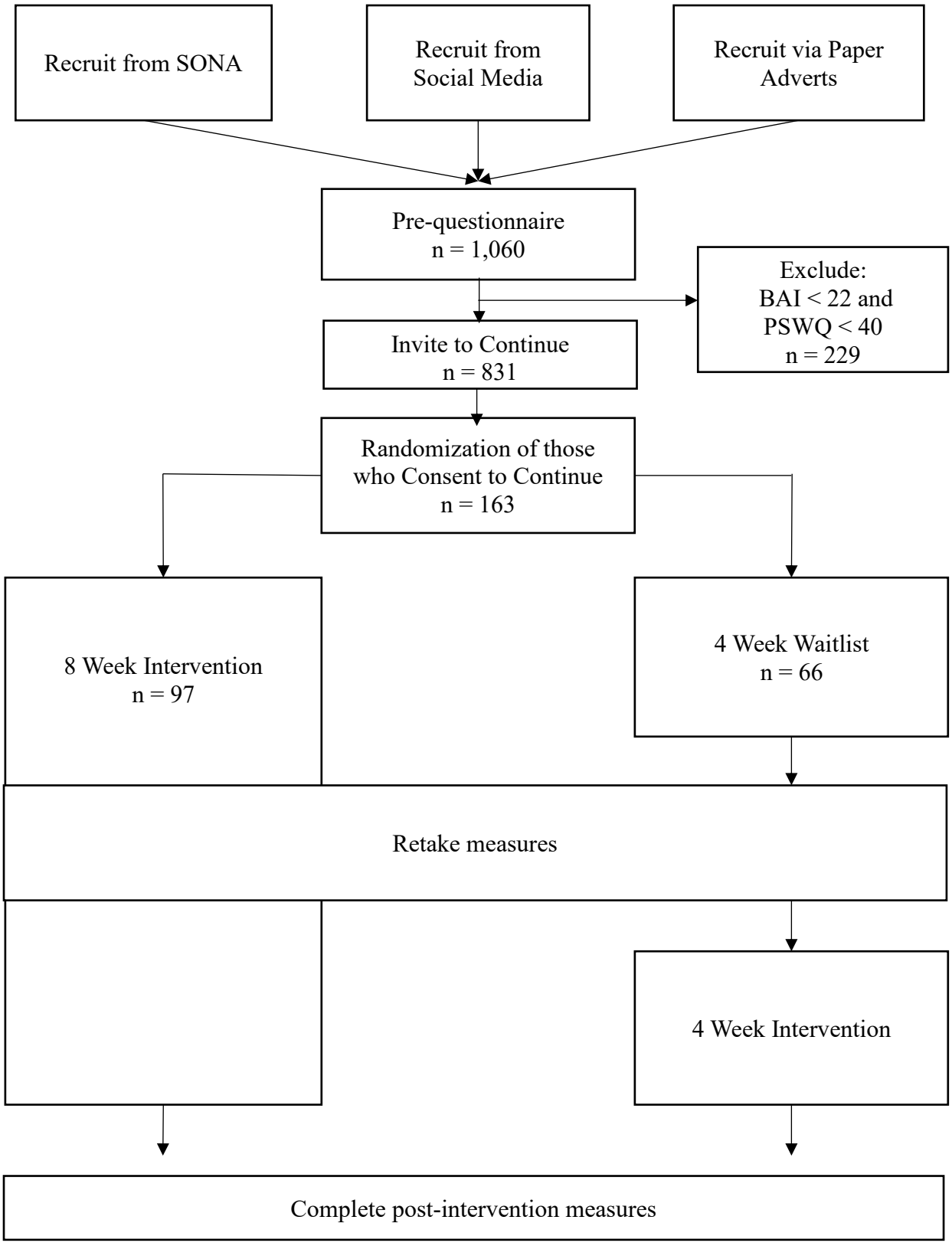

Figure 1. Diagram of participant flow through the study.

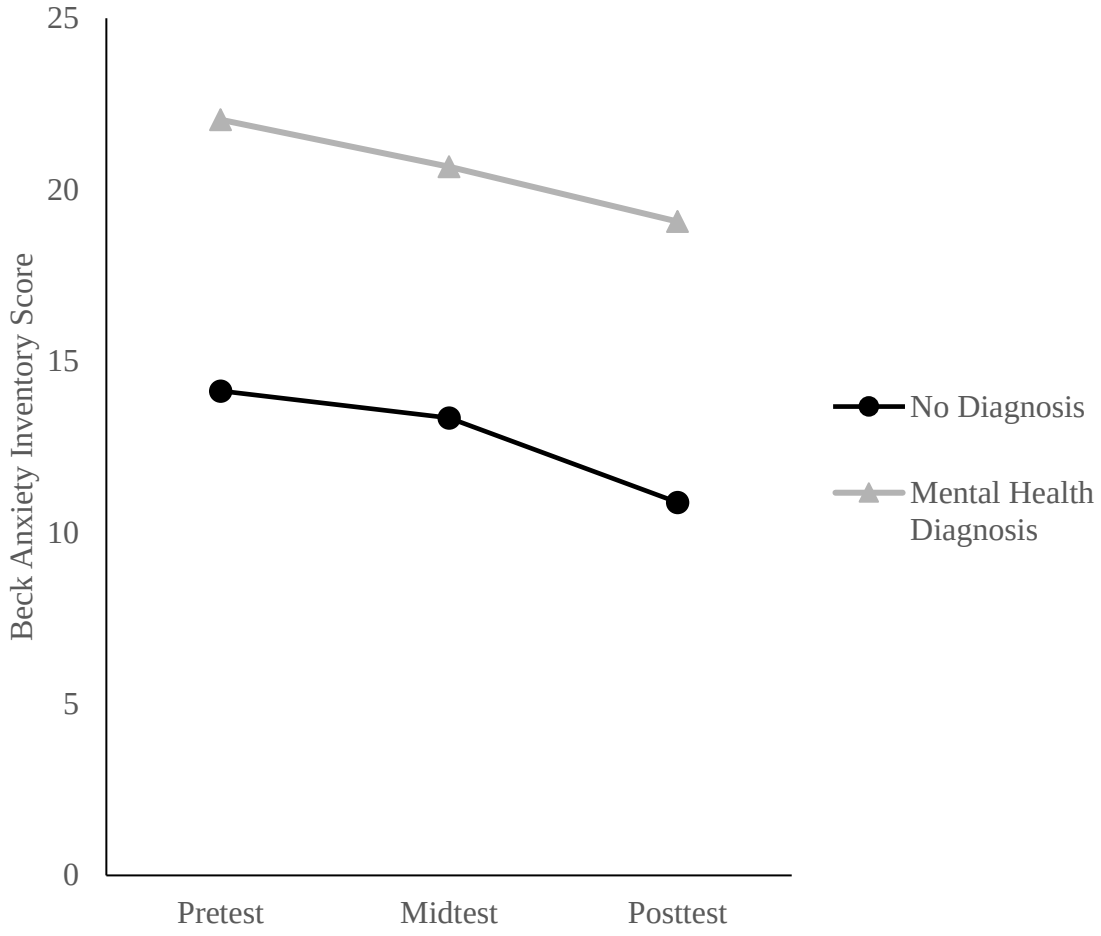

Figure 2. Graph of Beck Anxiety Inventory score means for participants with and without mental health diagnoses.

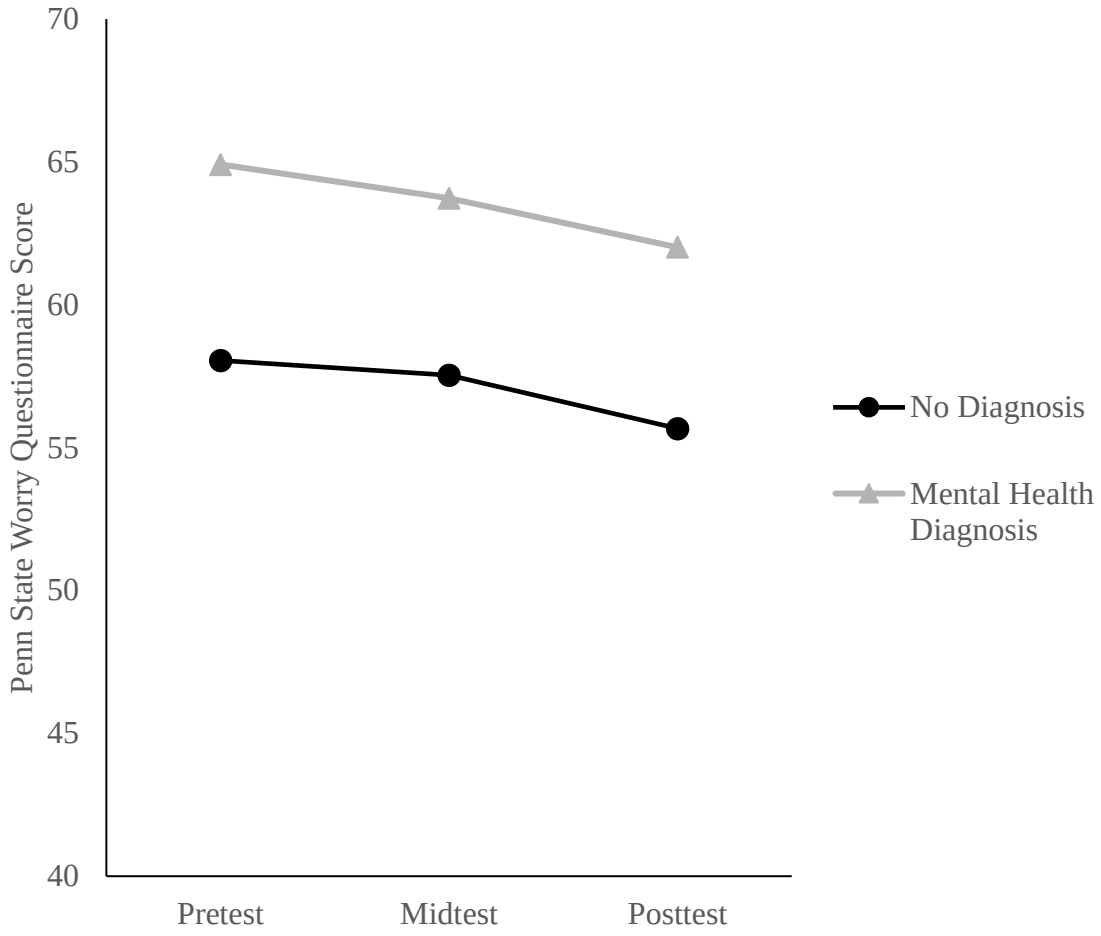

Figure 3. Graph of Penn State Worry Questionnaire score means at pretest, midtest, and posttest for participants with and without mental health diagnoses.

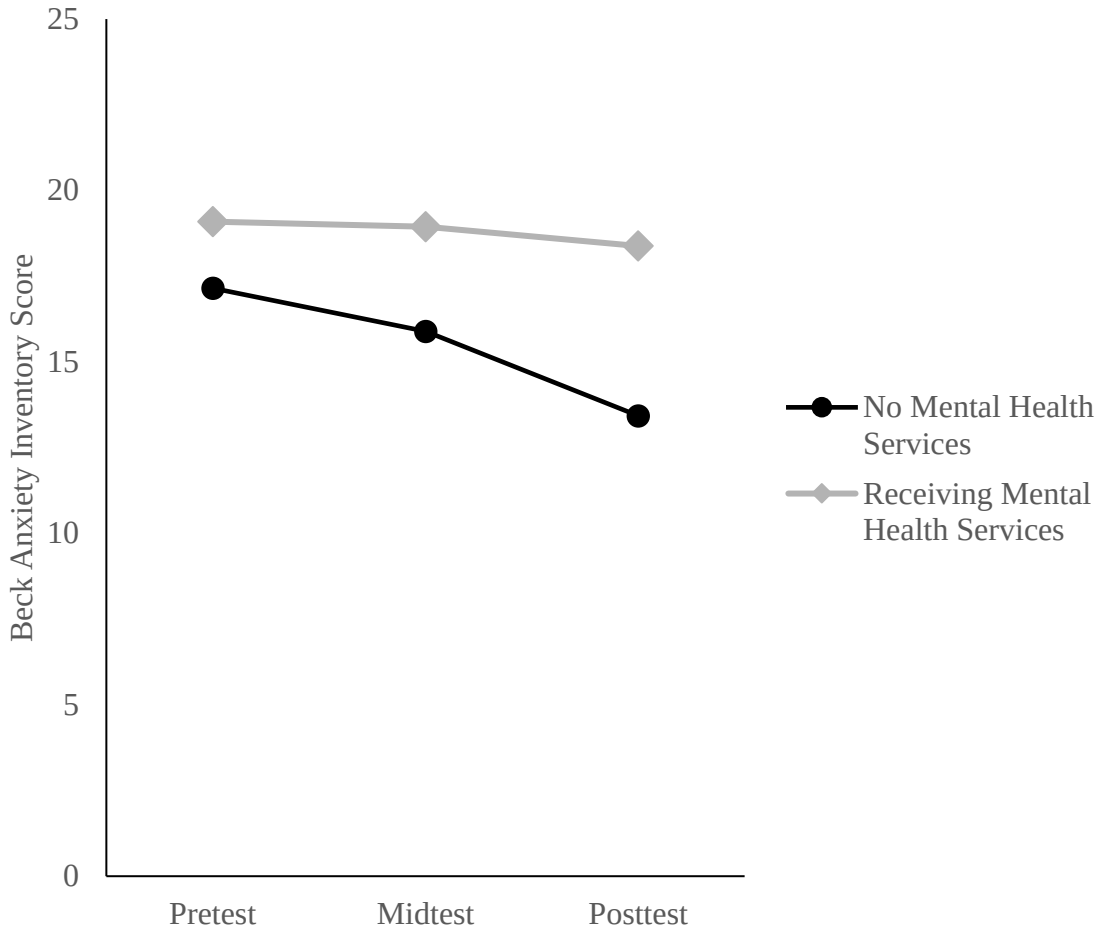

Figure 4. Graph of Beck Anxiety Inventory score means at pretest, midtest, and posttest for participants who are and are not receiving counseling or other mental health services.

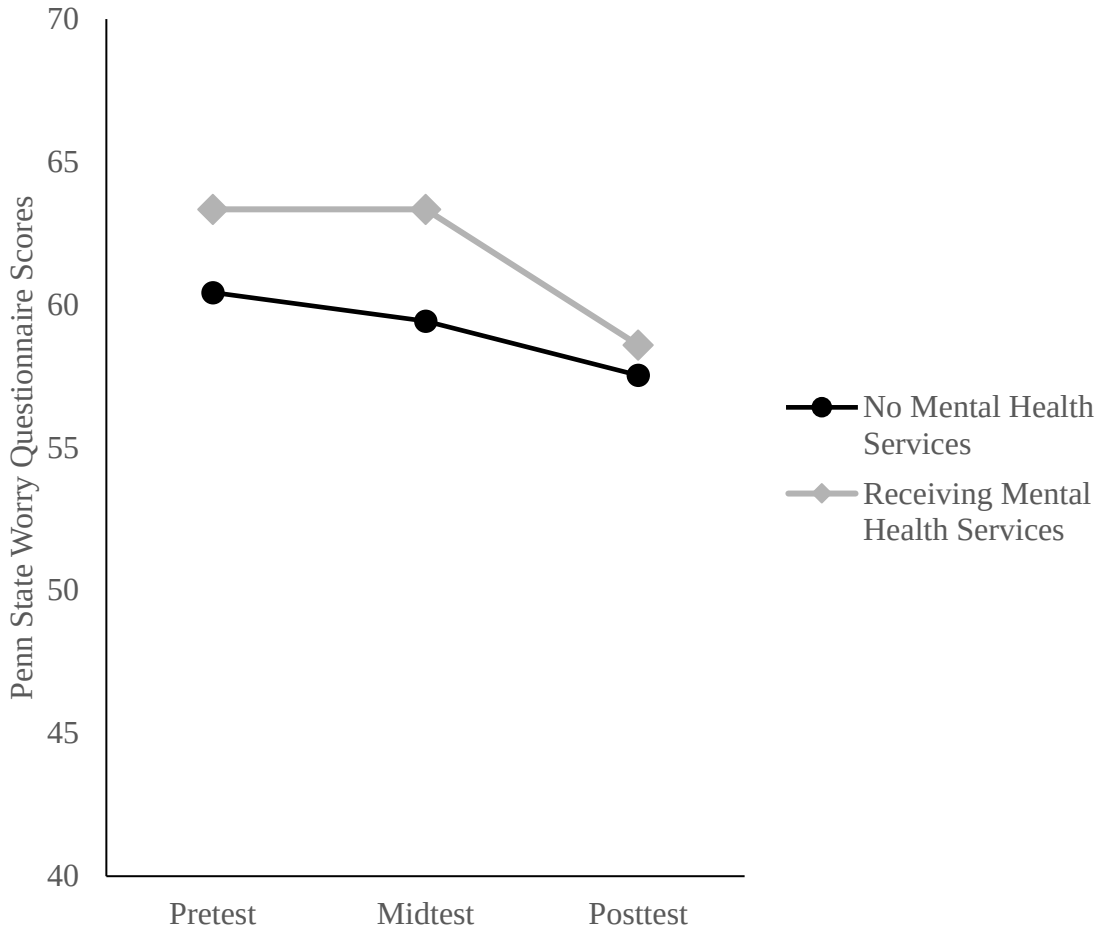

Figure 5. Graph of Penn State Worry Questionnaire score means at pretest, midtest, and posttest for participants who are and are not receiving counseling or other mental health services.

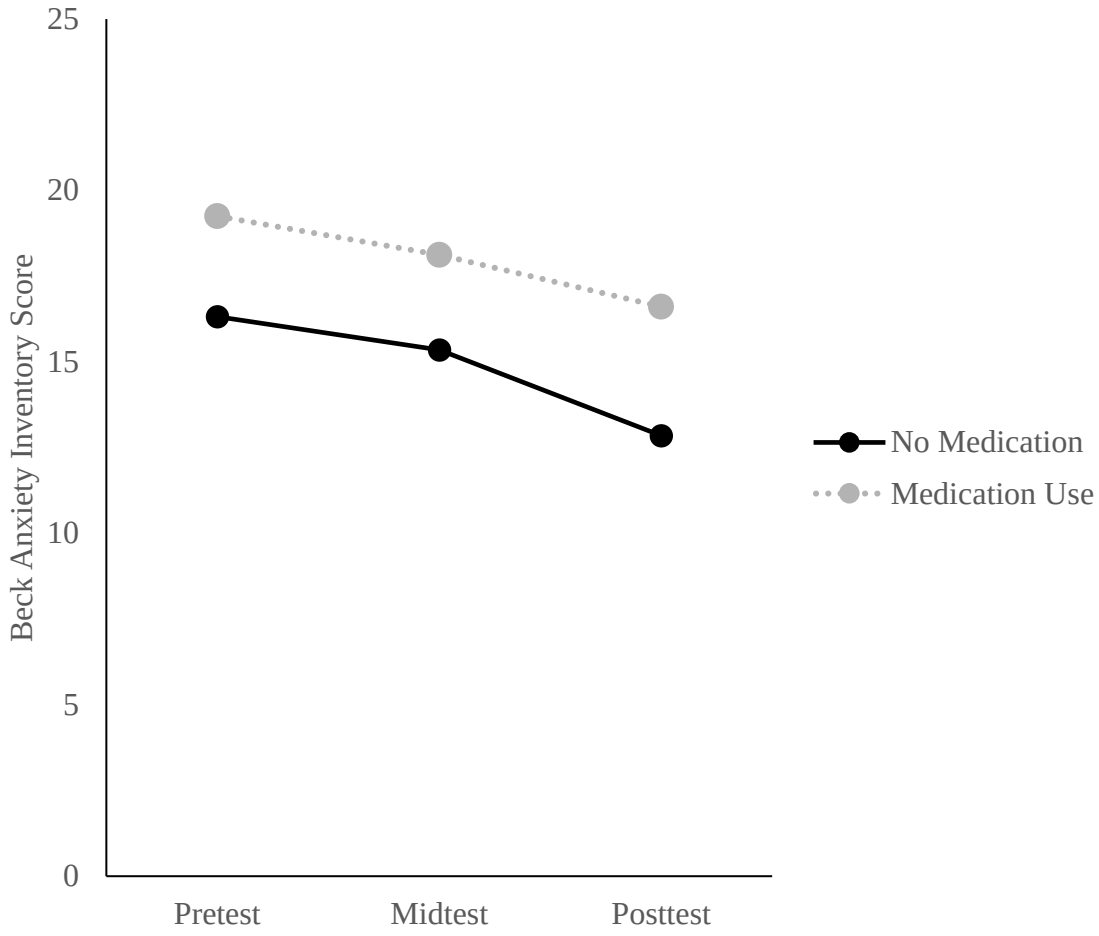

Figure 6. Graph of Beck Anxiety Inventory score means at pretest, midtest, and posttest for participants who are and are not taking medications.

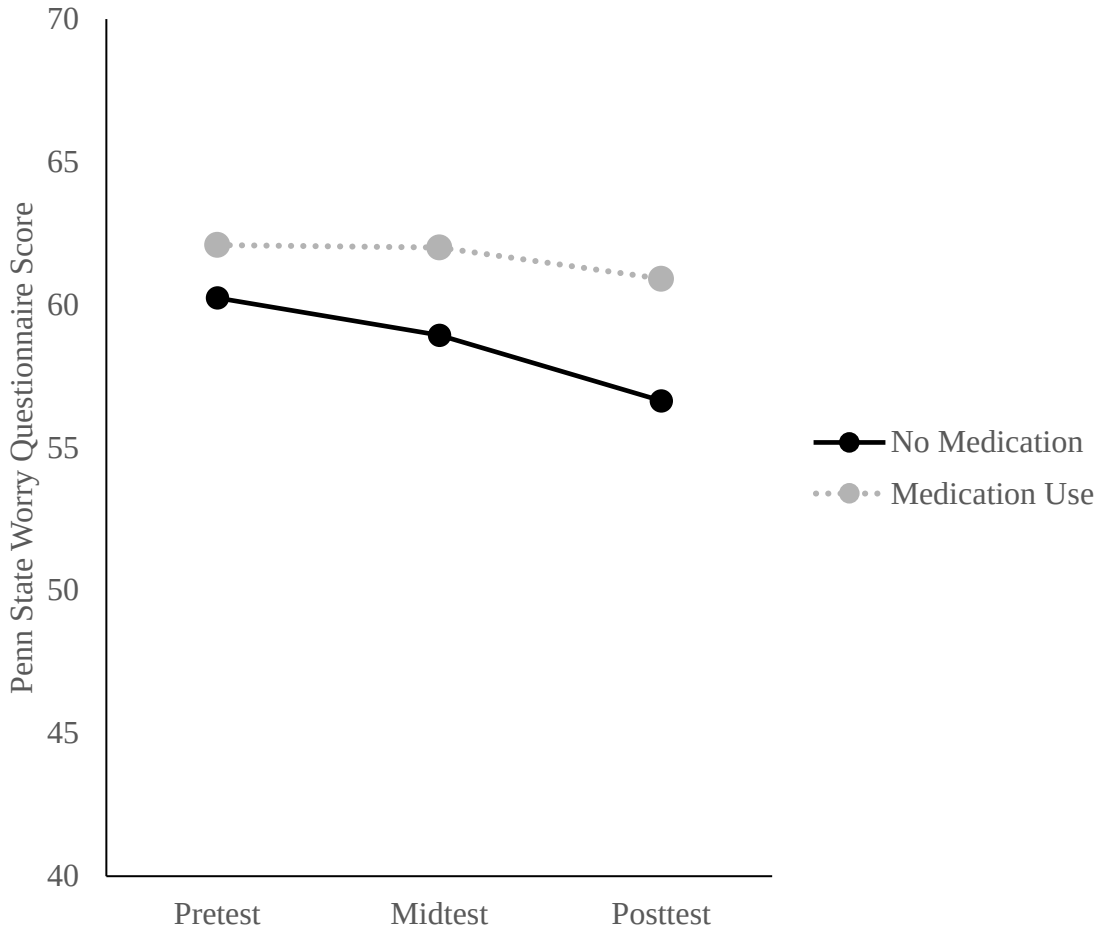

Figure 7. Graph of Penn State Worry Questionnaire score means at pretest, midtest, and posttest for participants who are and are not taking medications.

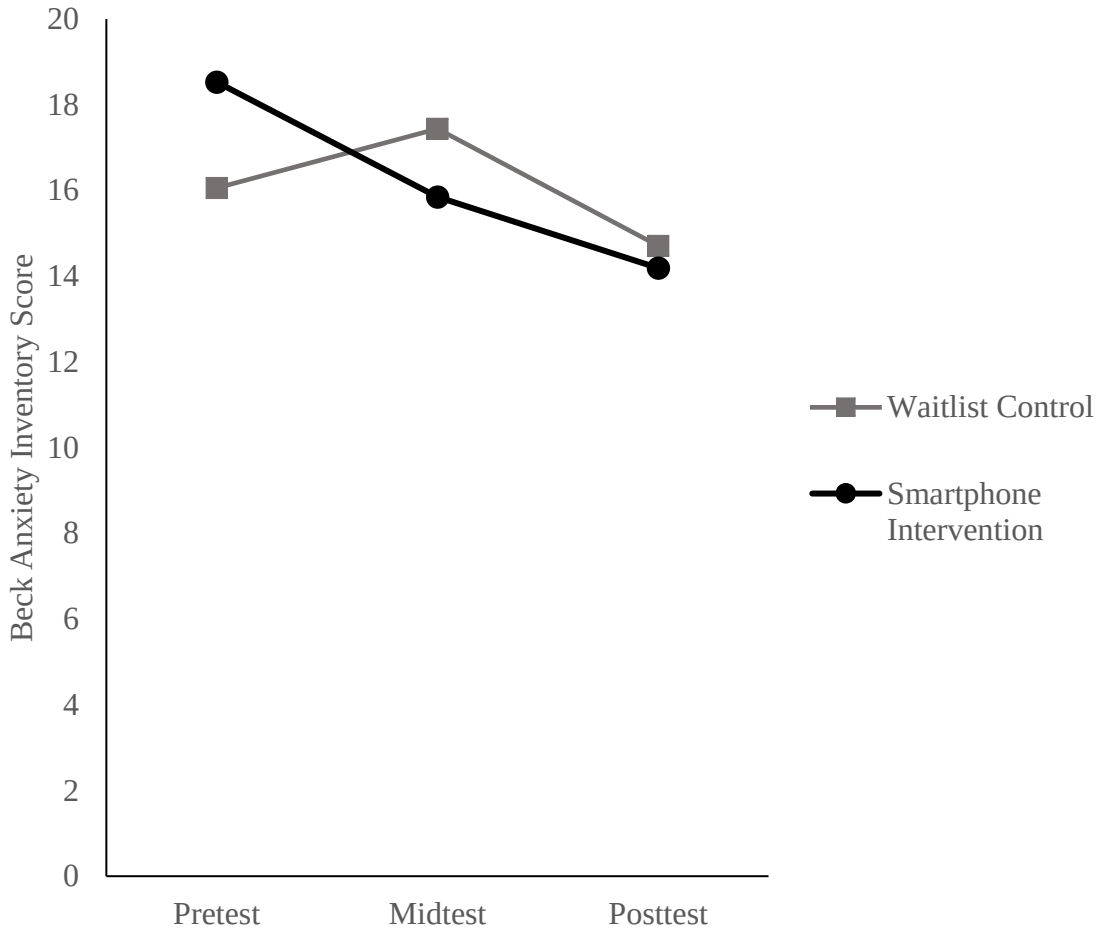

Figure 8. Graph of last observed carried forward intention to treat (LOCF ITT) Beck Anxiety Inventory score means at pretest, midtest, and posttest for participants in the four week waitlist/four week intervention group and the eight week smartphone intervention group.

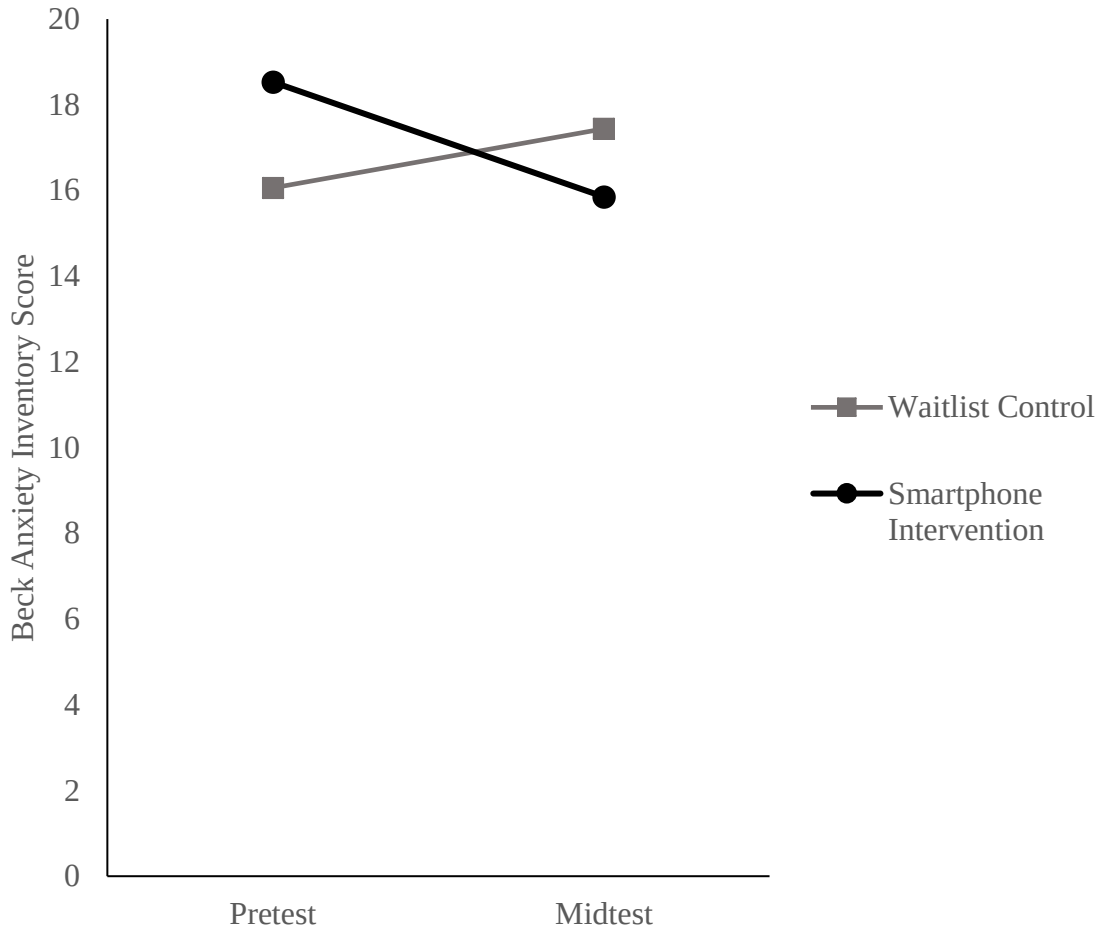

Figure 9. Graph of last observed carried forward intention to treat (LOCF ITT) Beck Anxiety Inventory score means at pretest and midtest for participants in the waitlist and smartphone intervention groups.

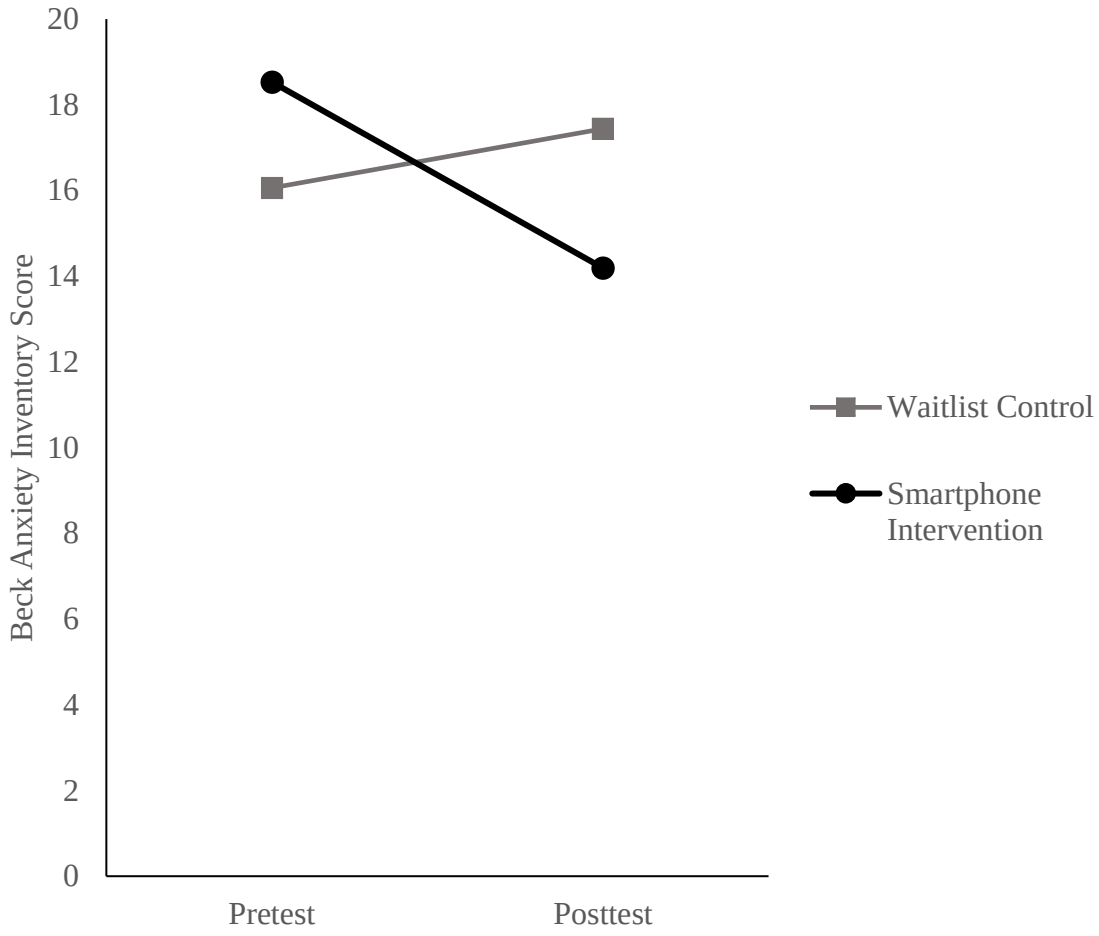

Figure 10. Graph of last observed carried forward intention to treat (LOCF ITT) Beck Anxiety Inventory score means at pretest and posttest for participants in the four week waitlist and the eight week smartphone intervention group.

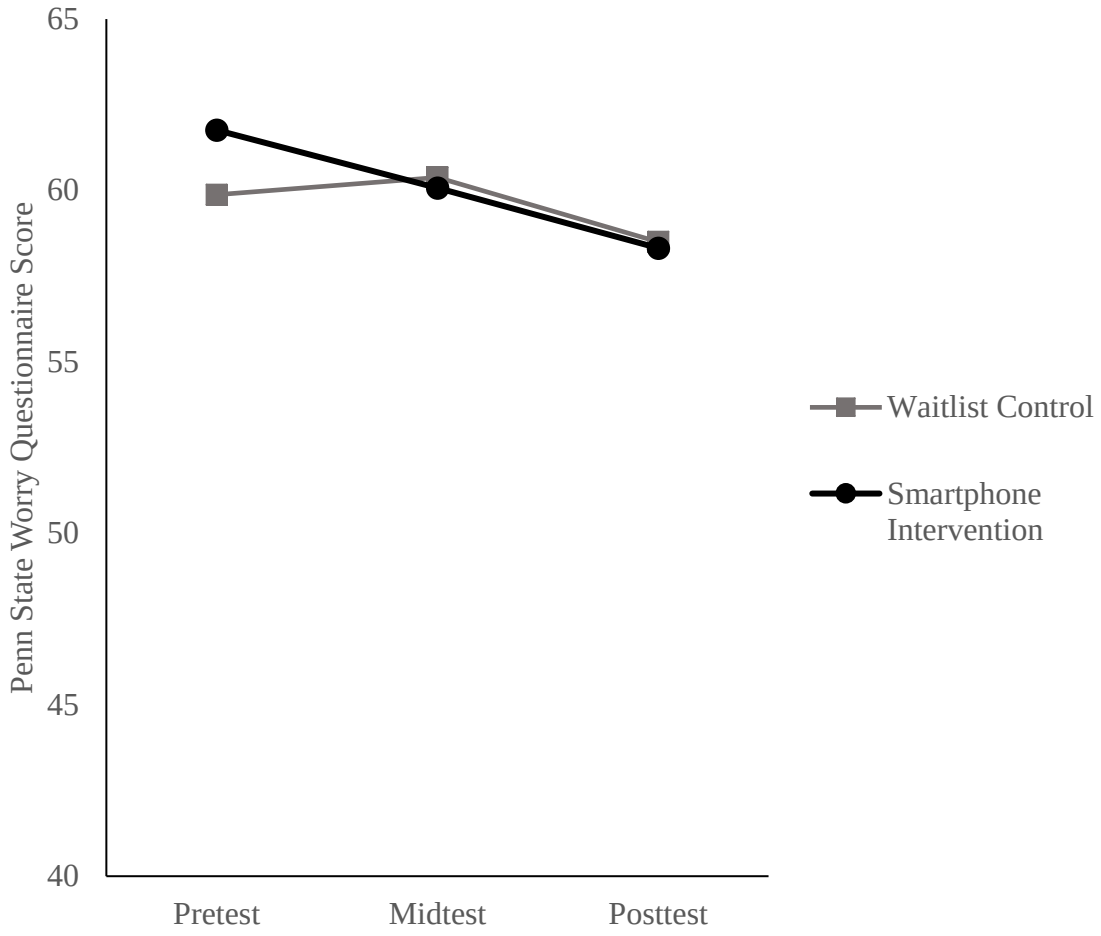

Figure 11. Graph of last observed carried forward intention to treat (LOCF ITT) Penn State Worry Questionnaire score means at pretest, midtest, and posttest for participants in the four week waitlist/four week intervention group and the eight week smartphone intervention group.

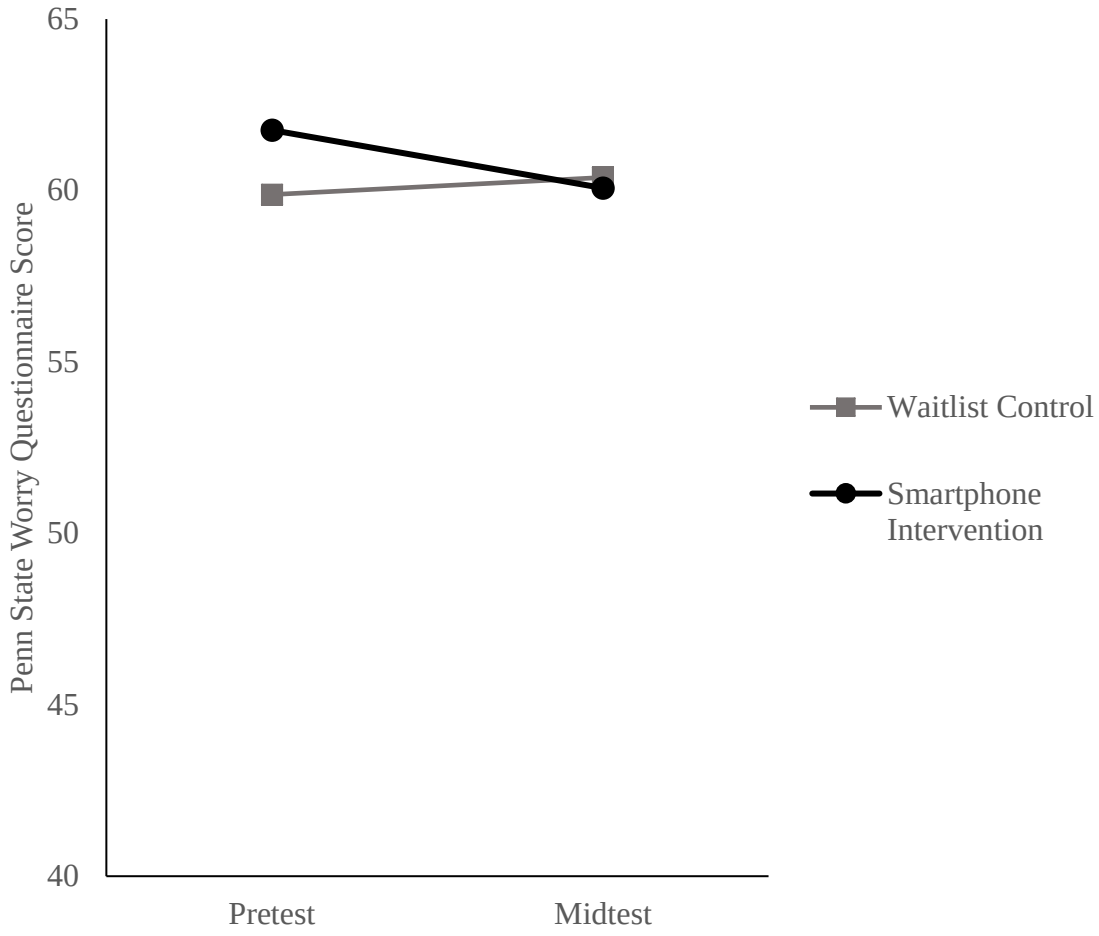

Figure 12. Graph of last observed carried forward intention to treat (LOCF ITT) Penn State Worry Questionnaire score means at pretest and midtest for participants in the waitlist and smartphone intervention groups.

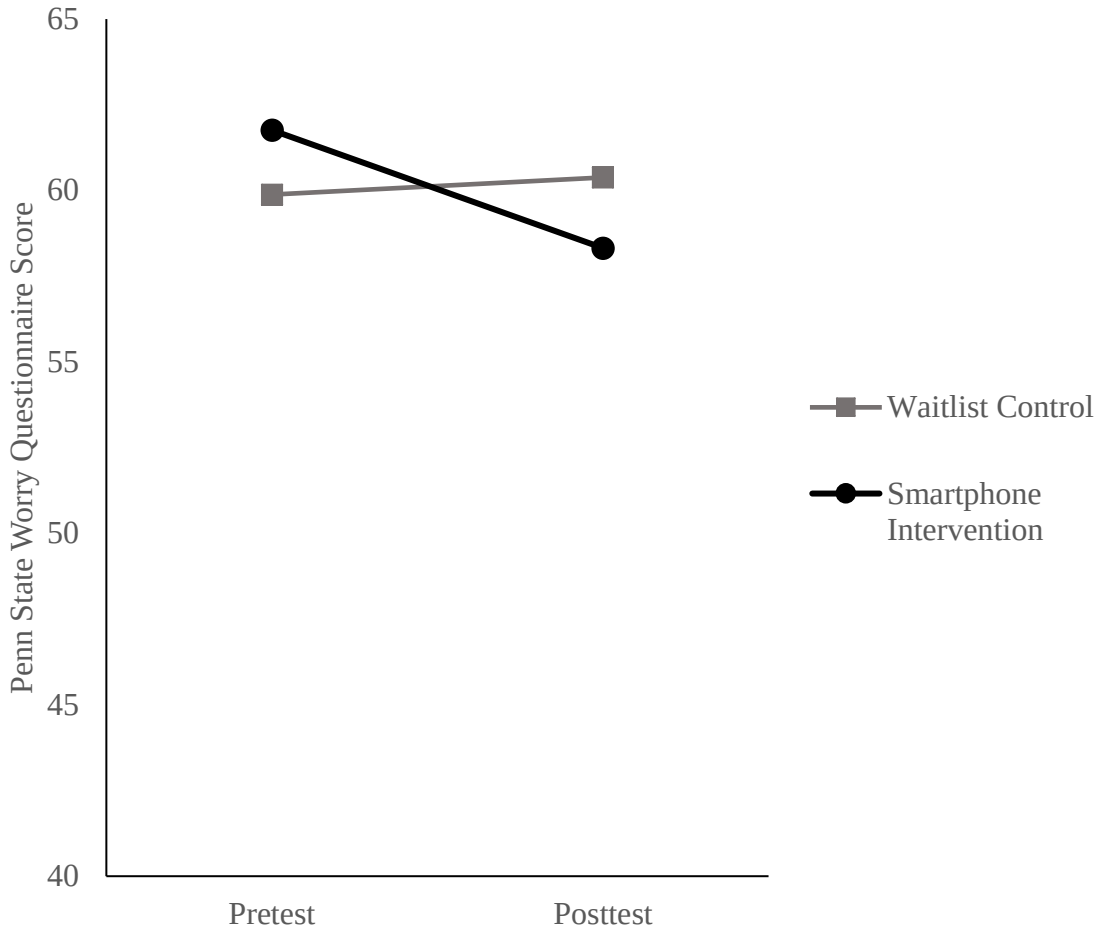

Figure 13. Graph of last observed carried forward intention to treat (LOCF ITT) Penn State Worry Questionnaire score means at pretest and posttest for participants in the four week waitlist and the eight week smartphone intervention group.

Appendix A

Demographic Questionnaire

1) What is your age in years?

_____

What is your biological sex?

A. Female

B. Male

c. Intersex

2) What gender do you identify as?

A. Female

B. Male

C. Another gender identity (Please Specify) _____

3) Which of the following best describes your sexual orientation?

A. Heterosexual

B. Homosexual

C. Bisexual

D. Asexual

E. Pansexual

F. Another sexual orientation (Please Specify) _____

40 What is your relationship status?

A. Single, never married
B. Dating
C. Married
D. Divorced
E. Widowed

4) Please specify your ethnicity or race (check all that apply):

A. African-American or Black

B. Asian

C. White Caucasian – Non Hispanic

D. Hispanic or Latino

E. Native American or Alaskan Native

F. Other (Please Specify) _____

5) Religion or spiritual worldview that you currently identify with:

Christian

Jewish

Muslim

Buddhist

Hindu

Wicca

Spiritual, not affiliated with an organized religion

Agnostic a

person who claims neither faith nor disbelief in god(s)

Atheist a

person who does not believe in the existence of god(s)

Other (please specify)

Undecided

None

6) If Christian, Select which Christian denomination you attend.

Baptist

Presbyterian

Catholic

Church of Christ

Pentecostal

Methodist

Mormon

Protestant (please specify denomination)

What is your relationship status?

Please specify your ethnicity (check all that apply)

Religion or spiritual worldview that you currently identify with:

Select which Christian denomination you attend.

Nondenominational

Other Christian, please specify

7) What is the highest level of formal education you have achieved?

Less than high school

High school

Some college

Two year degree

Four year

(undergraduate) degree

Some graduate work

Master's degree

Doctorate

Postdoctorate

8) What is your annual household income per year? _____

9) What is your country of origin?

A) United States of America

B) Other (Please Specify) _____

10) What is your country of residence?

A) United States of America

B) Other (Please Specify) _____

11) If you live in the United States, in which state do you currently live? ____

12) Are you fluent in English?

A. Yes

B. Somewhat

C. No

13) Are you currently taking any psychotropic medications?

A. Yes

B. No

14) Please select each of the medications you are currently taking.

A. Antidepressants

B. Antianxiety

C. Stimulants

D. Sleep medication

E. Don’t know what type

F. Other (Please Specify) _____

15) Are you currently receiving counseling or other mental health services?

A. Yes, Counseling

B. Yes, another mental health service (Please Specify) _____

C. No

16) Have you ever been diagnosed with a mental health disorder?

A. Yes

B. No

C. I choose not to answer

17) If yes, what mental health disorder have you been diagnosed with?

_____

Appendix B

Beck Anxiety Inventory (BAI)

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by circling the number in the corresponding space in the column next to each symptom.

	Not At All	**Mildly but it didn't bother me much**	**Moderately - it wasn't pleasant at times**	**Severely – it bothered me a lot**
Numbness or tingling	□	□	□	□
Feeling hot	□	□	□	□
Wobbliness in legs	□	□	□	□
Unable to relax	□	□	□	□
Fear of worst happening	□	□	□	□
Dizzy or lightheaded	□	□	□	□
Heart pounding/racing	□	□	□	□
Unsteady	□	□	□	□
Terrified or afraid	□	□	□	□
Nervous	□	□	□	□
Feeling of choking	□	□	□	□
Hands trembling	□	□	□	□
Shaky / unsteady	□	□	□	□
Fear of losing control	□	□	□	□
Difficulty in breathing	□	□	□	□

Fear of dying	□	□	□	□
Scared	□	□	□	□
Indigestion	□	□	□	□
Faint / lightheaded	□	□	□	□
Face flushed	□	□	□	□
Hot/cold sweats	□	□	□	□

Appendix C

Penn State Worry Questionnaire (PSWQ)

Instructions: Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
1. If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
2. My worries overwhelm me.	1	2	3	4	5
3. I do not tend to worry about things.	1	2	3	4	5
4. Many situations make me worry.	1	2	3	4	5
5. I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
6. When I am under pressure I worry a lot.	1	2	3	4	5
7. I am always worrying about something.	1	2	3	4	5
8. I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
9. As soon as I finish one task, I start to worry	1	2	3	4	5

about everything else I have to do.					
10. I never worry about anything.	1	2	3	4	5
11. When there is nothing more I can do about a concern, I do not worry about it any more.	1	2	3	4	5
12. I have been a worrier all my life.	1	2	3	4	5
13. I notice that I have been worrying about things.	1	2	3	4	5
14. Once I start worrying, I cannot stop.	1	2	3	4	5
15. I worry all the time.	1	2	3	4	5
16. I worry about projects until they are all done.	1	2	3	4	5

Appendix D

Per Protocol Statistics

Table D1

Descriptive information for the Beck Anxiety Inventory (BAI) Penn State Worry Questionnaire (PSWQ) for each group of the Per Protocol Analysis (60 minutes per 4 weeks of use)

	Waitlist Control/ 4 Week Intervention Group			8 Week Intervention Group			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Beck Anxiety Inventory (BAI)									
Pretest to Midtest (2 x 2)									
Pre	56	16.48	13.53	49	18.65	11.38	105	17.50	12.56
Mid	56	18.25	13.20	49	14.76	10.37	105	16.62	12.03
Pretest to Midtest to Posttest (2 x 3)									
Pre	26	14.38	11.19	40	18.55	10.63	66	16.91	10.96
Mid	26	17.15	13.61	40	15.65	10.63	66	16.24	11.82
Post	26	11.92	11.65	40	12.30	8.60	66	12.15	9.83
4 Week Waitlist to 8 Week Intervention (2 x 2)									
Pre	56	16.48	13.53	42	18.43	10.38	98	17.32	12.26
Post	56	18.25	13.20	42	12.28	8.43	98	15.69	11.73
Penn State Worry Questionnaire (PSWQ)									
Pretest to Midtest (2 x 2)									
Pre	55	59.60	14.24	50	62.28	10.86	105	60.88	12.75
Mid	55	60.07	13.40	50	60.08	11.43	105	60.07	12.44
Pretest to Midtest to Posttest (2 x 3)									
Pre	26	60.31	13.03	41	62.39	10.20	67	61.58	11.33
Mid	26	61.85	11.32	41	59.85	11.85	67	60.62	11.60
Post	26	58.19	10.07	41	58.19	10.07	67	57.39	11.79
4 Week Waitlist to 8 Week Intervention (2 x 2)									
Pre	55	59.60	14.24	41	62.39	12.69	96	60.79	12.86
Post	55	60.07	13.40	41	56.88	12.86	96	58.71	13.20

Table D2

Mixed-ANOVA model effects for the Beck Anxiety Inventory (BAI) for Per Protocol (60 minutes of use per 4 weeks of access) analysis

Analysis type	Factor	*Df*	*Df error*	*F*	*p*	η_p^2
Per Protocol Pre to Mid to Post (3x2)						
	Time	2	128	10.28	<.001	.138
	Group	1	64	.17	.679	.003
	Time x Group	2	128	3.44	.035	.051
Per Protocol Pre to Mid (2x2)						
	Time	1	103	1.11	.294	.011
	Group	1	103	.11	.762	.001
	Time x Group	1	103	7.88	.006	.071
Per Protocol 4 Week Waitlist to 8 week Intervention (2x2)						
	Time	1	96	5.37	.023	.053
	Group	1	96	.81	.370	.008
	Time x Group	1	96	17.57	<.001	.155

Table D3

Mixed-ANOVA model effects for the Penn State Worry Questionnaire (PSWQ) for Per Protocol (60 minutes of use per 4 weeks of access) analysis

Analysis type	Factor	*Df*	*Df error*	*F*	*p*	η_p^2
Per Protocol Pre to Mid to Post (3x2)						
	Time	2	130	6.37	.002	.089
	Group	1	65	.03	.875	<.001
	Time x Group	2	130	1.77	.175	.026
Per Protocol Pre to Mid (2x2)						
	Time	1	103	.83	.363	.008
	Group	1	103	.35	.557	.003
	Time x Group	1	103	2.00	.161	.019
Per Protocol 4 Week Waitlist to 8 week Intervention (2x2)						
	Time	1	94	7.36	.008	.073
	Group	1	94	.007	.936	<.001
	Time x Group	1	94	10.38	.002	.099