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The Mechanism of Reducing Anxiety through Mindfulness Interventions: Digital Therapeutic Program

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THE MECHANISM OF REDUCING ANXIETY THROUGH MINDFULNESS INTERVENTIONS: DIGITAL THERAPEUTIC PROGRAM

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ABSTRACT

THE MECHANISM OF REDUCING ANXIETY THROUGH MINDFULNESS INTERVENTIONS: DIGITAL THERAPEUTIC PROGRAM

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The COVID-19 pandemic exacerbated the prevalence of anxiety disorders, making it a population health concern in the United States and worldwide. The growing need for effective prevention and treatment of anxiety coincides with a deficit of mental health providers and physicians. With the healthcare system currently overwhelmed and the slow training pipeline of new providers, the gap between patient demand and treatment providers will not be closed in the next decade. There is a growing need for evidence-based treatments for anxiety disorders that can increase access to care while addressing the underlying mechanisms of anxiety. Digital therapeutics is a fast-developing field that can be one such solutions provided in "one-to-many" format. It can be used in conjunction with individual therapy, as well as independently, depending on the severity of patients' symptoms. This quantitative dissertation study aimed to investigate the mechanism of reducing anxiety in the digital application (app) Unwinding Anxiety Program and its impact on emotion regulation, self-representation (self-esteem), and the degree of attachment security in adults. The study used a single-case experimental design to assess the effect size of the intervention in these domains. Five study participants completed the program. The results of the study demonstrated the efficacy of the intervention for reducing anxiety among participants with medium to large effect size and decrease of attachment-related anxiety for all participants with small effect size. All study participants demonstrated improved

emotion regulation with moderate effect size for the sample. Self-esteem scores improved for some participants, while decreased for others. These findings support the existing evidence for the efficacy of mindfulness-based interventions for anxiety demonstrating the key role of emotion regulation in the mechanism of change. This study brings the novelty of examining the impact of digital therapeutic intervention on attachment security. This dissertation is available in open access at AURA, http://aura.antioch.edu/, and Ohio Link ETD Center, https://etd.ohiolink.edu/etd.

Keywords: anxiety, digital therapeutics, emotion regulation, attachment security, attachment anxiety, self-esteem, mindfulness-based interventions, population health

Dedication

In loving memory of my parents and my brother Michael. You are always in my heart.

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CHAPTER I: INTRODUCTION

Generalized anxiety disorder (GAD) is a complex mental health condition that impacts millions of people all over the world. In the general population, the rates of GAD are approximately 2–5%, with a 12-month prevalence (Guglielmo et al., 2014; Lieb et al., 2005). The complexity of GAD is defined by its high comorbidity with other mental health disorders and high levels of recurrence (Newman et al., 2013). Despite its prevalence among different populations and a variety of symptom presentations across the lifespan, there is little agreement in the research on its etiology (Azab, 2022; Behar et al., 2009). Generalized anxiety disorder is a mental health condition, it is defined by the presence of excessive worry about a variety of issues, for a minimum of six months. To meet diagnostic criteria for GAD, at least three somatic and cognitive symptoms such as restlessness, fatigue, muscle aches, sleeping difficulties, and others must be present (American Psychiatric Association [APA], 2013).

Mainstream Approach to Treatment

Cognitive behavioral therapy (CBT) is the most widely used psychotherapy for treating GAD in healthcare settings (Altis et al., 2015; Carrier et al., 2022; Mangolini et al., 2019). Another first line of treatment is psychopharmacology, with the rates of prescriptions for GAD increasing each year (Altis et al., 2015; Garakani et al., 2020). However, both treatment approaches have limitations. On average, only 50% of patients who went through CBT successfully reached a reduction of symptoms in frequency, severity, and duration in the long-term (Andersen et al., 2016). The main focus of CBT is to provide the patient with coping skills when the anxiety episodes occur; building an integrative attachment-informed model of treatment can address the underlying cause of anxiety and ensure the long-term efficacy of treatment (Andersen et al., 2016; Talia et al., 2019). Attachment-informed treatments are rooted

in psychodynamic theory. Several studies have demonstrated the efficacy of psychodynamic interventions for treating agoraphobia, panic disorder, and GAD with significant remission rates and at least the same treatment efficacy as CBT (Keefe et al., 2019).

However, the psychopharmacological line of treatment raises concerns about tolerability of the long-term treatments and do not address the issue of recurrence of symptoms, up to 60–80% with certain drugs (Garakani et al., 2020). The multiple side effects of medications are another area of concern, especially in vulnerable populations including children and older adults (Cuijpers et al., 2014; Strawn et al., 2018). A recent metanalysis of 79 randomized controlled trials showed medium to large effect size for evidence-based psychotherapies and small effect size for medication on GAD (Carl et al., 2019). Despite the evidence of low success rates of psychopharmacological interventions for anxiety, and the recent challenge of the "serotonin theory" which most prescriptive medications rely on (Moncrieff et al., 2022), the COVID-19 pandemic has been characterized by not only an increase in prevalence of anxiety (up to 24.3% during 2020 alone), but an increase in pharmacological treatment for anxiety (22% of the population using medication compared to 9% using therapy (Coley & Baum, 2021).

GAD interferes with the level of functioning and well-being of individuals, and it has detrimental effects at the societal level as well. Overall, the estimated cost of anxiety disorders in the United States alone is estimated to be between 42 and 45 billion dollars, with GAD being the most frequently diagnosed condition among the other anxiety disorders in primary care (Altis et al., 2015; Terlizz, 2021). The COVID-19 pandemic exacerbated the prevalence of anxiety disorders across all age groups, making it a population health concern (Coley & Baum, 2021; U.S. Preventative Services Task Force, 2022). The purpose of this study is to explore the mechanism of reducing anxiety using the digital therapeutic program, Unwinding Anxiety

Program, and its impact on key psychological well-being domains: emotion regulation, self-esteem, and the security of attachment style. The study aimed to bring novelty to assessing the effect of evidence-based digital interventions which have the potential to increase access to mental health care.

Attachment Informed Perspective

An attachment-informed perspective on psychopathology has become a growing area of interest in clinical psychology, among both researchers and therapists (Borkovec et al., 2004; Read et al., 2018; Valikhani et al., 2018). A secure attachment style in adults is linked to well-adaptive functioning; while an insecure attachment style is a predictor of several mental health conditions, including excessive substance use, depression, and anxiety (Gillath et al., 2016; Mikulincer & Shaver, 2012; Zhang et al., 2022). The development of new prevention and treatment modalities to address the complexity of GAD is an important priority in mental health care. An attachment-informed treatment approach to GAD can be an option. Although available research evidence for attachment-informed treatment modalities is sparse, there are some promising findings that examine new possibilities. Mentalization-based therapy demonstrates a growing body of evidence for a variety of mental health conditions, including anxiety (Høgenhaug et al., 2021; Vogt & Norman, 2018). Some approaches focus on an integrative approach to treatment including CBT and other therapies that address interpersonal challenges and emotion regulation (Borkovec et al., 2004; Koerner et al., 2020).

Attachment theory and GAD are related in several ways. People with secure or insecure attachment styles respond to treatment differently (Nielsen et al., 2017). Attachment style contributes to the patient's willingness to seek help and stay in the treatment, which has a direct impact on therapy outcomes (Bifulco et al., 2006). While both avoidant and anxious attachment

styles can be considered a risk factor for the onset of GAD (Nielsen et al., 2017), a more detailed understanding of specifics of the patient's attachment style can become a valuable part of the intervention. The understanding of the patient's attachment style helps the therapist develop an integrative treatment plan and increase the chances of success in individual therapy (Mangolini et al., 2019).

The therapies that address the interpersonal and the emotional regulation challenges of patients with insecure attachment styles can be included in treatment plans in addition to CBT. Interpersonal and emotional processing therapy modalities are good examples of an integrative approach (Newman et al., 2015). Although currently the research findings on such models of treatment are limited, some researchers have developed and tested integrative modalities in randomized control trials. Specifically, Borkovec et al. (2004) examined their integrative model of treatment which included elements of CBT, interpersonal therapy, and emotional processing therapy with positive clinical outcomes. Further, researchers discovered this treatment is specifically effective with patients with a dismissive-avoidant attachment style (Newman et al., 2015; Orvati Aziz et al., 2020).

Mindfulness-Based Interventions

Another treatment modality that can be included in the attachment-informed approach to treatment is mindfulness-based interventions. Both the attachment-informed approach and mindfulness-based interventions can be used as prevention and treatment models. Several studies show both the short-term and long-term benefits of the mindfulness practice. Mindfulness practice is related to neuroplasticity, neural integration, pain management, mental clarity, as well as increased emotion regulation, enhanced immune response, increased ability to concentrate, and, overall, the enhancement of general well-being. The development of the mindfulness results

in fostering self-compassion, reflective abilities, improved emotional regulation, enhanced emotional self-awareness, increased attention span in patients (Ma, 2008; Siegel, 2014; Stevenson et al., 2021).

With the advancement of telehealth, digital programs delivered via phones can aid behavioral health providers in offering valuable resources to patients between appointments (Marshall et al., 2019). The development and research on efficacy of such programs can contribute to increasing the access of integrated treatments of GAD for many populations. This dissertation examines the application of attachment theory to mindfulness-based interventions for GAD that can be applied in a variety of settings with diverse populations. There are several attachment theories. This study uses the models applicable to evidence-based interventions within integrated primary care systems.

CHAPTER II: REVIEW OF LITERATURE

Attachment System: Theory and Empirical Findings

The first foundations of the attachment theory developed in the early 1930s when British psychoanalyst, John Bowlby, started to look at the effects of love and loss in children (Bowlby, 1982). Later, he formulated the key principles of attachment behaviors. These attachment behaviors are regulated by the attachment behavioral system; it is a motivational system that serves the important goal of ensuring a child's safety and survival. Bowlby's colleague, Mary Ainsworth, contributed to the further expansion of the attachment theory framework by developing a procedure which defined three types of behaviors observed in children in response to separation (Gillath et al., 2016).

Although the primary focus of the early research on attachment was on infants, Bowlby unequivocally recognized the importance of attachment in adult life. The next generation of researchers proposed that individual differences in attachment styles in adults formed in a similarly to infants. Bowlby introduced the concept of the attachment working models (the mental representations of self and others). The mental representations of self that are attributed to insecure attachment styles contribute to low self-esteem and low self-efficacy, which sustain certain vulnerabilities that impact adjustment in adulthood (Gillath et al., 2016; Mikulincer & Shaver, 2012; Shen et al., 2021).

Another aspect of poor adjustment to insecure attachment is related to interpersonal deficits, which results from the specific mental representation of others (Zhang et al., 2022). In general, both anxiously and avoidantly attached individuals have negative views about others (Valikhani et al., 2018). Insecure attachment style has an impact on the process of emotional regulation in adults. Specifically, people with secure attachment respond to distress by

engaging in problem-solving, planning, and cognitive reappraisal (Johnson, 2018). People with insecure attachment either inhibit emotions (insecure-avoidant), or intensify the undesirable emotions by making catastrophic appraisals, perceiving minor disturbances as major threats, and maintaining pessimistic beliefs about their inability to cope with distress (insecure-anxious) (Mikulincer & Shaver, 2012). The factors listed above are the major contributors to attachment insecurity as a risk factor for mental health. Over 100 studies investigated the connection between anxiety and depression and showed attachment anxiety demonstrates a consistent association with both (Brown & Elliott, 2016; Zhang et al., 2022).

The classification of attachment styles selected for the purpose of this dissertation presents the four adult attachment styles in a two-dimensional space, categorized by two scales: attachment anxiety and attachment avoidance. Individuals with low anxiety and low avoidance represent a secure attachment style. The insecure attachment styles are represented by preoccupied (also known as anxious), avoidant, and fearful-avoidant. Preoccupied characterized by low avoidance, high anxiety, dismissing in presentation. Avoidant is characterized by low anxiety and high avoidance in presentation. Fearful-avoidant is characterized by high avoidance and high anxiety in presentation (Gillath et al., 2016).

Attachment Behavioral System

The attachment behavioral system is a construct which describes the organization of human behavior around attachment needs (Gillath et al., 2016). The primary attachment needs both in adults and children are proximity-seeking (e.g., spending time together); safe haven (e.g., providing support in the time of distress); and secure base (e.g., allowing to take risks, explore, and be welcomed back; Gillath & Karantzas, 2019). The original biological function of this behavioral system is to provide survival and reproductive function. The biological function of the

attachment system is achieved by maintaining proximity to a stronger and a wiser caregiver (or attachment figure). The activation of the attachment system is triggered by the sense of a perceived threat, which can be internal (e.g., cognitive appraisals) or external (environmental) (Gillath et al., 2016). The response behaviors of the attachment system are primary and secondary strategies individuals use to meet their attachment needs. The primary strategies are used by individuals to regain the feeling of security. When the primary strategies fail, the secondary strategies will be used, which leads to hyperactivation or deactivation (depending on the attachment style) of the system to establish a system balance (Gillath et al., 2016; Mikulincer & Shaver, 2012).

Emotion Regulation

In their review of multiple studies, Mikulincer and Shaver (2012) identified that attachment insecurity is a risk factor for a variety of mental health disorders, including GAD. Several contemporary theoretical conceptualizations of the origins of GAD indicate insecure attachment styles (both avoidant and anxious styles) can be viewed as a precursor to developing GAD (Behar et al., 2009; Brown & Elliott, 2016; Luyten et al., 2020). The link between attachment insecurity and GAD can be established through at least three factors: emotional regulation, interpersonal relations, and self-representation. Emotion regulation is a set of strategies individuals employ to either suppress or increase their experience of emotions. While all these factors are significant in the understanding and treatment of GAD, the majority of current research focuses on emotion regulation as a mediator between insecure attachment and GAD (Marganska et al., 2013; Schwarzer et al., 2021).

Self-Representation and Emotion Regulation

The attachment theory perspective used in this dissertation, the inner working models (mental representations) of oneself and others define an individual's ability to relate to the world in a safe way and engage in challenging demands effectively. Secure attachment style promotes trust in relationships with others and in the process of life overall, and effective threat-coping mechanisms (Mikulincer & Shaver, 2012). Secure attachment patterns provide a well-balanced sense of self-efficacy in times of stress. Insecure attachment activates secondary attachment strategies to cope with external and internal stressors by either the deactivation of the attachment system (in avoidant attachment styles), or the hyperactivation of the attachment system (in anxious attachment style; Brown & Elliott, 2016). These secondary strategies work through the emotion regulation system: individuals with avoidant attachment styles suppress emotions and deny threat; while individuals with anxious attachment style use such strategies as rumination (repetitive cycle of thoughts about the origin and consequences of one's negative mood, leading to the intensifying of the difficult emotions) and magnifying of threats/stressors (Brown & Elliott, 2016).

Individuals with an anxious attachment style can develop a heightened sense of threat and perceive stressful events with a pessimistic view of their ability to cope with the stress and the potential outcomes. An insecure attachment style makes it difficult for an individual to use the strategy of cognitive reappraisal (the ability of an individual to mentally shift expectations about a future event to minimize its negative emotional impact or emphasize its positive impact; Cassidy et al., 2009; Marganska et al., 2013).

Emotion Regulation Mediates Attachment and GAD

Multiple studies confirm the positive correlation between anxious attachment style and GAD symptoms in various samples, with contradictory findings regarding the correlation between avoidant attachment styles, such as dismissive-avoidant, and GAD (Bifulco et al., 2006). For example, anxious attachment style has predicted "anxiety symptoms at 2-year follow up" (Marganska et al., 2013, p. 132), and individuals with both anxious and fearful-avoidant attachment styles report more anxiety symptoms than individuals with secure attachment. GAD is associated with several ineffective emotion regulation strategies, such as the lack of clarity about one's emotions and the lack of acceptance and understanding of one's emotions. One of the contemporary theoretical models for GAD, Emotion Dysregulation Model (EDM), states individuals with GAD experience emotions, specifically negative emotions, more frequently and more intensely than those who did not have GAD (Marganska et al., 2013).

While a significant body of research is focused on emotional dysregulation in GAD, fewer studies explore the origin of the dysregulation itself. Schore and Schore (2007) argue the modern view of attachment theory has shifted towards regulation theory, which is empirically supported by neuroscientific research. Fonagy's mentalization approach emphasizes the central role of forming a secure attachment in the therapeutic alliance promotes effective intervention (Fonagy & Adshead, 2012; Luyten et al., 2020).

Insecure attachment style is characterized by ineffective emotion regulation strategies which can lead to the development of clinically significant anxiety. One study examined the connection between insecure attachment styles, emotional regulation, depression, and GAD in a sample of college students (Marganska et al., 2013). The re searchers found insecure anxious and fearful-avoidant attachment styles predicted symptoms of GAD. Three

emotional regulation domains (perceived access to effective emotion regulation strategies, nonacceptance of negative emotions, and inability to control impulsive behavior) were significant in the relationship between GAD and attachment styles. Another study explored emotion regulation as a mediator for GAD in a clinical population (Nielsen et al., 2017). The researchers found anxiety was "significantly related to emotion dysregulation," while "emotion dysregulation was significantly related to anxiety symptoms," with emotion dysregulation accounting "for 77 % of the association between attachment anxiety and anxiety symptoms severity" (Nielsen et al., 2017, p. 257). Thus, an attachment-informed perspective on GAD offers a more in-depth approach to the conceptualization and treatment of GAD, providing an explanation of the possible causes of emotional dysregulation in patients with insecure attachment styles.

Mindfulness-Based Interventions

Mindfulness-based interventions show efficacy in improving emotion regulation, developing self-compassion, and reducing anxiety levels in adults (Mikulincer & Shaver, 2012; Roy et al., 2020). Mindfulness is described as a nonjudgmental awareness of the moment-to-moment experiences (Kabat-Zinn, 2013). With practice, the state of mindfulness that occurs during the mindfulness practice can result into the trait mindfulness. Trait mindfulness leads to a number of cognitive, emotional, and physiological benefits. The benefits include an increased ability to sustain attention, increased emotional regulation, reduced impulsivity, increased immune response, enhanced pain tolerance, and others (Stevenson et al., 2017). The growing interest in mindfulness research indicates mindfulness-based interventions are effective in the treatment of depression and anxiety (Goleman & Davidson, 2017). Mindfulness interventions not only lead to the enhanced well-being of patients, but also can serve as

relapse-prevention methods. The mindfulness interventions promote personal responsibility for one's well-being and provide the tools that make it possible (Alsubaie et al., 2018; Kabat-Zinn, 2013; Shapiro & Carlson, 2017).

The concept of mindfulness was introduced into Western culture, psychology, and psychotherapy in the second part of the twentieth century. The origin of this term relates to several spiritual traditions, including Buddhism. A secular version of mindfulness entered the mainstream partly due to the Mindfulness-Based Stress Reduction Program (MBSR), developed by John Kabat-Zinn in the University of Massachusetts Medical School in 1979. According to Kabat-Zinn (2013), mindfulness means paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally.

The construct of mindfulness is multifaceted. It is related both to the practice of paying attention, as well as a set of qualities, including non-judgement, patience, non-striving, acceptance, and letting go. While different mindfulness measures emphasize various aspects of mindfulness, most would describe the awareness of the present experience, and how one attends to the experience: with acceptance, curiosity, and kindness (Hölzel et al., 2011; Macaulay et al., 2015). Being aware of the experience does imply an observer's perspective, but it does not mean detachment from the experience. Mindfulness practice implies several aspects of awareness, including awareness of body sensations; feeling tones (pleasant, unpleasant, or neutral); thoughts and emotion; and mental states (aversion, attraction, indifference). The attitudes of acceptance, curiosity, compassion, and kindness lead to a fuller and richer experience of the present, as well as a new means of relating and responding to the experience (Stevenson et al., 2017). One recently developed measure in mindfulness—The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2004), includes: non-reactivity to the inner experience; observing, noticing,

and attending to sensations, perceptions, thoughts, and feelings; acting with awareness, concentration and nondistraction; describing and labeling the experience with words; and non-judgement of the inner experience as the key constructs of mindfulness (Ma, 2008).

Mindfulness-Based Interventions for GAD

The status of the mental health system in the United States does not adequately address the needs of several populations (e.g., people in rural areas, patients with lower socioeconomic status, ethnic and racial minorities, and patients with comorbid mental and medical health conditions; Hunter et al., 2017). There is a strong need for preventive mental health treatments, as well as treatments that are short-term and will address multiple issues. Short-term treatments can address attachment insecurity in adults target multiple symptoms which appear in the diagnostic criteria of several disorders and enhance the general well-being and functioning of the patients. There are few evidence-based treatments available that specifically target insecure attachment style (Brown & Elliott, 2016).

While recent research has established a connection between mindfulness and secure attachment style (Stevenson et al., 2021), it has yet to establish the impact of specific mindfulness interventions on adult attachment. If researchers conclude specific mindfulness interventions do contribute to the increased security of attachment style in adults, it would create a catalyst for the development of effective short-term treatments that can be delivered both in-person and remotely.

The Mechanism of Change in Mindfulness-Based Interventions and Its Efficacy

The research evidence of mindfulness-based therapeutic interventions has increased in the last 15 years (Goleman & Davidson, 2017). Mindfulness-based interventions have been included in treatment in two ways: (a) as a meditation training program (MBSR,

Mindfulness-Based Cognitive Therapy), or (b) embedded as an important part of treatment protocols in cognitive, behavior, and other theories of psychotherapy (Dialectical Behavior Therapy; Acceptance and Commitment Therapy; Interpersonal Process in Cognitive Therapy; Safran, 1996). The mechanism of change in mindfulness-based interventions has much in common with humanistic psychotherapy (these psychotherapies were formed under the influence of Buddhist psychology): present-moment awareness (Gestalt psychotherapy); being aware of existential suffering and relating to it a new way (existential psychotherapy). Nonjudgmental and moment-to-moment awareness is an important part of the mechanism of change in mindfulness interventions (Ma, 2008).

The self-observation part of mindfulness interventions allows individuals to not only to attend to the present experience but also to let go of present distressing mental and emotional patterns. In most therapeutic approaches, the presence of a therapist is required to enter the process of self-reflective functioning or to attend to this type of awareness. While in mindfulness interventions such as MBSR, self-reflective functioning develops through a regular mindfulness meditation practice (Hoge et al., 2018; Ma, 2008).

Several studies show both the short-term and long-term benefits of mindfulness practice. It is related to neuroplasticity, neural integration, increased emotional regulation, enhanced in the immune response, pain management, the ability to concentrate and mental clarity, and, overall, enhancement of general well-being (Mangolini et al., 2019). MBSR showed efficacy in improving symptoms in patients with chronic pain, generalized anxiety, and binge eating disorder (Ma, 2008). The development of trait mindfulness results in developing self-compassion, reflective abilities, improved emotional regulation, enhanced emotional self-awareness, and increased attention span (Ma, 2008; Siegel, 2014).

Mindfulness and Attachment Security

Since mindfulness practice addresses both cognitive and affective deficits in individuals, such as excessive emotional reactivity, inappropriate emotional responses to events, and poor reality testing, as well as facilitates nonjudgmental and kind attitude to the present experience, it can address the key deficits of insecurely attached clients (Ma, 2008; Macaulay et al., 2015; Stevenson et al., 2018). The key mediators that promote well-being in securely attached individuals are reflective functioning, emotional regulation, and observing ego (Ma, 2008). Macaulay et al. (2015) examined whether mindfulness facets would meditate the relationships between the insecure attachment and anxiety sensitivity showed that the facets of mindfulness such as to "accept without judgment," "act with awareness," and "observe" each mediated the relationship between attachment anxiety and cognitive concerns (one of the dimensions of anxiety sensitivity). "Accept" moderated the association between attachment avoidance and the three anxiety sensitivity dimensions (physical, social, cognitive concerns). "Observe" mediated the relationship between attachment anxiety and physical concerns, and "Accept" mediated the relationship between attachment anxiety and social concerns (Macaulay et al., 2015). The meta-analyses of the research that explores the link between mindfulness and attachment anxiety (Stevenson et al., 2017, 2021) showed attachment anxiety in adults negatively correlates with mindfulness. Most of the studies reported associations between attachment dimensions and total mindfulness. Further research is needed to address the directionality of this connection.

The Use of Digital Therapeutic Programs

In the last several years, the development and use of mobile mental health apps has grown significantly. With the pandemic and increase of telehealth use in mental health, the question of estimating their efficacy and use of research methodology to assess their role in

interventions becomes increasingly important. Only 3.41% of apps currently available in the Apple App Store and Google Play Store are advertised as therapeutic programs to address anxiety and depression have research evidence to support their claims (Marshall et al., 2019).

The Present Study

The purpose of this dissertation was to explore the mechanism of reducing anxiety in the digital app Unwinding Anxiety Program and its impact on emotion regulation, self-representation (self-esteem), and the degree of security the attachment style in adults. If the research concludes specific mindfulness interventions contribute to the increased security of attachment style, improve internal working models of self, and improve emotion regulation, it can open a gateway to the development of effective short-term treatments that can be delivered both in-person and remotely.

Research Questions

This study explored the following questions:

1. What is the efficacy of mindfulness-based intervention delivered via the digital app Unwinding Anxiety Program on reducing symptoms of anxiety in adults over the period of three months?
    a. If the intervention is effective, what is the impact of the Unwinding Anxiety Program on emotion regulation, degree of attachment security, and self-esteem?

Hypotheses

1. GAD-7 scores will decrease for participants in the intervention phase compared to baseline phase.

2. For the participants with improved GAD-7 scores, emotion regulation will increase (DERS-SF scores will decrease), attachment security will increase (attachment anxiety scores will decrease), and self-esteem scores will increase.

CHAPTER III: METHOD

Procedure

The study used single-case experimental design (SCED) to assess the effect of the Unwinding Anxiety (UA) digital therapeutic program for five study participants. It compared repeated measurements of four dependent variables under two manipulated conditions, a baseline and an intervention condition. In this AB design, repeated measurements of the dependent variables were first made under a control condition in the A phase, or baseline phase, and then continued under an experimental condition in the B phase, or intervention phase.

Study participants were assigned different number of measurement occasions to increase the statistical power of the study and ensure internal validity (Heyvaert et al., 2016). During the baseline phase, participants completed four outcome measures per week. Participants 1 and 2 had three measurement occasions in phase A (baseline phase); participants 3, 4, and 5 had four measurement occasion in the baseline phase.

Following three to four weeks of baseline phase, study participants continued to complete the four questionnaires throughout the intervention phase that lasted three months. Following the guidelines for single-case study design, subjects had various number of measurements in the intervention phase, with a minimum of five measurement occasions (Lane & Gast, 2013). See Table 3.1 for random assignment of measurement occasions in baseline and intervention phase for study participants (Lane & Gast, 2013).

Participants

Participants were recruited from the pool of scholarship applicants of the Unwinding Anxiety (UA) digital therapeutic program. UA offers a scholarship program that provides a free 3-month access for individuals experiencing financial constraints. To apply for the scholarship

program, the individuals are encouraged to contact the program's support desk with a brief description of their situation and request a free license. Participation in the study was offered to scholarship applicants, clearly stating their agreement to participate in the study would not impact the decision for their free three months access to UA.

Study participants were not asked to disclose their sex and gender identity. Sex and gender identity were not inclusion criterion for the study. Other demographic information, including race, ethnicity, and socio-economic status, were not collected during the study. See appendices for all recruitment related materials.

Five participants selected for the study met the following criteria:

Inclusion:

1. 18 years or older
2. GAD-7 score more or equals five on established cut-off suggesting GAD
3. Able to read and speak English (UA app is available in English only)
4. Owns a smartphone (UA app can only be used on a smartphone or via web browser)
5. Has daily access to the internet (UA program requires internet access to synchronize data)

Exclusion:

1. Using psychotropic medication (to prevent the effect of medication impact the results of the study)
2. Currently in psychotherapy or planning to enroll in psychotherapy in the next four months (to prevent the effect of psychotherapy impact the results of the study)
3. Psychotic disorder (Mindfulness meditation has to be carefully monitored with people experiencing psychosis. We are not able to provide this type of monitoring given budget

constraints.)

4. Post-Traumatic Stress Disorder (Mindfulness meditation has to be carefully monitored with people experiencing PTSD. We are not able to provide this type of monitoring given budget constraints.)

5. Lives in same household as someone already enrolled in this study (to prevent study participants from sharing study information with one another)

6. Staying on a fixed income due to age, disability, etc. (to avoid recruiting vulnerable population)

Five study participants were selected based on the inclusion and exclusion criteria. All participants signed an informed consent. Consenting participants were provided a 3-month access to the UA digital program and a $100 Amazon gift card for completion of all the questionnaires.

Intervention

Unwinding Anxiety is a digital therapeutic program that targets anxiety. It was developed at Yale University School of Medicine by Dr. Jud Brewer MD, PhD, and is based on (a) research on how the brain forms habits, (b) evidence-based mindfulness practices that have been translated for modern-day use through programs such as mindfulness-based stress reduction (MBSR), and (c) digital delivery platforms. Over the course of six rounds of interactive pilot testing with individuals ranging in age from 13 to 77 meeting criteria for anxiety disorders, Unwinding Anxiety participants experienced a 47% reduction in the Generalized Anxiety Disorder-7 (GAD-7) scale. In a clinical study with physicians with moderate to severe anxiety, Unwinding Anxiety reduced GAD-7 scores by 57% three months after treatment initiation. The program was comprised of both mobile app-based and web-based platforms that delivered

progressive daily trainings via 30 short daily video modules. A built-in self-assessment was taken after every seven modules to ensure key concepts were learned before moving on (with automated suggestions on which modules to repeat based on one's answers; Roy et al., 2020).

Measures

Generalized Anxiety Disorder -7 (GAD-7; Spitzer et al., 2006)

The Generalized Anxiety Disorder-7 (GAD-7) is a seven-item self-report questionnaire widely used in a variety of settings as a screening tool and outcome measure for assessing and tracking the intensity of anxiety symptoms. A 4-point Likert scale of frequency ranging from "not at all" to "nearly every day" is used to measure each item. The validation of the GAD-7 in a large primary care sample showed the measure has good reliability (internal consistency $\alpha = 0.89$), and good criterion, factorial, and procedural validity. Experiences in Close Relationships-Revised questionnaire (ECR-R; Fraley et al., 2000)

ECR-R is a self-report measure that assesses the dimensions of attachment-related anxiety and attachment-related avoidance. It is a revised version of Brennan et al.'s (1998) Experiences in Close Relationships (ECR) questionnaire.

The questionnaire consists of 18 items assessing attachment anxiety and 18 assessing avoidant attachment. Participants rate their level of agreement with each of the items on a 7-point Likert scale ranging from 1 (*Disagree Strongly*) to 7 (*Agree Strongly*). The measure yields scores for two subscales of anxiety and avoidance, while security of attachment is represented as the "low" ends of these two dimensions. ECR-R's internal consistency reliability is reported to be .90 or higher for the two ECR-R scales. ECR was validated through hierarchical linear modeling analyses suggesting that it explained between 30% to 40% of the between-person variation in

social interaction of attachment-related emotions experienced during interactions with a romantic partner.

Difficulties in Emotion Regulation Scale Short Form (DERS-SF; Kaufman et al., 2015)

The 18-item DERS-SF is a shortened version of emotion regulation self-report measure developed by Gratz and Roemer (2004). The measure assesses understanding and acceptance of emotions, modulation of emotional arousal, and the ability to sustain a goal-oriented behavior in the presence of emotions. While the measure consists of six scales, the overall score was only calculated for the purpose of this study. Participants rated their responses on a 5-point Likert-type scale, where 1 is *Almost Never* and 5 is *Almost Always.* Cronbach's alpha coefficients for each of the 3-item DERS-SF subscales exceeded .70 and ranged from .79 to .91 and were comparable to the original DERS. DERS-SF has comparable concurrent validity to the original DERS. The outcome variables were generally consistent in statistical significance and magnitude of correlation, across all scales.

The Rosenberg Self-Esteem Scale (RSES; Rosenberg, 1968)

RSES is a self-report self-esteem measure widely used in social-science research. It uses a scale of 0–30 where a score less than 15 may indicate a problematic low self-esteem. RSES is a 10-item Likert-type scale with items answered on a 4-point scale from *1 (Strongly Agree)* to 4 (*Strongly Disagree*). Five of the items have positively worded statements and five have negatively worded ones. The scale results in the score that represents overall ("global") self-worth by assessing both positive and negative feelings about the self. Cronbach's alpha values for the RSES range from 0.85 to 0.90. RSES demonstrates good construct validity across several measures with correlations range from -.38 to -.51 across the age and sex groups (all $p <$ .001).

CHAPTER IV: RESULTS

Data Analyses

All five recruited participants completed the study. The data analysis included visual and statistical analyses for four measures from each participant. The purpose of the study was to explore whether GAD-7 scores would decrease for participants in the intervention phase compared to baseline phase; for the participants with improved GAD-7 scores, whether emotion regulation would increase (DERS-SF scores would decrease), attachment security would increase (demonstrated by decrease in attachment anxiety), and self-esteem scores would increase.

Visual Analysis

The results of the four measures for each participant were graphed and visually inspected for trends and normality of distribution. Figures 4.1, 4.2, 4.3, and 4.4 show the visual representation of the main outcome measures, with the dotted horizontal line representing the median. Visual inspection of Figures 4.1,4.2,4.3, and 4.4 suggests the Unwinding Anxiety program was effective in decreasing GAD-7 scores in all participants; decreasing attachment anxiety in all participants; improving emotion regulation in all participants; and increasing self-esteem in three out of five participants. The results of visual analysis support the hypothesis of the study for the decrease in anxiety, decrease in attachment anxiety, and improvement in emotional regulation. Visual analysis supports the hypothesis of increase of self-esteem for three out of five participants.

Based on the visual analysis, GAD-7 scores in the intervention phase decreased for all five participants supporting the initial hypothesis (Figure 4.1). Participant 1 experienced the most significant reduction in anxiety after the intervention, based on their pre and post intervention

scores. The baseline for Participant 1 presented the most stable scores among all the participants. Stable scores in the baseline strengthen the validity of GAD-7 scores decreased in the results for this participant. Participants 2 and 4 also demonstrated decreases in GAD- 7 scores after the intervention. However, their baseline data showed an improvement trend prior to the start of the intervention. Baseline improvement trend was accounted for in statistical analysis when calculating the effect size of the intervention. Participant 3 showed a decrease in GAD-7 scores from the first measurement in the baseline phase to the last measurement in the intervention phase based on the absolute difference between the pre and post intervention scores. There was no visible change in median in baseline and intervention phases due to high levels of variability in data pre and post intervention, including significant increase in GAD-7 scores (increase in anxiety) in the baseline phase. Participant 5 demonstrated a decrease in GAD-7 scores in intervention phase as compared to their baseline with no significant baseline improvement trend. Visual analysis of GAD-7 scored supported the hypothesis that GAD-7 scores would decrease for study participants.

Figure 4.2 represents the results for baseline and intervention phase scores on attachment anxiety for five participants. The scores for Participants 1 showed a slight decrease in the intervention phase compared to baseline phase with no improvement trend in baseline data. The baseline scores for Participant 1 showed a significant increase followed by the rapid increase in the intervention phase. There was a significant decrease in attachment anxiety for Participant 2 with no improvement trend in baseline data, demonstrating the positive effect of the intervention. For Participants 4 and 5, there was a decrease in attachment anxiety scores after the intervention, with a more significant decrease for Participant 5. However, for both Participants 4 and 5, there

were slight baseline improvement trends present that needed to be accounted for in statistical analysis.

Figure 4.3 illustrates the change in emotion regulation for five study participants. None of five participants showed improvement trends for the baseline of difficulty in emotion regulation measure. Participant 1 DERS scores showed a significant decrease in absolute difference in pre and post values, with a stable baseline data and high variability of measurements in the intervention phase, demonstrating the positive effect of the intervention. Participants 2, 4, and 5 showed a significant decrease in difficulties in emotion regulation after the digital therapeutic intervention. Participant 3 scores resulted in a slight decrease of scores between baseline and intervention phases with high variability of data in the baseline phase (no improvement trend).

Figure 4.4 demonstrates the changes in self-esteem (RSES) scores for five study participants. RSES scores for Participant 1 resulted in a decrease in median in the intervention phase compared to baseline phase, with high variability of scores in the intervention phase. Participant 2 demonstrated an increase in RSES scores in the first half of the intervention, with lower scores in the second half of the intervention timeline, resulting in an overall increase in scores based on the median level. Participant 3 scores were characterized by high variability of data in both baseline and intervention phases, resulting in a slight decrease in median scores in the intervention phase compared to baseline phase. Participant 4 scores showed an improvement trend in the baseline trend to be adjusted in statistical analysis, with an increase in self-esteem in the intervention phase compared to the baseline phase. Participant 5 scores illustrate the highest efficacy of intervention among all participants, with no baseline improvement trend and a steady increase of RSES scores in the intervention phase. Following visual analysis, statistical analysis

of the data was computed to assess the effect size of the intervention of all the four measures for five participants.

Statistical Analysis

Statistical analysis of SCED is a field that lacks standard guidelines. Several authors recommend reporting the results of more than one analysis procedure complementary to each other to estimate the effect of the intervention. The Tau-U approach was used to estimate the effect of the intervention across five participants in the sample. Tau-U is a nonparametric order correlation test that has been used as a newer approach in SCED for small datasets. The TAU-U calculation derives from the Mann-Whitney test on nonoverlaps between groups and Kendall rank correlation statistics for calculating within phase trends. TAU-U accounts for outliers in the data, as well as correction for both baseline and intervention trends. Correction of the baseline data is helpful in cases where there is a baseline trend that suggests that a study participant demonstrates improvement prior to the intervention. Tau-U calculation for intervention effect provides the p-values that allow to estimate the statistical significance of the presence of treatment effect across all study participants (Heyvaert et al., 2016).

The between-case standardized mean difference statistics (BCSMD) was used to calculate the effect size (without corrected baseline trend). This effect size calculation used for single-case design studies like Cohen's d statistics requires a minimum three cases for computation and compares the means of two phases—baseline and intervention. It does not require normality or equal variance of the data but nor does it account for a baseline trend. It does require variance of data between the phases (Brossart et al., 2018). The results of the effect size obtained via standardized mean difference (SMD) was compared to TAU-U results. See Tables 4.1 and 4.2 for SMD and TAU-U results.

For GAD-7 scores, Tau-U result is in 0.58 (0.53 with baseline trend correction), $p = 0.0035$, which is significant at $p < 0.05$; BC-SMD effect size is 0.75 – medium approaching large. Statistical analysis of GAD-7 scores demonstrates medium to large efficacy of the digital therapeutic intervention on decreasing symptoms of anxiety among participants. This finding is consistent with the results of visual analysis and supports Hypothesis 1: GAD-7 scores will decrease for participants in the intervention phase compared to baseline phase.

For ECR anxiety scales scores, TAU-U calculation resulted in 0.72 (0.74 with baseline trend correction) which is significant at $p < 0.05$ ($p = 0.0001$), whereas BC-SMD effect size is 0.37 – small. While visual analysis of ECR anxiety scores suggests a reduction in attachment anxiety for participants and Tau-U statistical analysis supports this finding, the effect size of intervention across all five participants is small.

For DERS scores, TAU-U calculation resulted in 0.53 which is significant at $p < 0.05$ ($p = 0.0043$). BC-SMD effect size is 0.73 – medium approaching large. Statistical analysis of DERS scores demonstrates medium to large efficacy of the digital therapeutic intervention on decreasing difficulties in emotion regulation among participants. This finding is congruent with the results of visual analysis and supports part of Hypothesis 2: for the participants with improved GAD-7 scores, emotion regulation will increase (DERS-SF scores will decrease).

For RSES scores, TAU-U calculation resulted in 0.44 (0.39 with baseline trend correction) which is significant at $p < 0.05$ ($p=0.0299$). BC-SMD effect size is 0.46 – small approaching medium. Statistical analysis agrees with visual analysis and results in showing low effect size of the intervention for an increase in self-esteem score; hypothesis 2 is not supported regarding self-esteem scores (for the participants with improved GAD-7 scores, self-esteem scores would increase).

CHAPTER V: DISCUSSION

The purpose of this study was to explore the mechanism of reducing anxiety in the digital therapeutic program, Unwinding Anxiety, through its impact on the degree of security of the attachment style, emotion regulation, and self-representation (self-esteem) in adults. Both visual and statistical analysis of data for five study participants demonstrated the efficacy of the intervention for reducing anxiety among participants with medium to large effect size, thus supporting hypothesis one: GAD-7 scores decreased for participants in the intervention phase compared to baseline phase.

Visual analysis of attachment-related anxiety suggested a decrease of ECR-RA scores for all participants, which was further supported by statistical analysis; the latter revealed small effect size of the intervention on the sample. All five participants demonstrated improved emotion regulation with decreased DERS scores both in visual and statistical analysis with moderate effect size. Self-esteem scores improved for some participants, while decreased for others. Thus, the second hypothesis was supported in the parts related to emotion regulation, partially supported for attachment anxiety, and rejected for self-esteem.

Reducing Anxiety Symptoms via Mindfulness App-Based Interventions

All study participants demonstrated a decrease in anxiety as measured by GAD-7, supporting the first hypothesis. The findings of this study showing the efficacy of a mindfulness-based program delivered via the app in reducing anxiety support the existing evidence on mindfulness as an effective intervention for generalized anxiety disorders (Freudenthaler et al., 2017). Several evidence-based therapies that consistently demonstrate improvement in anxiety disorders for patients, such as ACT and MBCT, incorporate mindfulness as a basis for their framework (Hoge et al., 2018).

Previous studies indicated the effectiveness of stand-alone mindfulness-based interventions to reduce anxiety (Goyal et al., 2014; Hoge et al., 2018). However, few of them use a single-case design to explore the efficacy of digital therapeutics delivery of interventions; in addition, some of those interventions are group interventions, such as MBCT and MBSR. One example of previous research findings in a single-case design research study exploring the effectiveness of ACT demonstrated a decrease of anxiety symptoms in participants as measured by GAD-7, with a large effect size for study participants. The protocol of the study used some interventions similar to the ones offered in Unwinding Anxiety Program; the interventions were offered by a clinician (Ruiz et al., 2020). Another recent study explored the effectiveness of brief mindfulness-based interventions (including paying attention to breathing and focus on bodily sensations) delivered via audio for patients undergoing quarantine while waiting for COVID-19 test results in a hospital setting. The results of the study demonstrated anxiety in the intervention group (pre and post GAD-7 scores) reduced, while GAD-7 scores in the control group increased (Liu et al., 2021).

Published research on the Unwinding Anxiety program in randomized control and one-arm studies consistently demonstrated the decrease in GAD-7 scores among study participants. A secondary analysis of phase one of the randomized control trial on the effect of Unwinding Anxiety program in adults with Generalized Anxiety Disorder showed 0.62-point reduction in the GAD-7 scale scores (Nardi et al., 2022). A one-arm study among physicians experiencing symptoms of anxiety and burn out resulted in a significant decrease (47%) of GAD-7 scores and 57% reduction at the 3-month follow-up (Roy et al., 2020). These findings are consistent with the results of the current study, indicating high efficacy of digital mindfulness-based intervention UA for anxiety symptom reduction measured by GAD-7.

Possible Mechanisms of GAD-7 Scores Reduction

This study is one of the few that explores the mechanism of mindfulness-based interventions delivered via phone app that led to a decrease in anxiety symptoms. From a neuropsychological perspective, the self-referential processing network, also referred as "default mode network," plays an important role in regulating the symptoms of anxiety (Shi & He, 2019). One of the more negative self-referential processes was associated with greater initial anxiety as indexed by greater symptoms of GAD. Neuroimaging studies demonstrated the effectiveness of mindfulness meditation on reducing the activity of brain regions, such as Posterior Cingulate Cortex (PCC), involved in such processes (Shi & He, 2019). Through the mindfulness perspective, worry can be seen as repetitive thoughts about the future. The structure of the Unwinding Anxiety Program consists of two major components: daily mindfulness exercises that teach program participants to pay attention to their experience (bodily sensations, thoughts, feelings), as well as integrative curriculum grounded in the cognitive behavior theoretical orientation. By directing attention from future-related worries to the experience of the present moment in a non-judgmental, accepting way the program addresses the worry component of anxiety as a habit, utilizing "trigger-behavior-response" framework.

It is worth mentioning that anxiety symptoms as measured by GAD-7 is a self-report questionnaire that adheres to the DSM-V diagnostic model. While GAD-7 describes the symptoms that refer to "worry" and physical symptoms of anxiety, it fails to incorporate more complex impact of anxiety on overall functioning and well-being, including relationships with significant others (Desrosiers et al., 2013).

Attachment Anxiety and Mindfulness-Based Interventions

Compared to the norms described by Fraley (2005), most of the study participants showed higher levels of attachment anxiety as measured by ECR-R (median in the baseline phase above the norm of 3.64 for four out of five participants). This finding is consistent with current literature, showing the experience of anxiety in adults is not limited to thoughts of general worry about the future and somatic symptoms, but also has an impact on the relationships with significant others. Attachment anxiety impacts an individual's quality of relationship through hyperactivating internal experiences and behaviors that arise in certain triggering situations, such as an inconsistent presence of significant other. In those moments, individuals may experience heightened emotional response, amplified attachment needs, hypersensitivity to signs of rejection, overwhelming negative emotions, including fear of abandonment, and active attempts to maintain connection (Brennan et al., 1998; Fraley & Shaver, 2000).

These responses make it difficult to navigate interpersonal relationships with psychological flexibility and result in lower levels of resilience. Attachment-related anxiety involves high levels of rumination about individual's shortcomings and threats to relationships (Mikulincer & Florian, 1995). Attachment anxiety is associated with lower adaptive functioning and cognitive control of emotional states function. As Caldwell and Shaver (2014) report, in Buddhism, attachment-related anxiety hyperactivation strategies are related to one of the traditional causes of human suffering—mind's tendency of craving/clinging.

In 2009, Gordon et al. explored whether adult attachment style moderated the effect of the MBSR program. Participants with initial higher scores of attachment anxiety demonstrated higher stress levels at the beginning of the program, as well as greater improvement of the levels

of perceived stress after completing the program compared to participants with more secure attachment style (Cordon et al., 2009; McLean et al., 2014).

A number of researchers agree on the connection between mindfulness and attachment security, including the commonality of neural pathways for secure attachment and mindfulness—networks involved in executive functioning and attention (Macaulay et al., 2015; Nielsen et al., 2017). One of the possible mechanisms that explains this commonality can be found in traditional forms of mindfulness mediation that endorse accepting, kind, and compassionate attitude to oneself and others (for example, loving kindness meditation practice). In addition, mindfulness practice in various forms endorses the idea of community ("sangha") as a reliable source of support, including moments of struggle and distress. Such notions are like "secure base" and "safe haven" functions of secure caregivers described in attachment theory (Macaulay et al., 2015). Mindfulness interventions invite participants to engage in observing one's thoughts and feelings with non-judgmental, accepting, and kind attitude—which is the opposite of feelings of unworthiness, hypervigilance, and rumination associated with attachment anxiety. Thus, the principals of mindfulness programs represent a more "secure" outlook on oneself and others, as well a more balanced relationship to one's internal experiences: thoughts, emotions, and bodily sensations. While trait mindfulness may develop in individuals along with secure attachment during comforting early childhood relationships with a responsible and emotionally mature adult caregiver, those who have gone through adverse childhood experiences may benefit from cultivating mindfulness and become what is often referred in literature as "earned secures" (Guina, 2016). In one study, participants who have experienced adverse events in their childhood who received mindfulness-based interventions during a 3-day program followed by home practice demonstrated improvement in rumination and emotion regulation, significantly

mediating the overall increase in composite mindfulness and attachment scores. In addition, researchers found the change in language structures associated with attachment experiences, with a shift towards more positive evaluations of oneself and others (Caldwell & Shaver, 2014).

These results support the claim that mindfulness-based interventions can be especially helpful for people with attachment anxiety that originated from difficult early childhood experiences. As indicated by empirical studies, mindfulness training can lead to developing self-trust, effective coping strategies, and ability to stay present for both pleasant and unpleasant life experiences for adults with attachment anxiety (Shi & He, 2019). While additional research is wanted to clearly establish the directionality between mindfulness and secure attachment, the present study demonstrates that mindfulness practice leads to decrease of attachment-related anxiety in a relatively short period of time (three months). Loving kindness practice, introduced during the first week of the program, and compassionate and acceptive attitude towards one's experience is re-emphasized throughout the duration of the intervention and may be one of the mechanisms that contributes to lower attachment anxiety scores after the intervention.

Traditionally, the therapeutic alliance is an essential part of attachment-related processes in patients. In Unwinding Anxiety, participants have an opportunity to engage with a supportive online community and attend weekly live calls once a week. The current study demonstrates that a program with very few virtual interactions with participants can potentially increase the security of attachment. It is important to note while ECR-R measure demonstrates solid validity and reliability, it can be viewed as a measurement of the trait, which makes its use and interpretation in designs that include repetitive measurements problematic. This does not impact the overall results of the current study since other attachment measures used for association between mindfulness and attachment reported similar associations. However, the "trait" nature of

the measure may be reflective of the low effect size found in the process of statistical analysis. Since ECR-A for study participants demonstrated a small effect size, further research is needed to establish the efficacy of digital mindfulness-based interventions for attachment anxiety.

Emotion Regulation

The results of the present study demonstrate the efficacy of a digital therapeutic program on emotion regulation as measured by DERS-SF. All program participants decreased difficulty in emotional regulation with a medium approaching large effect size for the sample. DERS-SF measures individual's ability to be aware and recognize their emotions, control impulsive behaviors, and take actions towards set goals in the presence of difficult emotions. It speaks to one's capacity to flexibly apply a variety of emotion regulation strategies across multiple contexts and situations (Gratz & Roemer, 2008; Freudenthaler et al., 2017).

The finding is consistent with current research on relationships between mindfulness, anxiety, and emotion regulation. Several studies found that higher trait mindfulness is associated with better emotion regulation. Mindfulness practice delivered as a series of short practices as well as within group programs such as MBSR and MBCT lead to decrease of emotional dysregulation (Desrosiers et al., 2013; Hill & Updegraff, 2012; Hölzel et al., 2011; Tran et al., 2014).

Several mechanisms in mindfulness-based interventions may lead to improved emotion regulation in individuals experiencing symptoms of anxiety. First, mindfulness practice has been shown to promote the process of reappraisal—changing interpretation of the meaning of the stimuli that caused emotion to modulate emotional response (Hölzel et al., 2011). Specifically, it promotes better emotion regulation by offering a non-judgmental view on one's emotions, which results in increased positive reappraisal (Chambers et al., 2009; Garland et al., 2011).

Second, mindfulness practice, such as “open awareness” and “mindfulness of emotional states,” promotes gradual exposure to unpleasant emotions and encourages participants to experience the the emotions in the moment, turning into the experience of the bodily sensations. This leads to extinction as emotions arise and fade away, as a transient experience. Mindfulness practice addresses unpleasant emotions similarly to exposure therapy, which is effective for the treatment of anxiety disorders. Lastly, the invitation of non-reactivity to any inner experience in mindfulness—“emotions as emotions, thoughts as thoughts”—promotes further reconsolidation and integration of emotional experiences in the presence of curious, kind awareness that permeates various emotional states. By turning towards emotional experiences one can develop a wider range of recognizing emotions and nuances of their emotional experiences, which can lead to less reactivity or hypervigilance (Hölzel et al., 2011).

Literature suggests that emotion regulation mediates the relationships between mindfulness and anxiety, with higher trait mindfulness associated with better emotion regulation. The findings of this study suggest mindfulness practice increases emotion regulation and decreases symptoms of anxiety. It may indicate that specific mechanism for decreasing of symptoms of anxiety works through emotion regulation.

A specific intervention, RAIN, that is introduced in the Unwinding Anxiety Program may be an important element in the mechanism of decreasing difficulties in emotion regulation among the study participants. This acronym introduced in Week 2 of the program stands for Recognize, Accept/Allow, Investigate/Inquire, Note. During the first step of RAIN, program participants are invited to Recognize that the “wave” of anxiety is coming. The “Allow” stage guides them to accept an experience and relax into it rather than resist it or push it away. The “Investigate” and “Note” stages are the steps that lead participants through a process of curious

inquiry of what arises in the awareness of bodily sensations and naming them. The program further offers to apply RAIN to "riding out" difficult emotions such as sadness and anger using the same technique. RAIN exercise supports participants' ability to de-identify with emotional experiences.

It is worth noting that DERS-SF consists of six subscales: strategies, non-acceptance, impulse, goals, awareness, clarity. The study of the change of each scale in response to mindfulness practice is beyond the scope of this study but could be an interesting topic for future research. In addition, mindfulness-based interventions demonstrated prevention of symptoms of anxiety. The mechanism of emotional regulation training available in the form of a digital therapeutic program may be potentially beneficial for prevention of symptoms of anxiety through emotion regulation strategies. (Alsubaie et al., 2018; Parmentier et al., 2019).

Self-Esteem

Both visual and statistical analyses yielded mixed results of change in RSES scores in study participants. One participant demonstrated a steady increase in self-esteem as measured by RSES. The other four participants' data demonstrated high variability both in the baseline and intervention phases, resulting in difficulties of interpretation of visual analysis for this measure. Statistical analysis yielded a small effect size of the Unwinding Anxiety program intervention on participants' self-esteem, thus not supporting the second hypothesis.

Self-esteem is a construct that can be viewed within the framework of self-related processes—self-as-an-object. While different theoretical orientations in clinical psychology conceptualize the concept of self from different perspectives, most of them agree psychological health implies a well-balanced self-attitude (Shi & He, 2019). Rosenberg emphasized higher self-esteem is about feelings of worth and being "good enough," not about superiority over

others (Rosenberg, 1968). In attachment theory, the internal working model of self is important in forming a secure attachment style (Brown & Elliott, 2016).

Previous studies showed self-esteem is a mediator between childhood and adult attachment, while adult attachment is a mediator between self-esteem and psychological distress. Low self-esteem is a predictor of developing several mental health issues, including symptoms of anxiety. Higher self-esteem can be a buffer for developing symptoms of anxiety (Rosenberg et al., 1995). It is worth mentioning that recent metanalysis on relationships between self-esteem, anxiety, and depression revealed a stronger correlation between depression and self-esteem than anxiety. One of the possible explanations for this could be that, similar to depression, self-esteem is correlated with both negative and positive affect, while anxiety correlates only with negative affect (Shen et al., 2021; Sowislo & Orth, 2013).

Negative self-evaluation includes rumination and self-criticism, while self-esteem is associated with positive self-evaluation. When it comes to creating and examining evidence around the efficacy of mindfulness-based interventions and self-related processes, the measure of self-esteem may not be fully relevant for the mechanism of their action. Originating in Buddhism theoretical concept of self, mindfulness is less concerned with the self-evaluation in the first place. Some mindfulness-based interventions in ACT, for example, propose de-identification from “self” as a fixed concept to promote psychological flexibility (Bach & Moran, 2008).

Some studies focused on the effectiveness of MBSR in improving self-esteem of participants. While most of these studies lack methodological quality, one randomized control trial demonstrated moderate effect size for participants (Jazaieri et al., 2012). Some of the promising results were found in the programs focused on self-compassion. When reviewing at the growing evidence of the efficacy of mindfulness-based interventions; self-compassion, rather

than self-esteem is the focus of research (Britton et al., 2021). The results of the present study show while self-esteem may be affected by mindfulness-based interventions, further investigation is needed to assess the efficacy of digital therapeutic interventions on self-esteem in adults, as well as its role in reducing symptoms of anxiety.

Implications

In September 2022, the U.S. Preventative Services Task Force recommended screening for anxiety in primary care settings for adults ages 65 and younger (U.S. Preventative Services Task Force, 2022). This recommendation is based on the impact anxiety disorders are having on the population nationwide, with a significant increase in the aftermath of the COVID-19 pandemic. According to the CDC, the prevalence of anxiety symptoms in the U.S. is accompanied by a reported unmet mental health care need (Terlizz, 2021). This gap continues to increase for the underserved populations with low socio-economic status. “One-to-many” interventions delivered via smartphones can address the disparity in care due to increased demand for mental health support and lack of available providers. The smartphone delivered interventions can be used in conjunction with individual therapy, as well as independently. The lack of evidence behind the interventions delivered via apps, however, continues to be one of the reasons for their low application in mental health and healthcare settings. The present study is one of the few aiming to show the efficacy of such interventions and their prospective use (Marshall et al., 2019).

The findings of this study demonstrate the prospective use of digital therapeutics to address symptoms of anxiety and improve emotion regulation. It indicates some evidence for a potential decrease in attachment anxiety through mindfulness-based interventions delivered via a phone app/web interface program. Digital therapeutics interventions increase access to

evidence-based treatments for anxiety. However, there is very limited evidence on the effectiveness of digital therapeutics for mental health, more research is needed in this area. While the Google Play store and App Store offer thousands of downloadable programs that mention anxiety and stress, the efficacy and the mechanism of action of most of these programs have not been studied.

This study aimed to contribute to closing this evidence gap and to demonstrate that a therapeutic program delivered in a form of consequent module curriculum rooted in evidence-based interventions with an online interactive community and live weekly calls, can go beyond symptom reduction and tap into universal mechanisms of emotional well-being. The findings of this study indicate emotion regulation is an important mechanism in reducing anxiety and mindfulness-based interventions delivered digitally can be an effective intervention utilized both in conjunction with individual/group therapy and as a standalone intervention.

Limitations

The design of this study has inherent limitations. While using single-case experimental design in the assessment of the efficacy of the interventions gains some momentum, it has not become the typical in clinical research. Some of these limitations include the presence of possible autocorrelations, limited external validity or generality. The combination of visual and statistical analyses in the present study with correction for trend improvement in the baseline addresses the autocorrelation concern. In addition, contemporary lines of thought in the single case design world encourage viewing autocorrelation as valuable information for evolving behavioral change and thus current advice is not to focus on “eliminating” it but rather to use statistical method and randomized multiple baseline design (used in the presence study) to account for it (Heyvaert et al., 2016).

While traditional group study designs, such as randomized control studies, are considered to have more generalizability, the sampling of these studies often does not reflect the "real-world" population. This study, on the contrary, recruited subjects who were initially interested in receiving the intervention and were completing the intervention in the real-world environment (BCG Global, 2020).

Another limitation of this study is its reliance on self-report measures. Some of these measures, such as RSES, demonstrated instability during the baseline period of data collection. While statistical analysis accounted for those trends, the question remains for the interpretation of the results for this measure. It is possible the intervention was not effective for self-esteem, or some other circumstances outside of the program impacted the baseline trend.

The COVID-19 pandemic has played a significant role in this study in several ways. First, the pandemic itself prompted the uptake in digital therapeutic interventions and thus made them a more acceptable form of addressing mental health challenges. This positive outlook and anticipation for a previously little-known field may have resulted in improvement trend scores in the baseline and intervention phases on self-report measures. Second, the end of the study coincided with a wave of a new Omicron COVID-19 variant, which has become a significant stress factor for many people. That additional stress could affect a participant's intervention phase responses in several ways. One of the ways to interpret this limitation is that study participants demonstrated significant reduction of anxiety symptoms even in the presence of a strong environmental stressor. However, the presence of such factor also limits the generalizability of the study since it was conducted in quite unusual if not extreme circumstances.

Future Directions

The key future direction for digital therapeutics research is twofold: analysis of real-world scientific evidence on the efficacy of interventions and the implementation research. Digital therapeutics interventions targeting anxiety represent a large portion of the apps available for download in the App Store and Google Play Store. Around half of them, however, have any reference to evidence-based frameworks. Out of these programs (162), only 6.2 % had published studies demonstrating their efficacy. In addition, closer analysis of the content of digital therapeutics raises concerns about their safety (Torous et al., 2021). The research on efficacy of digital therapeutics needs to be expanded both in the quantity and quality of studies. Deeper evidence-based understanding of mechanisms of change offered during these interventions can support their safe and effective use. In addition, research on cultural adaptation of such programs to meet the needs of diverse populations is needed (Dallery et al., 2013).

In implementation research, the barriers for adoption of smartphone apps among mental health providers include concerns and/or lack of information about patients' data security and privacy, cost of the apps, and lack of time and other resources among providers to engage in decision-making processes and educate themselves about the apps. However, when the implementation of digital therapeutics is built into the workflow of the providers and they receive additional resources, such as care partners, to guide patients in the usage of the apps, the uptake among providers significantly increases (Wienert & Zeeb, 2021). The future research in implementation can assess the effectiveness of inclusion of digital therapeutics into mental health providers' work with patients, in both individual and group formats.

Conclusion

This study used a single-case design to examine the efficacy and mechanism of a digital therapeutic program Unwinding Anxiety in reducing anxiety, improving emotion regulation, self-esteem, and the security the attachment style in adults. Visual and statistical analyses yielded medium to large effect size for anxiety reduction and improvement in emotion regulation, small effect size for decreasing attachment anxiety, and no significant effect for self-esteem. These findings align with existing research on the efficacy of mindfulness-based interventions for anxiety and highlight the role of emotion regulation as its core mechanism. In addition, it brings the novelty of examining the impact of digital therapeutic intervention on attachment security.

This study is one of the few to examine the mechanisms of reducing anxiety via digital therapeutics that go beyond measuring symptom reduction and evaluate the overall impact of the intervention on key domains of psychological well-being. The novelty of this approach opens a possibility for future increased access of evidence-based interventions delivered in the form of a phone app both as an independent intervention, as well as in conjunction with individual and group therapy. The rapidly developing field of digital therapeutics in mental health calls for evidence-based interventions that provide quality and safe process for patients. Development and implementation of such programs can contribute to increased access to care and address population health needs.

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APPENDIX A: RECRUITMENT LETTER

Hello,

My name is Maria Neizvestnaya, and I am a doctoral student in the Clinical Psychology program at Antioch University New England. I am seeking participants for my dissertation study examining **how mindfulness training in Unwinding Anxiety program impacts anxiety symptoms, emotion regulation, self-esteem, and the security of attachment in adults**. Attachment system is an innate human behavioral system that, in many ways, defines the ways we perceive others and ourselves. It impacts our ability to regulate emotions and respond to stress. Secure attachment promotes overall well-being and is essential for building fulfilling relationships.

If you decide to participate in this study, you will complete four online questionnaires 8-11 times within four months. It will take you **20-30 minutes each time** to complete the four questionnaires. You will complete these questionnaires once a week for 3-4 weeks prior to starting the program, which will delay the start of your program. You will complete the same questionnaires again 5-7 times within 3 months after starting the program.
You will get a free access to Unwinding Anxiety program for three months and an Amazon gift card of USD 100 value after completing the program and completing all the questionnaires.

Your participation is completely voluntary. **Your decision to not participate in the study will not impact your eligibility for our 3-month scholarship for Unwinding Anxiety.** The study is confidential, anonymous, and voluntary.

I appreciate your consideration of the study. If you agree to participate, please read the informed consent document attached to this email, sign it and sent it to my email. After that, I will send you the link to the first survey.

Sincerely,
Maria Neizvestnaya

APPENDIX B: INFORMED CONSENT

The Mechanism of Reducing Anxiety through Mindfulness Interventions: Digital Therapeutic Program

I am a doctoral student from the clinical psychology department at Antioch University New England. I would like to invite you to take part in a research study about the impact of mindfulness training. In this study, I will examine how Unwinding Anxiety program impacts anxiety symptoms, emotion regulation, self-esteem, and attachment security in adults.

The purpose of this study is to explore the mechanism of reducing anxiety in the digital app Unwinding Anxiety Program and its impact on emotion regulation, self-representation (self-esteem), and the security the attachment style in adults. The results of this study can be used to develop new effective approaches in the treatment and prevention of mental health conditions.

If you agree to take part, you will be asked to complete four questionnaires 8-11 times within 4 months. Each set of questionnaires will take approximately 20-30 minutes of your time. The questionnaires include questions about your emotions, thoughts, behaviors, and attitudes, including questions about your relationships with significant others.

The information you provide will be combined with information from other participants. Neither you nor anyone else taking part in the study will be named or identified. Your information will be kept entirely confidential. No one will know that you participated in the study unless you share that information yourself. Before completing the questionnaire, you will be offered to create a code. This code will be used for matching purposes so that we can examine the change in pre and post program responses. This code will not disclose your identity. It will not be linked to this consent form. Thus, your answers to the questions will remain anonymous. No reports about this study will contain identifying information.

Participating in this study might not directly benefit you. Yet, the information you provide will help to add to the growing body of research of the potential benefits and impact of mindfulness practice. In the long run, it will help to develop new ways of preventing and treating different mental health conditions. After the dissertation is complete, I will share with you the results of the study.

As a study participant, you will get free access to Unwinding Anxiety program for 3 months. After participating in this study, I will send you USD 100 Amazon gift card.

There is a small possibility that you may experience discomfort in responding to items that inquire about your relationships. Other than possible discomfort in thinking about your relationships, we do not anticipate any risk to you. You are welcome to skip any question or stop filling out the questionnaire if it feels too stressful.

Taking part is voluntary. You have the right not to participate at all, or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any consequence or loss of benefits. It will not harm your relationship with Mindsciences in any way.

If you have any questions about the study, you may contact Maria Neizvestnaya. In this case, please email me. Please put "Mindfulness Study" in the subject line of any email you send.

If you have any questions about your rights as a research participant, you may contact Dr. Kevin Lyness. Chair of the Antioch University New England Institutional Review Board.

Thank you for helping us understand how mindfulness practice impacts anxiety symptoms, emotion regulation, self-esteem, and the security of attachment in adults.

I agree to take part in the Antioch University New England study about the impact of **Unwinding Anxiety program on anxiety symptoms, emotion regulation, self-esteem, and attachment security in adults.**

By signing below, I indicate that I understand all of the above information. Any questions I had have been answered. Further, I can ask to be withdrawn from this study at any time.

_____I, _____, am willing to take part in this study.
_____ I, _____, am not willing to take part in this study.

By signing this form, you are consenting to participate.

(Participant's Signature) (Date)

APPENDIX C: TABLES

Table 3.1

Randomization of Participants

Baseline phase	Intervention phase	Participant
AAA (3)	BBBBB (5)	1
AAA (3)	BBBBBB (6)	2
AAAA (4)	BBBBB (5)	3
AAAA (4)	BBBBBB (6)	4
AAAA (4)	BBBBBBB (7)	5

Table 4.1

Results of TAU-U Effect Size Analysis (A vs. B Phases)

		Tau	Var-Tau	Z	P-Value*	CI 95%
GAD-7	Without correction	-0.5841	0.1841	-3.1724	0.0015	-0.9450<>-0.2232
	Corrected baseline	-0.5372	0.1841	-2.9175	0.0035	-0.8980<>-0.1763
RSES	Without correction	0.441	0.1841	2.3954	0.0166	0.0802<>0.8019
	Corrected baseline	0.3998	0.1841	2.1713	0.0299	0.0389<>0.7606
DERS-SF	Without correction	-0.5259	0.1841	-2.8563	0.0043	-0.8868<>-0.1650
	Corrected baseline	-0.5093	0.1841	-2.766	0.0057	-0.8701<>-0.1484
ECR-RA	Without correction	-0.7218	0.1841	-3.9201	0.0001	-1<>-0.3609
	Corrected baseline	-0.735	0.1841	-3.9919	0.0001	-1<>-0.3741

Note: *significant at <0.05 level

Table 4.2

Results For GAD-7, RSES, DERS-SF, and ECR-R Anxiety Scores in Between-Case Standardized Mean Difference Statistics for Single-Case Design

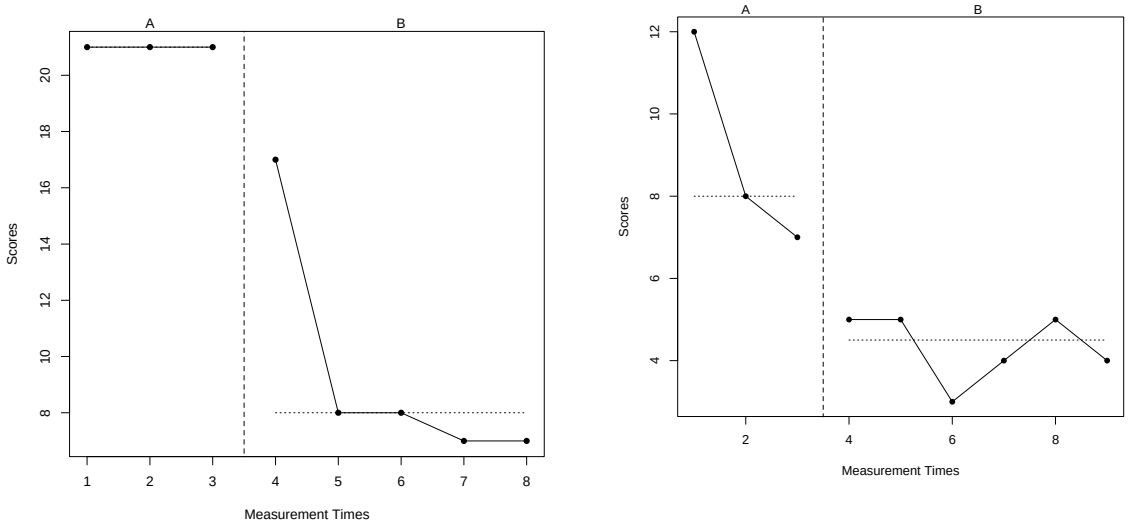
	BC-SMD estimate	Std. Error	95% CI (lower)	95% CI (upper)	Degrees of freedom
GAD-7	-0.752832803	0.33316803	-1.505488772	-0.000176835	9.0809158
RSES	0.463230808	0.28489257	-0.177935549	1.104397164	9.31485407
DERS-SF	-0.725132371	0.3066651	-1.39535231	-0.054912433	11.6772356
ECR-RA	-0.36745366	0.1984793	-0.888137095	0.153229775	4.68545568

APPENDIX D: FIGURES

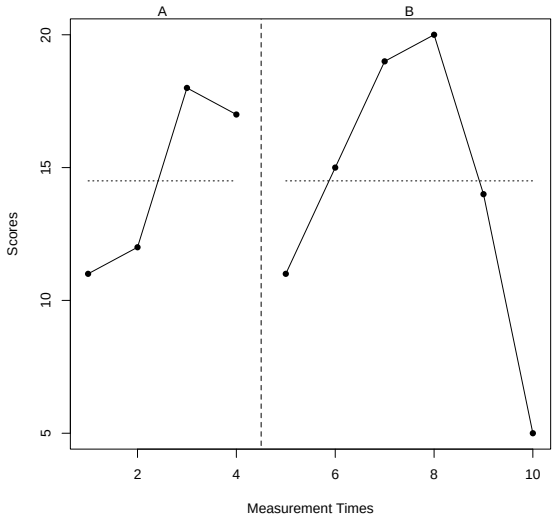
Figure 4.1

Baseline (A) and Intervention (B) Phases GAD-7 Scores for Study Participants

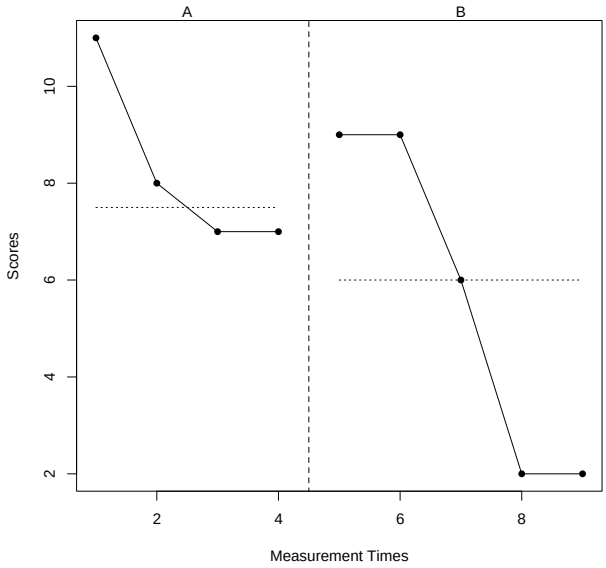
Participant 1 *Participant 2*

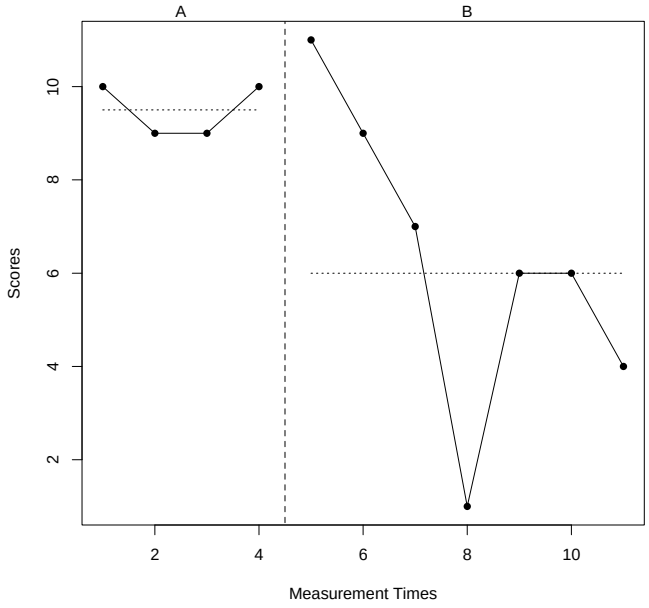


Participant 3



Participant 4





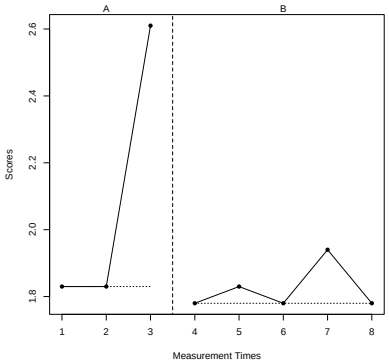
Participant 5

Note: This figure demonstrates visual representation of GAD-7 scores for study participants, with dotted horizontal line representing the median.

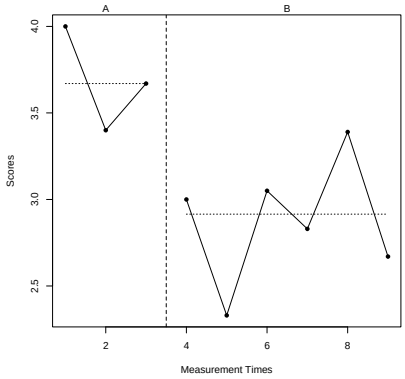
Figure 4.2

Baseline (A) and Intervention (B) Phases ECR-R Anxiety Scores for Study Participants

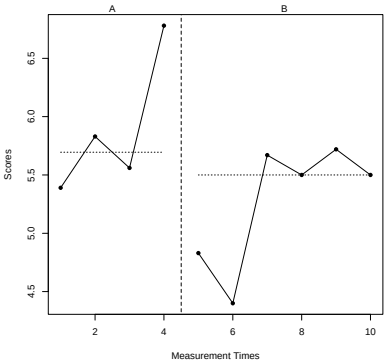
Participant 1



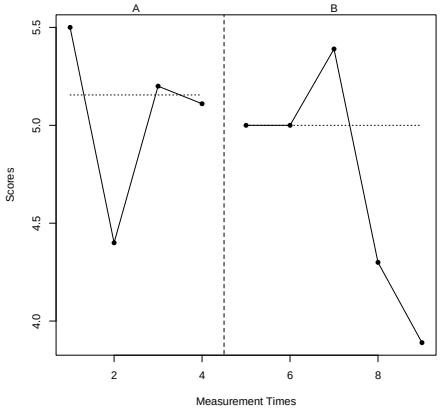
Participant 2



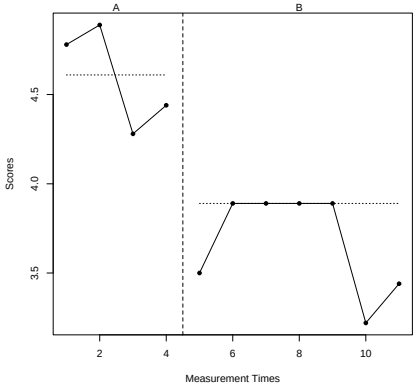
Participant 3



Participant 4



Participant 5

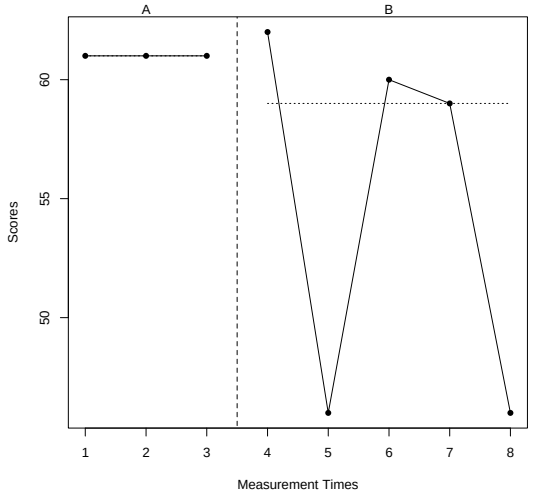


Note: This figure demonstrates visual representation of ECR-R anxiety scores for study participants, with dotted horizontal line representing the median.

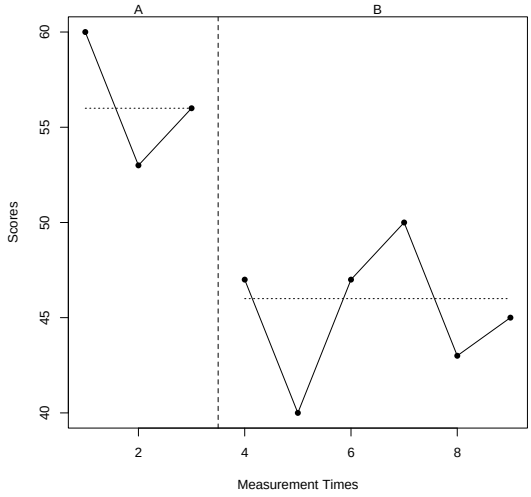
Figure 4.3

Baseline (A) and Intervention (B) Phases DERS-SF Scores for Study Participants

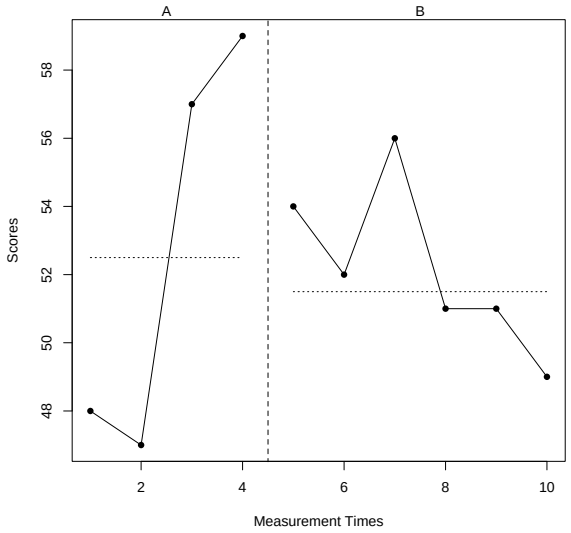
Participant 1



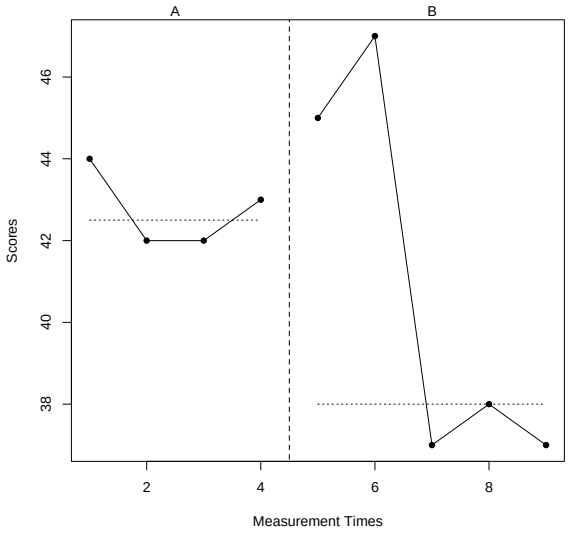
Participant 2

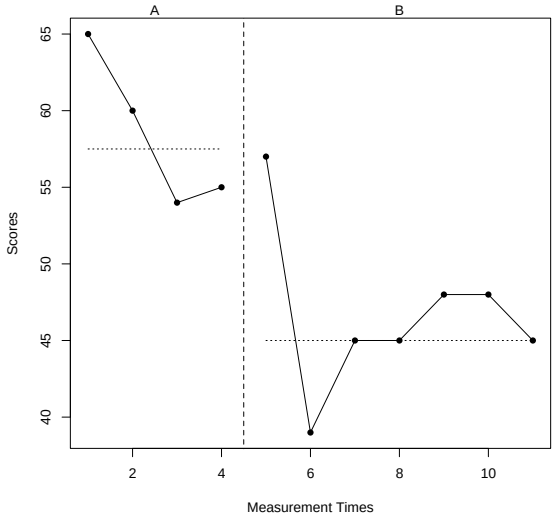


Participant 3



Participant 4





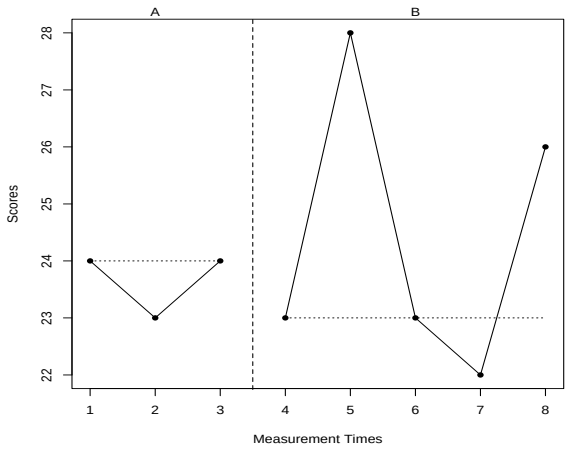
Participant 5

Note: This figure demonstrates visual representation of DERS-SF scores for study participants, with dotted horizontal line representing the median.

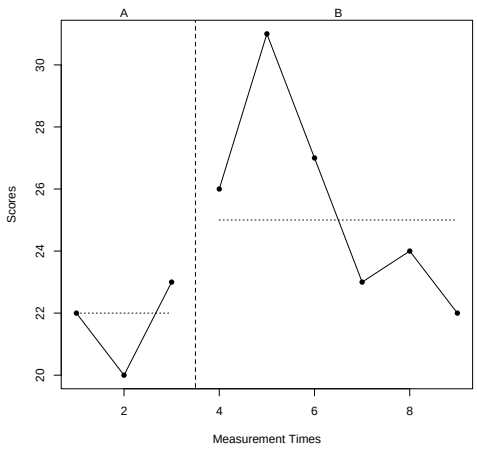
Figure 4.4

Baseline (A) and Intervention (B) Phases RSES Scores for Study Participants

Participant 1



Participant 2



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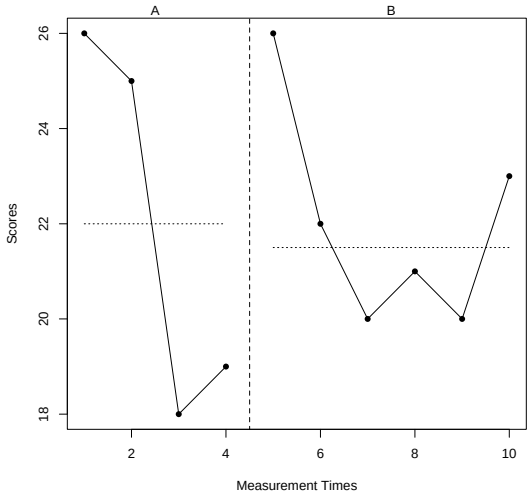

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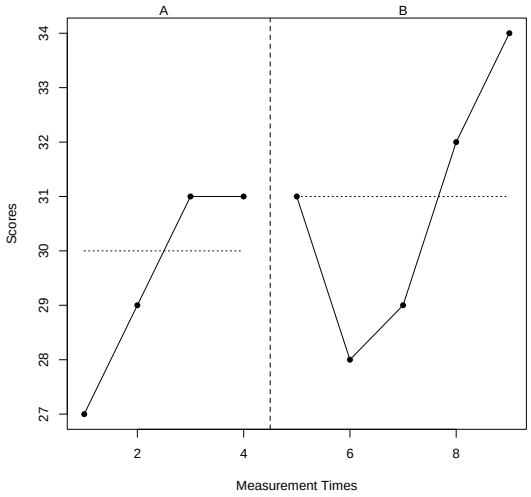

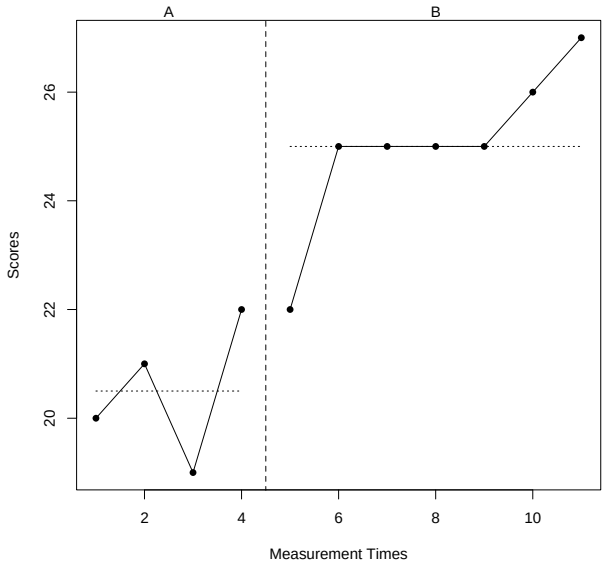

Participant 5

Note: This figure demonstrates visual representation of RSES scores for study participants, with dotted horizontal line representing the median.