DEVELOPMENT AND EVALUATION OF A GAMIFIED M-HEALTH SYSTEM FOR IMPROVING ECOLOGICAL MOMENTARY INTERVENTION (EMI) IN CHILD ANXIETY TREATMENT

by

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Submitted to the Graduate Faculty of

School of Health and Rehabilitation Sciences in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

University of Pittsburgh

2017

UNIVERSITY OF PITTSBURGH

SCHOOL OF HEALTH AND REHABILITATION SCIENCES

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University of Pittsburgh, 2017

Cognitive-Behavioral Therapy (CBT) is an efficacious, short-term treatment for anxiety in children. Although efficacious, many children (40-50%) do not show a significant reduction in symptoms and/or full recovery from primary anxiety diagnoses. Children may fail to improve because they do not fully understand or apply the skills learned in the clinic to their daily life. Homework is routinely assigned in CBT with the goal of generalizing skills beyond the therapy session. Many children however, are likely to struggle with homework completion due to a variety of reasons, including (1) lack of motivation, (2) forgetfulness, and (3) lack of CBT skills understanding. Mobile health (m-Health) gamification provides a potential solution to improving CBT efficacy by delivering more engaging and interactive strategies to facilitate CBT skills practice in everyday life (*in vivo*).

This dissertation describes both the process of redesigning an existing m-Health system entitled Smartphone-enhanced Child Anxiety Treatment (SmartCAT 1.0) and the utilization of the redesigned SmartCAT (SmartCAT 2.0) in brief (8-session) CBT (BCBT) clinical trial. SmartCAT consists of a smartphone app, and a therapist portal.

Results from the clinical implementation indicate that the app was frequently used throughout the treatment. On average, anxious children spent 40.43 minutes on the app (SD=55.51) completing 13.93 activities per session (SD=11.23). At the .10 level, the app usage

of SmartCAT 2.0 (Median=82.5) was higher than that of SmartCAT 1.0 (Median=39), U=34.00, p<.01, Cohen's r=.52. The amount of time spent (in minutes) on SmartCAT 2.0 (Median=184.97) was also higher than that observed in SmartCAT 1.0 (Median=106.03), U=64.00, p=.075, Cohen's r=.31. Post-treatment analysis revealed that remission of anxiety was not associated with app usage patterns, behaviors, patient demographics, and clinical characteristics. On average, the therapist visited the portal twice per week, spending an average of 5.5 minutes per visit, per patient.

In conclusion, SmartCAT 2.0 showed good acceptability, usefulness, and engagement among anxious youth receiving BCBT treatment. The therapists rated the portal as both acceptable, and useful when integrated as a part of treatment. Integrating an m-Health gamification system within BCBT for anxious children increases involvement in treatment and may facilitate dissemination of effective procedures.

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LIST OF ABBREVIATIONS

\rightarrow	Anxiety and Related Disorders Interview Schedule
\rightarrow	Attention Deficit Hyperactivity Disorder
\rightarrow	American Psychological Association
\rightarrow	Application Programming Interface
\rightarrow	Brief Cognitive-Behavioral Therapy
\rightarrow	Child-Adolescent Anxiety Multimodal Study
\rightarrow	Cognitive-Behavioral Therapy
\rightarrow	Children's Global Assessment Scale
\rightarrow	Clinical Global Impression-Improvement
\rightarrow	Clinical Global Impression-Severity
\rightarrow	Diagnostic and Statistical Manual of Mental Disorders
\rightarrow	Ecological Momentary Assessment
\rightarrow	Ecological Momentary Intervention
\rightarrow	Food and Drug Administration
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\rightarrow	System Usability Scale
\rightarrow	User-Centered Design
\rightarrow	User Interface
\rightarrow	Extensible Messaging and Presence Protocol
	<u> </u>

PREFACE

I would like to thank my dissertation advisor and committee chair Dr. Bambang Parmanto, whose guidance, support, and encouragement are greatly appreciated. Dr. Parmanto has given me countless opportunities to freely pursue those areas of research I am most interested in. Additionally, I would like to thank my committee members, Dr. Jennifer Silk, Dr. Valerie Watzlaf, and Dr. Leming Zhou for their valuable efforts and time.

To my colleagues at the Health and Rehabilitation Informatics (HARI) Lab at the School of Health and Rehabilitation Sciences: thank you for being both exceptional friends and invaluable teammates.

To the members of the Families, Emotions, Neuroscience, and Development (FEND) Lab at the Department of Psychology: thank you for all your help with data management; I could not have completed this study without you.

To my family —my mother, father, brother, and sister: thank you for your endless compassion, constant support, and bolstering encouragement.

A special thank you goes to my lovely sons, Deva and Nanda. Your love and smiles are always there when needed most.

Finally —and perhaps most importantly— I would like to thank my lovely wife, Eka, for her unflinching support, compassionate understanding, invaluable assistance, and consistent encouragement.

This work was funded in part by the National Institute of Mental Health (NIMH) grant # R34MH102666, and the RERC on ICT "From Cloud to Smartphone – Accessible and Empowering ICT", grant #90RE5018 from the National Institute for Disability, Independent Living and Rehabilitation Research (NIDILRR).

1.0 INTRODUCTION

1.1 PROBLEM STATEMENT

Anxiety disorders comprise the most common disorders of childhood and adolescence (Costello, Egger, & Angold, 2005; Rapee, Schniering, & Hudson, 2009). The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V), recognizes 12 different types of anxiety disorders, six of which are likely to emerge during childhood. Among these six disorders are separation anxiety disorder (SAD), generalized anxiety disorder (GAD), social anxiety disorder (social phobia), specific phobia, panic disorder, and selective mutism (American Psychiatric Association, 2013). Notably, these anxiety disorders rarely occur in isolation (Rapee et al., 2009) but instead are known to coincide. GAD, social anxiety disorder (social phobia), and SAD are reported to be highly comorbid and prevalent (Kendall et al., 2010). In spite of this knowledge, child and adolescent anxiety disorders are often go undetected or are left untreated (Connolly & Bernstein, 2007) —some current estimates indicate that more than half of anxious children are not receiving treatment (Chavira, Stein, Bailey, & Stein, 2004; Egger & Burns, 2004). This creates a serious situation as untreated anxiety in youth can not only have a negative impact on academic work and social competence (Kendall, 1994) but also can contribute to the development of depression and substance abuse (Costello & Angold, 1995; Ferdinand & Verhulst, 1995; Pine, Cohen, Gurley, Brook, & Ma, 1998; Strauss, Frame, & Forehand, 1987; Woodward & Fergusson, 2001).

Cognitive-Behavioral Therapy (CBT) has been recognized by the American Psychological Association (APA) Taskforce as a relatively efficacious treatment for mild to moderate childhood anxiety (Hollon & Beck, 2013; Mohatt, Bennett, & Walkup, 2014), based on the results of multiple independent randomized clinical trials (RCTs; Barrett, 1998; Barrett, Dadds, & Rapee, 1996; Beidel, Turner, & Morris, 2000; Kendall et al., 1997; Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008; Silverman et al., 1999; Walkup et al., 2008). Notably, one study has shown that anxious children receiving CBT treatment for their anxiety are three times more likely to recover as compared to those receiving no treatment (Ginsburg & Becker, 2009). Typically, CBT requires ten to twenty weekly sessions with a CBT therapist (James, Soler, & Weatherall, 2005) and is considered the first-line choice by most children and families (Asarnow et al., 2005). During the weekly sessions, a CBT therapist teaches the children CBT skills for coping with anxiety-provoking situations. Additionally, the therapist assigns "homework" that provides repeated practice for complete skill acquisition and refinement beyond CBT sessions (Seligman & Ollendick, 2011). Exposures to feared, uncomfortable situations, are also incorporated into the homework with the goal of generalizing skills beyond the clinic (Kendall et al., 2005).

However, while this standard treatment is efficacious, approximately 40% of anxious children do not respond to treatment and/or fully recover from primary anxiety diagnoses (Compton et al., 2014; James et al., 2005). One possibility why the youths do not benefit from the treatment is because they do not apply the skills learned in the clinic to their daily life. Perhaps, one of the main drawbacks of CBT is that it depends on the child's willingness to learn

and practice the skills for them to be effective. Although homework is routinely assigned, many anxious children fail to complete homework beyond sessions (Hudson & Kendall, 2002) because they (1) do not remember to do it, (2) do not want to complete it, and (3) do not understand the skills needed to complete the homework.

Mobile health (m-Health) technologies present a potential solution to overcoming barriers to home-based skills practice for youth. First, the "always-carried" and "always-on" nature of smartphones creates opportunity to deliver CBT interventions to anxious children in natural settings during their everyday lives, an approach referred to as "Ecological Momentary Intervention" (EMI; Heron & Smyth, 2010). EMI's can provide skills coaching to anxious children in the real world outside of sessions, when it is most needed. The children can also access training materials *in situ* at their convenience throughout the day. Second, the increased processing and sensing capability of smartphones allows for more sophisticated, interactive, and engaging health intervention applications. This provides an opportunity for developers to make context-aware m-Health applications that can automatically detect when and where youths require skills coaching during real-world emotional situations.

Despite this potential, the repetitive tasks (i.e. self-monitoring, self-management) that characterize most m-Health applications can be exhausting and may lack intrinsic rewards (Cafazzo, Casselman, Hamming, Katzman, & Palmert, 2012). An alternative to traditional m-Health applications is the use of gamification, one of many persuasive approaches that uses game design elements to engage people in non-game contexts (Deterding, Sicart, Nacke, O'Hara, & Dixon, 2011). The concept has been widely used in enterprise (Herzig, Ameling, & Schill, 2012), social media (Zeynep, Cramer, Holmquist, & Rost, 2011), education (Cronk, 2012), environmental monitoring (Herrlich, Malaka, & Masuch, 2012), and self-management of

diabetes (Cafazzo et al., 2012; Klingensmith et al., 2013) to influence and motivate people to do desired behaviors. When integrated with m-Health applications, gamification can potentially make tedious activities on m-Health applications more engaging to people, thus increasing their motivation to use them.

1.2 RESEARCH AIMS

The work presented in this dissertation is an attempt to improve CBT treatment response and/or recovery by overcoming barriers to home-based skills practice for anxious children. To achieve this goal, an existing m-Health system entitled Smartphone-enhanced Child Anxiety Treatment (SmartCAT 1.0), consisting of a smartphone application (app) and a therapist portal, was redesigned and implemented as an adjunctive component to a brief (8-session) version of CBT (BCBT) treatment in an open clinical trial. The new system (SmartCAT 2.0) is designed to address those aforementioned barriers by (1) providing automatic cues to the children to practice skills at prescribed times and places, even when they forget to initiate skills practice on their own; (2) motivating the children to practice skills; and (3) providing interactive ways to learn the skills and offering *in situ* learning exercises to increase understanding of skills as well as daily personalized home-based exposures. To achieve the research goal, the following specific aims are formulated:

Primary Aims

Aim 1. To develop a gamified m-Health system to maintain anxious children's motivation when using the system during the treatment.

Aim 2. To assess whether the integration of gamification can motivate the children to use the smartphone app during the treatment.

Exploratory Aims

- Aim 3. To identify usage patterns or behaviors of the children who benefit the most from the treatment; these include amount of engagement (time spent on app, the number of features completed), reminder adherence, and proximity of the device from the children.
- **Aim 4.** To identify characteristics of anxious child who benefit the most from the BCBT + m-Health treatment, including the child's demographic characteristics (age, gender) and clinical characteristics (severity, comorbidity, anxiety subtype).
- **Aim 5.** To identify CBT therapists' technology-related efforts from the BCBT + m-Health treatment; these include the average of time spent on the portal, the number of portal visits per week, and the number of patients reviewed per week.

1.3 DISSERTATION OUTLINE

In this report, there are 7 chapters, beginning with Chapter 1's dissertation introduction. Chapter 2 follows, covering topics relevant to anxiety disorders such as symptoms, age of onset, assessment, and treatments. Next, Chapter 3 offers an overview of SmartCAT 1.0 and is followed in Chapter 4 by a literature review of gamification. To achieve the previously delineated research aims, the study has been conducted in two phases: development and then implementation in a pilot clinical trial. The development phase was conducted to achieve Aim 1 and is highlighted in Chapter 5, and is followed in Chapter 6 by the clinical implementation of SmartCAT 2.0 in a pilot clinical trial (conducted towards realizing Aims 2, 3, 4, and 5). Finally,

Chapter 7 offers a discussion of the studies limitations, a summary of the results and analysis, and finally a conclusion that highlights, in particular, the future directions this research might take.

2.0 CHILDHOOD ANXIETY DISORDERS

Reactions to fears and anxieties commonly occur and are generally considered to be a part of normal development in childhood (Miller, Barrett, & Hampe, 1974). According to Marks (1969), "Fear is a normal response to active or an imagined threat in higher animals, and comprises an outer behavioural expression, an inner feeling, and accompanying physiological changes" (p. 1). Whereas anxiety may be defined as "a diffuse, unpleasant, vague sense of apprehension, often accompanied by autonomic symptoms—such as headaches, palpitations, tightness in the chest, restlessness, mild stomach discomfort that can be an appropriate response to a threatening situation or stimulus" (Kaplan & Sadock, 1988, p. 591). Anxiety disorders are conditions in which heightened, often disabling anxiety or fear marks a shared primary symptom (Keeley & Storch, 2009). The symptoms are diagnosable when either anxiety or fear cause significant distress or functional impairment (American Psychiatric Association, 2013). A clinical diagnosis becomes necessary once the frequency and intensity of anxiety/fear induced symptoms meets a set of specific diagnostic criteria (described below) and causes a significant impairment in functioning.

Epidemiological studies estimate the prevalence of anxiety disorders in school-age children to range between 10% and 20% (Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Gurley, Cohen, Pine, & Brook, 1996; Shaffer et al., 1996), indicating that these disorders are among the most common health concerns in this age group (Costello et al., 2005; Rapee et al.,

2009). Moreover, between 40% and 60% of anxious children are diagnosed with more than one anxiety disorder (Benjamin, Costello, & Warren, 1990; Kashani & Orvaschel, 1990; Last, Hersen, Kazdin, Francis, & Grubb, 1987), suggesting that these disorders rarely occur in isolation. Three of these anxiety disorders, GAD, social anxiety disorder, and SAD, are highly comorbid and prevalent in children (Kendall et al., 2010). Furthermore, research has demonstrated that anxious children suffer from impairments in academic work and social or familial functioning (Kendall, 1994; Langley, Bergman, McCracken, & Piacentini, 2004), with those experiencing chronic symptoms often becoming depressed or abusive of addictive substances (Costello & Angold, 1995; Ferdinand & Verhulst, 1995; Pine et al., 1998; Strauss et al., 1987; Woodward & Fergusson, 2001).

2.1 SYMPTOMS OF DSM-V ANXIETY DISORDERS

The symptoms of anxiety, according to Langs (1968), are created and maintained by three concurrent factors that can be identified as either cognitive, physiological, or behavioral. The cognitive factor usually specifies processes where distortions in information processing lead to developing anxious thoughts, memory biases privileging or distorting stressful/distressing events, becoming hypersensitive to perceived threat cues, and fostering a bias toward interpreting ambiguous situations as threatening (Vasey & MacLeod, 2001). In general, these thoughts tend to focus on the risk of being harmed (Rinck & Becker, 2005). For example, children with SAD have worries of being separated from their caretaker because something bad will happen to them or their caretaker.

The physiological component of anxiety is associated with autonomic or somatic reactions to anxiety. When experiencing threatening situations, individuals with anxiety disorders often experience physiological symptoms that are more excessive in duration or intensity compared to non-anxious individuals (Hoehn-Saric & McLeod, 2000). According to Alfano et al. (2007), sleep-related problems (SRP) such as insomnia, nightmares, and refusal/reluctance to sleep alone are also more prevalent among anxious children.

The behavioral component of anxiety relates to the action that individuals take towards reducing/preventing anxiety from triggering stimuli/situations. Avoidance, in which individuals avoid specific stimuli (e.g., dark places) or situations (e.g., meeting new people) to prevent anticipated harm, is among the most common behavioral symptoms (Seligman & Ollendick, 2011).

The main symptoms for six anxiety disorders are listed in the DSM-V (American Psychiatric Association, 2013) and are described below.

2.1.1 Separation Anxiety Disorder

SAD is characterized by excessive worry or fear about separation from home or from attachment figures (i.e., parents, caretaker). Children with SAD usually demonstrate excessive distress upon real or threatened separation (i.e., crying, tantrums, complaints of physical symptoms), fear of losing major attachment figures (i.e., illness, injury, disasters, death), and worry about getting lost, kidnapped, or dying. For these reasons, they refuse to go out, away from home, to school, or elsewhere to avoid separation. School refusal is particularly common in children with SAD, affecting 75% children with the diagnosis (Masi, Mucci, & Millepiedi, 2001). Children with

SAD may also experience sleep problems (i.e., nightmares associated with separation/harm from/to the attachment figures) and various other somatic complaints (i.e., stomachache).

2.1.2 Generalized Anxiety Disorder

GAD involves excessive worry or fear about a wide variety of events or activities such as school performance, the health of family members, or social concerns. It is characterized by 6 months or more of uncontrolled, diffuse apprehensive expectation and tension. In children, the anxiety and worry are accompanied by one of the following symptoms: restlessness, being easily fatigued, difficulty concentrating, irritability, muscle tension, or sleep problems (American Psychiatric Association, 2013). Many children with GAD also experience somatic symptoms such as sweating, nausea, headaches, frequent urination, or diarrhea. Avoidant behavior is also common in children with GAD (Akiskal, 1998).

2.1.3 Social Anxiety Disorder (Social Phobia)

Social anxiety disorder is marked by a significant amount of fear or anxiety in one or more social or performance situations, in which the individual is exposed to negative evaluation received in social interactions (e.g., having a conversation, meeting new people) or performing in front of others (e.g., giving a speech). The DSM-V notes that, in children, the anxiety must occur during interactions with peers as well as adults (American Psychiatric Association, 2013). Notably, Kashdan and Herbert (2001) highlight three main factors contributing in the maintenance of social anxiety disorder. These are: (1) cognitive biases (e.g., beliefs that individuals will predictably behave in ways that will elicit rejection or negative evaluation from others), (2)

deficits in social skills, and (3) operant conditioning (e.g., negative reinforcements of avoidance behaviors). When interacting with new people, children with social anxiety disorder may present as shy and socially withdrawn and may show noticeable somatic symptoms (e.g., blushing, sweating, and shaking). Limited eye contact, or speaking with an overly soft voice is also common.

2.1.4 Panic Disorder

PD is characterized by recurrent panic attacks that occur without an obvious cue or trigger at the time of occurrence. Panic attacks are an abrupt surge of intense fear or intense discomfort that reach a peak within minutes. The abrupt surge appears to occur from out of the blue, such as when the individual is relaxing or emerging from sleep (nocturnal panic attack). According to the cognitive model of panic proposed by Clark (1986), panic attacks emerge from "catastrophic misinterpretation" of the bodily (i.e., somatic) sensations – perception of the somatic symptoms that are more dangerous than the actual ones. Heart palpitations, for example, may be interpreted as a sign of impending heart attack. Panic attacks are commonly accompanied by at least four physiological symptoms including, but not limited to, pounding heart, sweating, trembling, shortness of breath, feelings of choking, chest pain, nausea, feeling dizzy, feeling chilled or overheated, numbness or tingling sensations, feeling of unreality, and a fear of losing control or dying (American Psychiatric Association, 2013). The frequency of panic attacks experienced by individuals with PD varies widely across individuals; they can be as sparse as two attacks per month over many years or as frequent as many short bursts every day, followed by periods of weeks or months without any attacks. According to Ollendick (1998), PD is less common in children than in adolescence, and the clinical presentation of PD may vary across the

development span. In younger children, panic attacks are often linked to particular events and are not unexpected or "out of the blue" (Ollendick, 1998).

2.1.5 Specific Phobia

Specific phobia is characterized by an intense, irrational fears of certain things or situations (e.g., animals, injections, the dark, escalators, seeing blood, etc.) typically lasting for 6 months or more (American Psychiatric Association, 2013). Children may not realize that these fears are unreasonable and often they can become extremely distressed when confronted with the feared object or situation, expressing this fear/distress by crying, throwing tantrums, freezing, or clinging. Additionally, they may also experience somatic symptoms such as rapid heart rate, dizziness, or sweaty palms and the feared object or situations become actively avoided or endured with intense fear or anxiety. This avoidance can significantly disrupt a child's routine, school performance, family functioning, or social interactions (LeBeau et al., 2010). Specific phobias are quite common among children, with reported prevalence rates of 5% (Costello & Angold, 1995; Muris, Schmidt, & Merckelbach, 1999).

2.2 AGE OF ONSET

According to Rapee et al. (2009), the age of onset of anxiety disorders can be very difficult to determine because determining this age relies on retrospective reports from adults, and can vary depending on the type of anxiety disorder. In general, anxiety disorders tend to have an earlier age of onset than other internalized psychiatric disorders (Kessler et al., 2005). Reports suggest

that a large proportion of SAD and specific phobia disorders start presenting in early to middle childhood (4-11 years), while social anxiety disorder commonly presents in early- to mid-adolescence (13-15 years), and PD presents in early adulthood (age 24 years) (Beesdo, Knappe, & Pine, 2009; Kessler et al., 2005; Öst & Lars-Göran, 1987). Among different types of anxiety disorders, the age of onset of GAD is spread over a very broad range (Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012) and is less consistent, varying from "lifelong" (Rapee, 1991) to adult onset (Kessler et al., 2005).

2.3 ASSESMENT

The psychological and behavioral assessment of anxiety disorders can be conducted in several ways including diagnostic interview schedules, rating scales, observations, and self-monitoring forms (Silverman & Ollendick, 2005). Diagnostic interviews are reliable and valid instruments designed to facilitate diagnostic decisions consistent with certain diagnostic systems such as DSM-V. The currently available diagnostic interviews used to diagnose DSM-V anxiety disorders include Anxiety and Related Disorders Interview Schedule for DSM-V: Adult and Lifetime Version (ADIS-5; Brown & Barlow, 2013), Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (KSADS-PL; Kaufman et al., 1997a), and Structured Clinical Interview for DSM-V (SCID-5; First, Williams, Karg, & Spitzer, 2015). Although diagnostic interviews are comprehensive and methodical, they require trained administrators, and can often be time-consuming (approximately 60-120 minutes per administer) and expensive to conduct.

Rating scales from self-reports or parent-reports are more efficicient, mostly because thy require minimal training for clinicians and are quicker to administer compared with diagnostic interviews. Thus, rating scales are often utilized for monitoring treatment progress (Velting, Setzer, & Albano, 2004). Self-report and parent-report instruments can also be used to assess both general and as well as more specific anxiety symptoms. For example, Screen for Child Anxiety Related Emotional Disorders (SCARED; Birmaher et al., 1997) (used for assessing general anxiety symptoms in children ages 8-18 years) can be administered quickly, at approximately 10 minutes, and can be completed by either children or parents (Children and Parent version). SCARED consists of five factor-derived subscales (Panic/Somatic, Separation Anxiety, Social Phobia, General Anxiety, and School Phobia) that allow the identification of problem areas related to anxiety.

2.4 TREATMENT OF ANXIETY DISORDERS

Efficacious treatments for childhood anxiety disorders (described below) include CBT (Kendall, 1994; Kendall et al., 1997), the use of selective serotonin-reuptake inhibitors (SSRIs; Birmaher et al., 2003; Walkup et al., 2001), or a combination of the two (Piacentini et al., 2014; Walkup et al., 2008). To date, CBT has received the most empirical support for the treatment of childhood anxiety (Barrett, 1998; Barrett et al., 1996; Beidel et al., 2000; Kendall et al., 1997, 2008; Silverman et al., 1999b; Walkup et al., 2008). Several RCTs suggest that anxious children receiving CBT treatment improve more significantly compared to those assigned to a waitlist condition (Barrett et al., 1996; Kendall, 1994; Kendall et al., 1997). Following 12 to 16 sessions of CBT, approximately 60% of the children are free from their principal anxiety disorder

(Kendall, 1994; Kendall et al., 1997; Walkup et al., 2008). The treatment effects of CBT have also been found to be maintained over time (Barrett, Duffy, Dadds, & Rapee, 2001; Garcia-Lopez et al., 2006; Kendall, Safford, Flannery-Schroeder, & Webb, 2004; Kendall & Southam-Gerow, 1996).

Several RCTs of SSRIs have provided evidence for the short-term efficacy of these medications in the treatment of childhood anxiety disorders, including GAD (Birmaher et al., 2003; Walkup et al., 2001), SAD (Birmaher et al., 2003; Walkup et al., 2001), and social anxiety disorder (Birmaher et al., 2003; Wagner et al., 2004; Walkup et al., 2001). Following eight sessions of pharmacotherapy, approximately 55% of anxious children are free from their principal anxiety disorder (Walkup et al., 2008). Although evidence for the efficacy of SSRIs in conjunction with CBT is still growing (Ipser, Stein, Hawkridge, & Hoppe, 2009), however it is recommended that the use of SSRIs be considered in moderate to severe anxiety symptoms, in cases in which the degree of impairment prevents participation in CBT, or when the initial CBT does not decrease anxiety symptoms (Kodish, Rockhill, & Varley, 2011). When augmented with CBT, the addition of an SSRI appears to improve the effects of CBT, with 81% of the children responding to treatment following 14 sessions of CBT + SSRI (Walkup et al., 2008). Despite the superiority of CBT + SSRI, many families still prefer not to use medication for children (Rushton, Clark, & Freed, 2000; Wisdom, Clarke, & Green, 2006).

2.4.1 Cognitive-Behavioral Therapy (CBT)

The aim of CBT is to teach anxious children to identify anxiety cues, utilize coping responses, and challenge anxiety-provoking thoughts. Well-regarded as an effective evidence-based treatment (Ollendick & King, 1998; Ollendick, King, & Chorpita, 2006), CBT for pediatric

anxiety has six key components. These are: 1) psychoeducation of child and caregivers regarding the nature of anxiety; 2) techniques for managing somatic symptoms including relaxation training and/or deep breathing; 3) cognitive restructuring by identifying and challenging anxiety-provoking thoughts; 4) problem-solving by generating and testing various methods for coping with specific problem situations; 5) systematic, graduated, and controlled exposure to feared situations or stimuli, including imaginal (e.g., through guided imagery), symbolic (e.g., through the use of pictures or props), simulated (e.g., through role-playing), and *in vivo* (e.g., contact with real situation/stimulus) methods; and 6) relapse prevention plans by consolidating anxious youth anxiety management skills and promoting generalization and maintenance of treatment gains (Velting et al., 2004). CBT can be delivered in several formats (e.g., individual, group, and family-based) and has been used in a variety of settings such as schools, outpatient clinics, inpatient or partial-hospitalization programs, and primary care practices (Seligman & Ollendick, 2011).

The Coping Cat program is a well-establish yet flexible CBT approach for treating anxious children, aged 7-13, who meet criteria for GAD, SAD, and social anxiety disorder (Kendall, 1994). The treatment components of the program include: emotions and somatic symptom identification, cognitive restructuring of negative thoughts into coping self-talk, relaxation, problem solving, self-monitoring and reinforcement, graded exposure therapy, and skills practice. The program is comprised of a 16-session, manual treatment (with a therapist guiding) and also implements a client workbook that contains tasks corresponding to various sequential points during the treatment (Kendall & Hedtke, 2006b). During the first 8 sessions, the anxious youth learn anxiety-management strategies, including how to identify bodily arousal, engage in relaxation, recognize anxious thoughts, and problem solve. To facilitate learning and

memorization of these strategies, the Coping Cat program provides the acronym "FEAR," which stands for:

<u>F</u>eeling frightened?,

<u>Expecting bad things to happen?</u>,

<u>A</u>ttitudes and actions that can help,

<u>**R**</u>esults and rewards.

Once the youth demonstrates an understanding of the FEAR plan, the remaining sessions are devoted to exposure. Exposure tasks in the Coping Cat program are conducted gradually using a hierarchy, in which the child is progressively exposed to anxiety-provoking situations (Kendall et al., 2005). The hierarchy is a collaborative effort between the CBT therapist and the child, and is constructed when the therapist has an apt knowledge regarding the child's fears and anxieties. In cases when the child is not able to describe his/her specific anxiety situations, the therapist can offer suggestions. Figure 1 provides an example of fear hierarchy to be used for exposure tasks with a child with social anxiety disorder. The therapist then asks the child to rate the extent of his/her anxiety for each situation using the Subjective Units of Distress/Discomfort Scale (SUDS; Wolpe, 1969), and uses this information with the child's guidance to place each situation in the hierarchy.

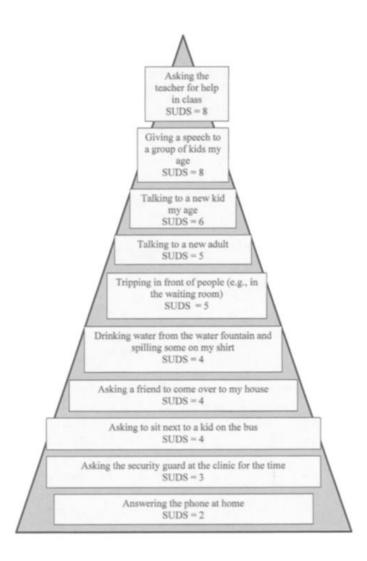


Figure 1. An example of fear hierarchy for a child diagnosed with social anxiety disorder (Kendall et al.,

2005)

2.4.2 Pharmacotherapy

The use of SSRIs is considered the first-line therapy for pharmacologic management of anxiety disorders in children (Kodish et al., 2011). Sertraline, fluvoxamine, and fluoxetine are among the SSRIs approved by the Food and Drug Administration (FDA) for treatment of GAD, SAD, and/or social anxiety disorder (Kodish et al., 2011).

The efficacy of sertraline treatment was examined in a 9-week, double-blind, placebocontrolled study of 22 children (aged 5-17) diagnosed with GAD (Rynn, Siqueland, & Rickels, 2001). In this trial, sertraline was initiated at 25 mg/day for the first week and increased to 50 mg/day for the following weeks. Clinical improvement was measured using Hamilton Anxiety Rating Scale (HAM-A) and Clinical Global Impression severity (CGI-S) and improvement (CGI-I) scores. The results suggest that sertraline was effective for the treatment of GAD. Additionally, there were no significant differences in side effects between sertraline- and placebo-treated patients.

The efficacy of sertraline was also examined in the Child-Adolescent Anxiety Multimodal Study (CAMS) involving 488 children and adolescents, aged 7-17 years, with GAD, social anxiety disorder, or SAD or a combination of these disorders, who received sertraline (n=133), cognitive behavioral therapy (CBT, n=139), a combination of the sertraline and CBT (n=140) or placebo (n=76) over the course of 12 weeks (Walkup et al., 2008). Clinical improvement was measured using PARS and CGI-I. The results suggest that sertraline + CBT (81%) was statistically superior to both sertraline monotherapy (55%) and CBT monotherapy (60%).

Fluvoxamine was examined in a study of 128 children and adolescents (aged 6-17 years) with GAD, SAD, and/or social anxiety disorder in an 8-week, double-blind, placebo-controlled study (Walkup et al., 2001). Anxious children receiving fluvoxamine showed a statistically significant improvement on the Pediatric Anxiety Rating Scale (PARS) score compared to those receiving a placebo. Although fluvoxamine was generally well-tolerated, adverse effects such as abdominal discomfort and increased motor activity were reported.

The efficacy of fluoxetine in reducing anxiety was examined in 74 children (aged 7-17 years) with GAD, SAD, and social anxiety disorder over the course of a 12 week treatment (Birmaher et al., 2003). In this trial, fluoxetine was initiated at 10 mg/day and, if tolerated, increased to a maximum fixed-dosage of 20 mg/day following the first week of treatment. Clinical outcome was measured using CGI-I and -S, PARS, SCARED-P and -C, and Children's Global Assessment Scale (CGAS). Although fluoxetine was effective in reducing anxiety symptoms and was generally well-tolerated, several adverse effects including nausea, abdominal pain, drowsiness and headaches were reported.

3.0 PRELIMINARY WORK: SMARTCAT 1.0

3.1 RATIONALE FOR ECOLOGICAL MOMENTARY INTERVENTION (EMI)

For decades, psychologists have assessed emotional behaviors in real life using Ecological Momentary Assessment (EMA), an approach that involves repeatedly sampling individuals in real time. Initially, EMA was performed using paper diaries but more recently has incorporated electronic devices such as palm pilots or smartphones. EMA includes the following key aspects (Shiffman, Stone, & Hufford, 2008):

- Momentary, real-time assessment. EMA was developed to address limitations of retrospective recall. Recollection are not just inaccurate but often systematically biased. For example, when people are in a negative mood, they are more likely to retrieved information associated with their negative emotion.
- Real-world data. EMA recognizes many behaviors and experiences can be affected by contexts. The assessed behavior or experience must be sampled in the contexts in which it naturally occurs to be representative.
- 3. Repeated assessment. EMA involves repeatedly assessing individuals, covering various extents of time (e.g., over a period of days) with varying intensity of assessment (e.g., as often as 30 minutes). Such dynamic measurements allow researchers to better

characterize an individual's average state across various situations as well as capture his/her experience or behavior dynamics over time and across contexts.

Although EMA has been most widely used for clinical assessment, it can be directly applied to clinical or psychological intervention by implementing real-time, in-the-moment intervention as individuals go about their daily lives. This mode of intervention is called Ecological Momentary Intervention (EMI) and can provide a supplemental component to an existing intervention or ongoing medical or psychological (e.g. cardiac rehabilitation or CBT) treatment respectively (Heron & Smyth, 2010).

Recent advances in m-Health technologies present opportunities to deliver EMIs to individuals during their everyday lives and in natural settings. Instead of offering intervention at only discrete, scheduled times, smartphone-based EMIs can provide clinical intervention to patients when it is most needed (Heron & Smyth, 2010). Moreover, smartphones are small and convenient to carry, have become widely available (Madden, Lenhart, Duggan, Cortesi, & Gasser, 2013), offer widespread network coverage, and have extensive computing abilities that allow them to run m-Health applications.

SmartCAT (Smartphone-enhanced Child Anxiety Treatment) 1.0 system (Pramana, Parmanto, Kendall, & Silk, 2014) marked an initial attempt to improve CBT efficacy using the EMI approach to engage anxious children in learning and practicing CBT skills in their everyday lives (*in vivo*). The system consists of a smartphone app, a therapist portal, and a two-way communication system that provides a direct connection between the two. The system was utilized to support clinician-directed CBT treatment by improving CBT skill acquisition and utilization, promoting *in vivo* skills coaching, and monitoring patients' skill utilization. As illustrated in Figure 2, the app works by cueing patients to use skills they may have learned in a

CBT session during their daily activities. Instead of an isolated local app, the app can receive treatment cues from a web-based portal and send monitoring data to the portal. Using the portal, therapists can monitor patients' adherence to treatment regimens and also view a graphical summary about patients' condition and app usage. The data are then available to be discussed in the weekly CBT session. Therapists can use the portal to manage reward points and/or to send audiovisual materials to patients.

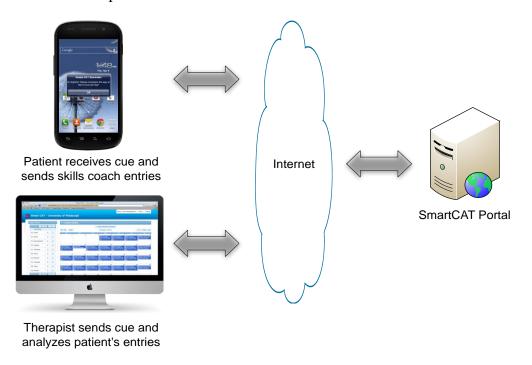


Figure 2. Functional Diagram of SmartCAT 1.0

3.2 SMARTCAT 1.0 APP

The smartphone app (Figure 3) was designed to ensure patients' sufficient CBT skills practice outside the clinic by reminding them to practice, providing motivation through rewards, enabling patients to receive personalized education materials from therapists, and to provide seamless

patient-therapist interaction. The app has four main components: a notification system, a skills coach, a reward bank, and a media library. These four components are described in detail below.



Figure 3. SmartCAT 1.0 App

- 1. **Notification:** Notification is the app's central component and offers two functions: to prompt patients when certain tasks need to be done (e.g., completing skills coach entries), and also to provide livability features (e.g., the ability to suspend prompting for a short time when responding would be inconvenient).
- 2. **Skills Coach (EMI):** The heart of the app is the "skills coach", which cues patients to complete a series of questions about recent emotional events and to use skills learned in therapy. The skills coach is scheduled by the therapist to launch automatically once per day (either at a fixed or random time) and can be completed more frequently if desired by the patient for "bonus points". Additionally, the skills coach can be activated when patients experience acute anxiety. Ultimately, the skills coach walks the patient through a series of steps (summarized in Table 1). Additionally, patients are asked whether or not a parent assisted in completing the entry and to describe their current social context (activity, companions, and location). To reduce patient burden, checklists are provided

that include common responses to items (i.e. typical activities, locations, negative scenarios, automatic thoughts, coping thoughts). Each skills coach entry ends with a customized motivational message from the therapist, entered weekly via the portal, that includes encouragement as well as a reminder to complete any assigned, home-based exposure or skills practice (i.e. "Great job, John! Remember to invite a friend to sleep over this week.").

Skill	Patient is asked to:
emotion identification	1. label and rate current emotions
	2. identify a recent scenario (since last entry) in which
	patient felt "scared, worried, nervous, or upset"
	3. identify somatic symptoms and emotions experienced
	during the scenario
automatic thoughts	4. identify negative automatic thoughts associated with
	the chosen scenario
coping thoughts	5. list coping thoughts used during the scenario
	6. list coping thoughts not used during the scenario that
	might be helpful in the future
problem-solving	7. list any problem-solving steps used during the scenario
overcoming avoidance	8. indicate whether or not a feared situation was avoided
self-assessment and reward	9. indicate any rewards earned
	10. rate self-efficacy at coping with the scenario

3. **Reward Bank:** Patients earn prizes for completing skills coach entries. They select from a collection of prizes of different values, such as small toys or games, accessories, or stickers, each of which can be earned with a specific number of points. Every time a patient completes an entry, the reward bank opens to show how many points they have earned and how many more are needed to obtain the selected reward. The reward bank is reset each time points are "cashed in" for a prize.

4. **Media Library:** The media library includes documents, photographs, and video/audio files provided by the therapist to help the patient remember and practice skills learned in treatment (i.e. "coping cards" completed during the session, video messages from the therapist, relaxation audio scripts).

3.3 SMARTCAT 1.0 PORTAL

The therapist portal (Figure 4) is a secure website that can be accessed from a computer, tablet, or smartphone. Therapists can use the portal for receiving or sending messages, documents, and audio/video files, to managing skills coach cues and rewards, and viewing data from skills coach entries. The therapist may view each entry in a table format or may view summary graphs that visualize information obtained from patients' entries. Graphs of summary information (average ratings for anxiety and self-efficacy, rates of use of specific coping thoughts, anxiety in different social contexts) are grouped by session. Graphs are also available that show session-by-session changes in these variables. The therapist selects graphs and/or entries to review with the patient at the beginning of each session.

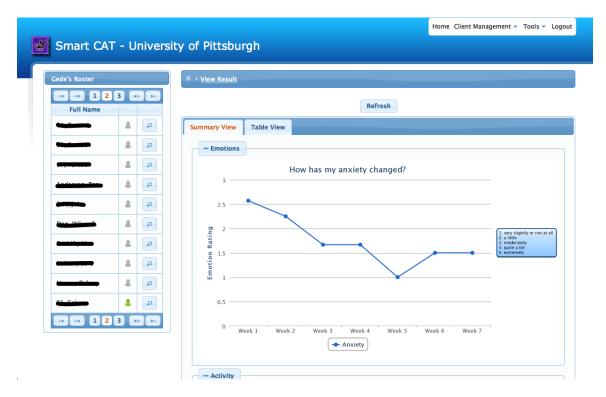


Figure 4. SmartCAT 1.0 Portal displaying patient's emotion

3.4 RESULTS FROM INITIAL FEASIBILITY STUDY

SmartCAT 1.0 was pilot tested with nine children (ages 9-14; M=11.33) with a Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994) diagnosis of GAD, social anxiety disorder (social phobia), specific phobia, ADHD, oppositional ODD, and/or SAD. Three patients were given a 16-session CBT, while the other six were given an 8-session BCBT. Patients were assessed by a trained independent evaluator using the Schedule for Affective Disorders and Schizophrenia for School-Aged Children-Present and Lifetime Version (KSADS-PL; Kaufman et al., 1997b) to establish diagnoses. A sixteen session treatment was delivered using the "Coping Cat" therapist manual and workbook (Kendall & Hedtke, 2006a, 2006b). An eight session BCBT was delivered using a new "Brief Coping Cat" manual and workbook (Kendall, Beidas, & Mauro, 2012; Kendall, Crawley, Benjamin, & Mauro, 2012). Therapists meet with parents for two 1-hour sessions in the 16-session treatment and two 30-minute sessions in the 8-session treatment. Treatment was delivered by Masters-level therapists trained in CBT for child anxiety.

The data from patient use revealed that the app was used frequently during treatment. As illustrated in Figure 5, the app was used more frequently during the first week and leveled off toward the end. The high usage frequency during the first week might reflect the fact that patients were becoming familiar with the app by self-initiating the skills coach entries several times.

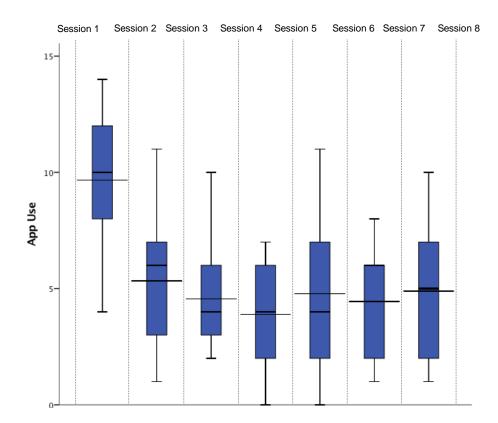


Figure 5. SmartCAT 1.0 App Use. Usage data was collected after Session 1 and calculated at the end of Session 8

The results from pilot testing indicated that patients were actively using the app, suggesting that the app was successfully integrated within treatment. On average, they completed 5.36 skills coach entries per session (SD=1.95) and took 3.44 minutes (SD=.98 minutes) to

complete the entries. Although the inclusion of rewards could increase patients' participation in treatment, patients and therapists noted several potential improvements including the potential for more interactive and entertaining ways for the children to learn and practice CBT skills in daily life, and the need for a more improved reward system to increase the rates of CBT skills practice.

4.0 M-HEALTH GAMIFICATION

4.1 INTRODUCTION

Gamification refers to the use of game design elements to engage people in non-game contexts (Deterding, Sicart, et al., 2011). In general, gamification aims to leverage the inherently engaging aspects of games towards encouraging specific human behaviors and ultimately increasing user motivation, engagement, productivity, and performance (Rojas, Kapralos, & Dubrowski, 2013). Gamification is slightly different from playing a game, mostly because games are aimed primarily at entertainment, can be addictive, and typically have rules or specific objectives. Moreover, when playing games, a player faces the possibility of losing. Gamification, however, tries to isolate the active ingredients that make games addictive (i.e., points, challenges, or rewards) and use them to make activities happening in real life contexts more engaging (Cugelman, 2013). These active ingredients (motivational affordances) should be the same as the ones used in games (Deterding, Dixon, Khaled, & Nacke, 2011) so that they can invoke the same psychological experiences as games do (Huotari & Hamari, 2012). Points, leaderboards, achievements/badges, levels, story/theme, clear goals, feedback, rewards, progress, and challenges are motivational affordances that have been used in gamification studies reviewed by Hamari et al. (2014). Among these motivational affordances, points, leaderboards, and badges were used the most often (Hamari et al., 2014).

Although the term "gamification" is relatively new, the concept has been around for a while and can be found in the form of loyalty/reward programs that offer frequent-flyer or fuel discounts. To some extent, the concept is already being used in manual-based CBT treatments such as the Coping Cat program. During weekly sessions, for example, Coping Cat therapists acknowledge or praise anxious children's efforts to engage in exposures challenges (i.e., talking with 5 people) by rewarding them with collectible cards (i.e., baseball card), stickers, or small toys.

Recent advances in interactive m-Health technologies now allow gamification concepts to be layered on top of activities provided by mobile applications. Swarm app (previously known as Foursquare app), for example, rewards its users for checking into a new place by giving points, badges, and mayor status. Its game mechanics serve two purposes: to help the users learn how to use the app, and to make a real-world experience more fun. Specifically, digital coins and badges give the users a sense of accomplishment and mayorships allow the users to compete with their friends.

Although gamification has gained popularity and is currently being used in a variety of contexts (Hamari et al., 2014), recommendations for implementing gamification are widely varying. Hamari et al. (2014) indicates that motivational affordances such as points, leaderboards, and badges are among commonly adopted methods for implementing gamification. In mobile psychological treatment specifically, other forms of motivational affordances such as goals, feedback, progress, and rewards have been used exclusively to help patients overcoming SAD by completing increasingly challenging interactions in real life (Miloff, Marklund, & Carlbring, 2015). These varying ways of implementing gamification indicate the need to

understand aspects of human cognition and behavior that can be changed using different kinds of motivational affordances.

4.2 THEORETICAL REVIEW

To build such understanding, a literature review of motivational theories in psychology was conducted. Three major motivational theories related to gamification (i.e., self-determination theory, expectancy theory, and goal-setting theory) are identified and described below.

4.2.1 Self-Determination Theory

Self-determination theory (SDT) has been extremely useful in understanding the motivation behind one's behavior in correlation with its conceptualization of intrinsic and extrinsic motivators. Intrinsic motivation is defined as a person being driven to engage in an activity for its inherent satisfactions. Intrinsic motivation moves a person to act for the fun or challenge entailed rather than because of external stimuli or rewards. For example, students join their school's sports team because they enjoy playing sports, they think sports are fun, or they love the challenge they get form participating in sports. Ryan and Deci (2000) further explained that intrinsic motivation can be maintained by satisfying three psychological needs. These are defined as follows:

- 1. Competence: gaining mastery of tasks and learning different skills; people will often perceive this drive as a need.
- 2. Autonomy: the perceived need to feel in control when performing activities or tasks,

3. Relatedness: the perceived need to feel connected to others.

Students experiencing intrinsic motivators will often aim at improving their skills, taking initiative, and interacting with others.

In contrast with intrinsic motivation, extrinsic motivation is defined as doing something for its outcome, or because of external stimuli or rewards. Extrinsic motivation is as important as intrinsic motivation because most activities that people do are not inherently satisfying. Educational activities, social demands, and roles, for example, require individuals to assume responsibility. For this reason, extrinsic motivation should not be viewed as subordinate to intrinsic motivation. Referring again to students who are motivated to join one of their school's athletic teams, sports might allow these students a realization of extrinsic motivators like receiving publicity, awards, and scholarships.

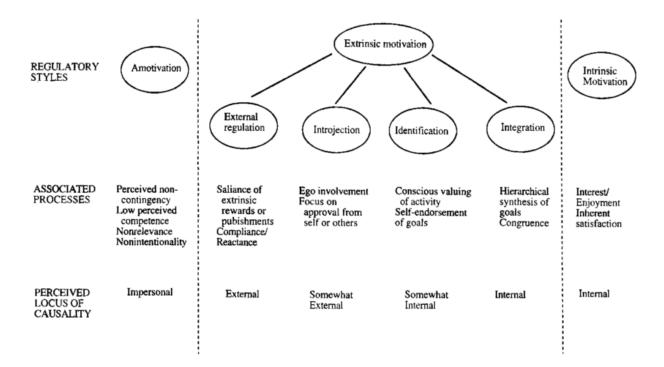


Figure 6. A taxonomy of human motivation.

As shown in Figure 6, SDT acknowledges that different types of motivation exist on a varying degree from left to right -extrinsic to intrinsic (Ryan & Deci, 2000). At the far left is *amotivation*, or a lack of motivation, which is characterized by a lack of intention to act. On the other end lies intrinsic motivation. In between these extremes lie different kinds of extrinsic motivation (i.e., external regulation, introjection, identification, and integration). These extrinsic motivations are varying from an entirely external locus of causality (less autonomous) to an internal locus of causality (more autonomous). Amotivation is characterized by an impersonal locus of causality or a lack of autonomy. In this state, a student would be completely unmotivated to join his/her school's sport team, perhaps due to feelings of incompetence or a belief that his or her effort will not result in a desired outcome. The first category of extrinsic motivation is external regulation, which represents the least autonomous form of extrinsic motivation. External regulation is characterized by performing behaviors to satisfy external demand or obtain an external reward. In this state, a student would be motivated to join his/her sports team to obtain scholarships or awards. The second category of extrinsic motivation is introjected regulation (introjection). Introjection is characterized by performing behaviors to avoid guilt or anxiety, or to attain pride or contingent self-esteem. In this state, a student would be motivated to join his/her sport team to avoid guilty feelings for not having participated with his/her friends. The third category of extrinsic motivation is identification, which is more autonomous than introjection. Identification occurs when the personal importance of a behavior is identified and accepted. In this state, a student may want to stay active physically or to maintain his/her weight by joining his/her sport team. The final category of extrinsic motivation is integration, which is the most autonomous form of extrinsic motivation. Integration and intrinsic motivation have similar internal locus of causality. Integration forms of motivation however are still considered external because the behavior is done for its presumed instrumental value with respect to some outcome. In this state, a student would be motivated to engage in sports to stay healthy.

Relationship between Self-Determination Theory and Gamification: Intrinsic and extrinsic motivation have been used in gamification framework as the drivers for behavior in game-like systems and the focus point for determining appropriate game design elements in the process of gamification. In one study, Kappen & Nacke (2013) developed a model that utilize both intrinsic and extrinsic motivations to drive behaviors in game-like systems. As illustrated in Figure 7, the model consists of several layers. These include:

- 1. The effective gamification core: the core objectives of gamified design;
- 2. The motivated behavior layer: the identification of user need based on intrinsic and extrinsic motivation;
- 3. The game experience layer: the integration of actions, challenges, and achievements using intrinsic and extrinsic motivation as a focus;
- 4. The game design process layer: the integration of game design principles, mechanics, model, patterns and interface design elements to create a fun experience;
- 5. The perceived layer of fun: the identification of excitable attributes or elements that would influence and motivate user behavior.

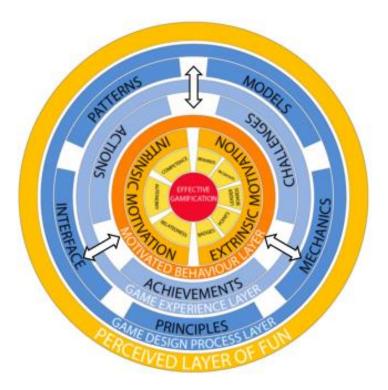


Figure 7. Kaleidoscope of effective gamification

In another study, Aparicio et al. (2012) defines a framework that determines the type of game mechanics that meet the needs of intrinsic motivation (autonomy, competence, and relatedness). For example, using profiles, avatars, macros, configurable, alternative activities, privacy control, and notification control can fulfill autonomy. To achieve competence, positive feedback, optimal challenge, progressive information, intuitive controls, points, levels, and leaderboards can be utilized while groups, messages, blogs, connection to social networks, and chat, can be used to fulfill the need for relatedness.

4.2.2 Expectancy Theory

Expectancy theory is one of many process theories of motivation that focus on cognitive processes that motivate individuals. It is based on the idea that there are relationships among the efforts people put forth, the performance achieved from that effort, and the rewards received

from the effort and the performance. Vroom's (1964) expectancy theory was the first expectancy theory with direct application to work settings. The theory was later expanded and refined by Porter and Lawler (1968).

Vroom's (1964) expectancy theory (Figure 8) has three key elements: expectancy (E), instrumentality (I), and valence (V). Expectancy is a person's belief that his action (i.e. effort) will lead to an outcome (i.e. performance) and is referred to as the relationship between effort and performance (Pinder, 2014). Expectancy is based on probabilities, and ranges from 0, no chance that action will lead to the desired outcome, to +1, certainty that action will lead to the desired outcome.

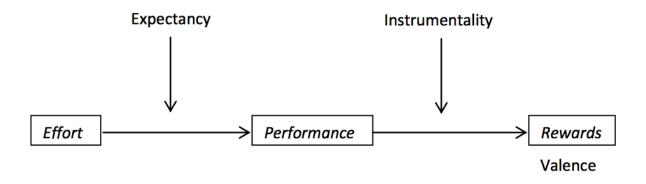


Figure 8. Basic expectancy model

Instrumentality is a person's belief that a given level of performance will lead to various rewards, and is referred to as the performance-reward relationship. Like expectancy, instrumentality ranges from 0 (no perceived relationship between performance and reward) to +1 (performance will lead to reward).

Valence is the strength of a person's preference for a particular reward. Valence ranges from -1, where the person prefers not to obtain a reward, to +1, where the person prefers to obtain a reward. A valence value of 0 indicates that the person is indifferent to a reward.

Vroom asserts that an individual's motivation to perform an act is a function of the three components. For him, motivation can be modeled as the products of expectancy, instrumentality, and valence:

Motivation = Expectancy x Instrumentality x Valence

The multiplier effect means that the highest level of motivation will be achieved when expectancy, instrumentality, and valence are all high. It also implies that if any of the three components are rated as zero, then the level of motivation will be zero.

Relationship between Expectancy Theory and Gamification: There are two ostensible links between expectancy theory and gamification. First, expectancy theory can be used to understand why the use of certain game design elements like points or badges leads to motivation because these elements can be considered to have valence. If an individual prefers to obtain points or badges and sees a clear way that his/her effort will lead to the desired performance and the performance will lead to the reward, then the individual is motivated to perform the action. Second, expectancy theory can be used to understand the relationship between actions and rewards. According to Hsu et al. (2013), clear relationships between the actions and rewards make the game-like system more attractive. In expectancy theory, this is consistent with instrumentality.

4.2.3 Goal-Setting Theory

Like expectancy theory, goal-setting theory is also one of the process theories of motivation. The theory was developed and researched by Edwin Locke in the 1960s based on the early work on levels of aspiration developed by Kurt Lewin. The research revealed that there is a relationship

between one's conscious goal and performance (Locke, 1968). Goal setting is the conscious process of establishing levels of performance to accomplish desirable outcomes.

Goal-setting theory acknowledges four mechanisms that can make goals effective in increasing motivation to act:

- 1. Goals serve as a directive function that direct attention and effort toward goal-relevant activities and away from goal-irrelevant activities.
- 2. Goals have energizing functions (high goals lead to greater efforts than low goals).
- 3. Goals affect persistence (hard goals prolong efforts).
- 4. Goals indirectly affect action through the use of task-relevant knowledge and strategies (Locke & Latham, 2002).

These mechanism however, remain inaccessible by the goal setter unless another set of five necessary criteria are met (Locke & Latham, 2002). These criteria are:

- Goal commitment/goal acceptance: before a goal can lead to performance, one must accept/be committed to the goal. Goal commitment is the degree of determination one uses to achieve an accepted goal and is the first step in creating motivation (Locke & Latham, 2002). Commitment is most relevant and most important when goals are difficult (Klein, Wesson, Hollenbeck, & Alge, 1999).
- 2. **Goal importance:** One of the factors that facilitates goal commitment. One who views a goal as important is likely more committed to the goal (Locke & Latham, 2002).
- 3. **Self-efficacy**: Another factor that facilitates goal commitment. One who is confident in the ability to attain a goal is likely more committed to the goal (Locke & Latham, 2002).
- 4. **Feedback:** Reveals one's progress toward goal completion. Combined with goals, feedback positively impacts performance (Becker, 1978; Kluger & DeNisi, 1996; Latham, Mitchell, &

Dossett, 1978) and has been shown to be an important determinant of performance (Kluger & DeNisi, 1996). Research also suggests that there is a relationship between feedback and goal revision (Donovan & Williams, 2003; Ilies & Judge, 2005). Individuals receiving negative feedback tend to revise their goals downward (make the goals easier), whereas individuals receiving positive feedback tend to revise their goals upward (make the goals more challenging).

5. Task complexity: Influences the effect of goal setting. As the complexity of the task increases, the effect depends on individuals' ability to develop appropriate task strategies (Locke & Latham, 2002). The strongest effect of goal setting is achieved when tasks are easy and the weakest effect is when the tasks are complex (Wood, Mento, & Locke, 1987).

Relationship between Goal-Setting Theory and Gamification: From a goal-setting perspective, a goal can be represented as trophies or badges, whereas feedback can be represented as progress bars. Progress bars can be used to track the likelihood of successful performance — that is, badge or trophy attainment. Consistent with goal-setting theory, studies in gamification implementation suggest that the combination of goals and feedback were found to be motivating to users (Hamari, 2013; Singer & Schneider, 2012). Having a variety of goals could also enhance motivation. Hsu et al. (2013) found that having diverse and unique badge types made gamified environments more attractive.

Several studies on goal-setting theory suggests that setting smaller, proximal goals can help individuals reach larger, distal goals (Donovan & Williams, 2003; Latham & Brown, 2006; Latham & Seijts, 1999). The studies found that participants who were assigned proximal and distal goals had increased self-efficacy compared to those who were assigned only distal goals or "do your best". In gamified system, this is similar to "levels" or "levelling up", which can be viewed as setting small, easier sub-goals within the framework of a larger, more challenging goal. Achieving these goals set at easier levels may increase one's perception of self-efficacy, a critical condition that must be met when using goals to increase motivation.

5.0 DESIGN AND DEVELOPMENT OF GAMIFIED M-HEALTH SYSTEM

The objective was to redesign the previous m-Health system (SmartCAT 1.0) to achieve the following goals:

- 1. Support clinician-directed CBT treatment by providing interactive home-based CBT skills practice, promoting in vivo skills coaching, and monitoring patient adherence;
- 2. Maintain patient motivation and engagement during the treatment;
- 3. Capture usage patterns or behaviors of anxious children when using the system;
- 4. Determine therapists' technology-related efforts by capturing therapists' activities when using the system.

Like SmartCAT 1.0, the redesigned system consists of a smartphone app and a web-based clinician portal connected by a two-way communication channel. This phase was focused on designing, developing, evaluating, and refining the system via the user-centered design (UCD) process, leveraging the previously pilot-tested SmartCAT 1.0 system (Figure 9).

UCD is an approach that put the perspectives of user and context of use at the center of the technological design process (Sotamaa, 2005). This method is appropriate for achieving a balance between fun and function (in more formal terms, between the internal goal of the system and the treatment goal of improving skills understanding; Barendregt, Bekker, Bouwhuis, & Baauw, 2006). To achieve this goal, the UCD process was conducted in three steps. The initial step of the UCD process was the development of design principles based on user information captured and interpreted by therapists that deliver CBT to anxious children. The therapists serve as the interface between the users (i.e. anxious children) and the designer/software developer. A literature review was used to collect information regarding strategies for improving user experience through user interface (UI) designs and game-based learning. The results from the design principles development step provided general guidelines for implementation by software developers in the iterative system development step. The therapists provided continuous input/feedback during the system development process. A formative usability study involving the children involved in the study was conducted following the system development process to collect feedback and usability data.

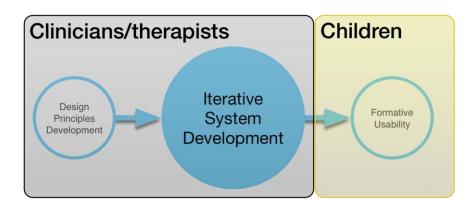


Figure 9. User-centered design (UCD) approach

5.1 METHODS

5.1.1 Design Ingredients Formulation

The process of developing a smartphone app can be complicated and challenging, especially when the app is targeting a specific population (i.e. children). Smartphone apps are arguably an important part of users' lives and thus the potential impact factor of apps is huge since they can provide both entertainment and education to children. To make the SmartCAT app appropriate for this population, the requirements and tastes of children need to be better understood.

Design ingredients providing guidelines for the system development process were developed to achieve this goal in this phase, meetings with CBT therapists were conducted to brainstorm and identify design ideas and criteria, including interactive features, treatment engagement/adherence, and educational content. The design ideas and criteria were translated into design principles, which then can be used to evaluate the system.

The initial UCD process revealed a conceptual model for the SmartCAT 2.0 system that included the ten design principles for improving EMI in childhood anxiety treatment (Figure 10). By implementing the principles on an m-Health system, it was expected that CBT treatment outcomes could be improved because this system provides reminders for anxious children to complete homework, reinforcement to increase motivation, and more interactive ways to learn CBT skills.

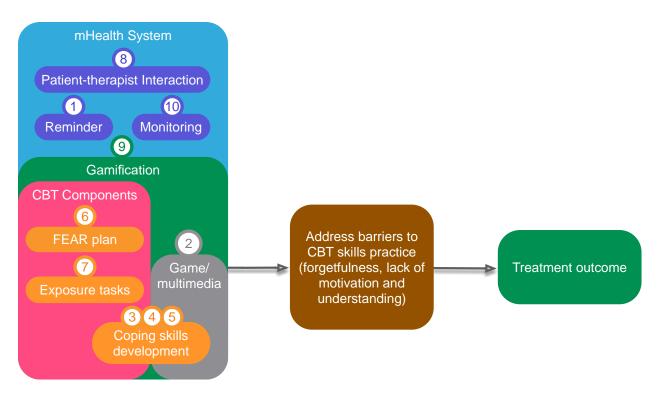


Figure 10. Conceptual model of SmartCAT 2.0 system

Customizable and location-aware reminders

One of the barriers to home-based skills practice is that children forget to practice CBT skills beyond the clinic. According to behavioral learning theory, behavior depends on internal (thoughts) or external (environmental) stimuli or cues (Leventhal & Cameron, 1987). This means that non-adherence behavior such as not remembering to practice CBT skills can be modified by introducing repetition of external stimuli or cues such as reminders. Although reminders can provide an effective way to modify non-adherence behavior, the timing of the reminders needs to be carefully tailored as several EMI studies have reported that poorly timed or fixed reminders can deter people from adhering to the treatment (Franklin, Waller, Pagliari, & Greene, 2006; Newman, Consoli, & Taylor, 1999; Weitzel, Bernhardt, Usdan, Mays, & Glanz, 2007). Children ages 9-14 usually have busy schedules comprising both school and extracurricular activities. This means that providing an opportunity for the children to set their own pre-programmed

reminders could potentially increase the efficacy of those reminders. Therefore, in this study, while the therapist initially programmed the reminder to alert at a random time in a two-hour window (i.e. 4-6pm, 5-7pm, 6-8pm, 7-9pm), if this time was inappropriate for the child, he/she could choose to reschedule it later (i.e. 30 minutes, 1 hour, 2 hour up to three times).

Another issue that children who suffer from an anxiety disorder face is that they experience fear, nervousness, and shyness, and so may start to avoid specific locations (e.g. school, doctor's offices, and dogs in the neighbors' house). Therefore, to complement time-based reminders, we also provided location-aware reminders. These would alert the children as they enter locations that would cause them anxiety to deal with the situation by developing their coping mechanism. *Principle 1: Reminders should be adapted to fit children's daily schedule and to be aware of specific locations*.

Game-/multimedia-based learning

The goal of CBT for anxious children is to help them reduce their anxiety and to prevent relapse. Being a skills-based treatment, much of the work in CBT involves teaching the children new behaviors, concrete problem-solving skills, and strategies for challenging anxious thoughts and beliefs. As an integrative approach, CBT commonly includes a number of components such as: psychoeducation, affect recognition, cognitive restructuring, relaxation, and gradual exposure (Kendall & Hedtke, 2006b; March & Mulle, 1998; Rapee et al., 2006). A CBT therapist guides the learning process by using techniques such as verbal instruction, activities, role-playing, and modeling. Here, game-based learning can be used to augment the learning process, providing an interactive yet fun learning environment beyond the weekly sessions. Furthermore, game-based learning provides a type of game play that has well-defined learning outcomes. Research also suggests that games can effectively model the learning process in so far as games require players to be active and to provide immediate feedback as a result of players' decisions during game play (Rankin, McNeal, Shute, & Gooch, 2008).

Modeling, as one of the techniques for teaching children relevant CBT skills can be translated into games using simulations. A simulation attempts to copy various activities from real-life in the context of the game, where the players are in complete control. In the context of CBT, game-based learning offers a number of advantages, which include the following: first, promoting home-based skills rehearsal beyond the clinic; second, providing increased opportunities for identifying triggers, sources of anxiety, and/or facial expressions and somatic reactions without actually experiencing anxiety-provoking situations; third, providing opportunities for conducting experiments when challenging anxious thoughts using coping thoughts or solving hypothetical problems by brainstorming and evaluating solutions and finally, providing embedded instructional features that enhance the instructional experience.

In addition to games, audio/video recordings can be useful in helping the children rehearse those deep breathing or relaxation skills that are taught in the face-to-face sessions. *Principle 2: Beyond-clinic learning activities should be interactive and fun with embedded instructional features.*

Emotion and somatic symptoms identification

Some anxious children are insufficiently skilled in recognizing different feelings (e.g. anxiety, anger, boredom, sadness; Gosch, Flannery-Schroeder, Mauro, & Compton, 2006). The first thing that an anxious child learns in a therapy session is how to identify his or her physiological/bodily reactions to anxiety, more specifically, his or her own physiological reactions to anxiety-provoking situations. During the session, the child is shown how physical reactions provide cues associated with anxiety and how to help the body relax. The child also learns how to identify and

classify what emotions a person is most likely experiencing based on contextual information (e.g. scenarios). To enable children to recognize somatic symptoms resulting from anxiety in contrast with other emotions or sensations, the presented scenarios include several themes such as anxiety, hunger, or physical pain. *Principle 3: Children should be able to recognize anxiety vs. other emotions from different scenarios and somatic symptoms.*

Cognitive-restructuring

Anxiety comes from irrational or maladaptive thoughts, beliefs, or self-talk. Although most children may have gained the ability to counter their own self-talk by around age 7 or 8, anxious children demonstrate distortions in information processing, memory biases for distressing events, hypersensitivity to threat cues, and a bias toward interpreting ambiguous situations as threatening (Vasey & MacLeod, 2001) that prevent them from paying attention to their own self-talk. In therapy sessions, a CBT therapist teaches an anxious child cognitive reframing techniques to modify the maladaptive nature of their self-talk. This requires the child to first recognize the existence of their self-talk. The next step is to learn to modify or reframe anxious self-talk by generating coping thoughts to counter the initial anxious thoughts. *Principle 4: Children should be able to identify their self-talk and choose coping thoughts that work best in a given situation.*

Problem-solving

Anxious children often present with limited skills for coming up with effective solutions to the problems they experience in their daily life. Often, they choose to avoid anxiety-provoking situations rather than to implement effective solutions. For example, they might refuse to go to school rather than facing social fears or anxiety about an upcoming test. While avoidance might be effective in reducing anxious distress in the short-term, it is an ineffective strategy in the long-term. For this reason, a CBT therapist leads the anxious child through the steps in the problem-

solving process during a therapy session. The problem-solving model proposed by Bedell and Lennox (1997) delineates seven steps in reducing anxiety. They are:

- 1. Recognize the problem
- 2. Define the problem
- 3. Brainstorm problem solutions
- 4. Evaluate the potential effectiveness of the alternatives generated
- 5. Select the best alternative or combination of alternatives
- 6. Implement the chosen solution
- 7. Verify the solution's effectiveness.

This model was translated into a dialog-based interaction involving the child and a virtual friend. The child was asked to help solve his/her virtual friend's problem by completing the dialog following the problem-solving steps. To reduce the child's burden when composing a response, a set of buttons with pre-defined responses was used. The number of steps was also adjusted to include defining the problem, coming up with as many solutions as can be thought of, evaluating all of the options, and picking one or two best solutions. *Principle 5: A dialog-based interaction with pre-defined responses should be used to guide anxious children through problem-solving steps.*

<u>Step-based plan for dealing with anxiety</u>

In this study, anxious children were treated using the "Brief Coping Cat Program" (Kendall, Beidas, et al., 2012; Kendall, Crawley, et al., 2012). One of the two key components of the program is CBT skills training, in which the child learns several basic skills that are integrated into a plan for dealing with anxiety. The plan, abbreviated as FEAR, is comprised of four concepts: (1) <u>F</u>eeling frightened? – awareness of physical symptoms of anxiety, (2) <u>E</u>xpecting

bad things to happen? – recognition of anxious self-talk, (3) <u>A</u>ttitudes and actions that will help – behavior and coping talk to use when anxious, and (4) <u>R</u>esults and rewards – self-evaluation and administration of reward for effort. A series of questions were developed to guide the child in developing a FEAR plan for a current or recent *in vivo* anxious experiences. For a current anxiety situation, the skills coach guided the child through the process of developing a FEAR plan. For a recent anxiety situation, the child was also guided through the same FEAR plan, but this time the child was instructed to report skills he/she had used during the experience. To reduce the child's burden, checklists were provided, which include common responses to items (i.e. typical negative scenarios, automatic thoughts, coping thoughts) that were generated from therapists' input. The child would select a pre-populated response from the checklist or type in a text response. As the session advances, the pre-populated responses from the checklist were replaced by text responses to encourage the child to generate his/her own response. *Principle 6: To help anxious children in developing a FEAR plan for recent or current anxiety situation, a series of questions with a checklist and/or text response should be used.*

Exposure tasks

Another important component of CBT is skills practice, which involves having the child experience anxious distress in real anxiety-provoking situations. Exposure tasks tailored to the child's fears are conducted once the child demonstrates an understanding of the concept within the FEAR plan (based on the therapist's clinical judgment). There are two types of exposure tasks imaginal and *in vivo*. Imaginal exposure tasks are often used when the child starts an exposure task for the first time or has more abstract worries (i.e. death or illness of family member, local violence, or family financial problems) that commonly occur in children with GAD. Imaginal exposure tasks are usually conducted during the therapy session, in which the

therapist asks the child to describe and role-play an anxiety situation in detail. *In vivo* exposure tasks, on the other hand, involve the child facing the feared situation in the real world. *In vivo* exposures are completed in session starting with session four. The child is encouraged to get additional practice with *in vivo* exposure at home. To facilitate the practice, a list of *in vivo* tasks that the child needs to conduct is provided in the app. The therapist collaborates with the child to prepare the list. He/she is asked to describe how each task is conducted in the real-world situation and/or provide a photograph showing that he/she completed the task for the therapist to see. *Principle 7: Anxious children should complete a list of in vivo tasks at home. For each task, the children should provide a short description of the way the task was conducted and/or provide a photograph showing the completed tasks.*

Therapist-patient interaction

Interactions between therapists and patients via electronic methods such as text messaging are becoming increasingly common (Padman, Shevchik, Paone, Dolezal, & Cervenak, 2010). As part of this m-Health system, a HIPAA-compliant messaging system was developed to support therapist-patient interaction beyond office visits Using this feature, the child can compose a message on his or her phone, and the message will be sent to a web-based portal rather than the therapist's private phone. This protects the private space of the clinician and allows the communication to be part of the record. The therapist may view these messages and/or send the patient a message at any time using the portal. *Principle 8: A secure messaging system should be used to facilitate therapist-patient interaction.*

Reinforcement through gamification

The application of therapeutic homework between sessions has long been recognized as standard practice in psychotherapy (Neimeyer, Kazantzis, Kassler, Baker, & Fletcher, 2008). It has been

incorporated into manual-based treatments for a diverse range of clinical conditions, including childhood anxiety disorders (Kazantzis, Deane, & Ronan, 2006). Homework assignments provide opportunities for patients to practice and generalize CBT skills learned during therapy sessions to everyday situations in which their problems occur (Kendall et al., 2005) and potentially increase patients' self-efficacy in real-life situations (Detweiler & Whisman, 2006). Despite the importance of homework compliance in increasing the effectiveness of CBT (Lebeau, Davies, Culver, & Craske, 2013; Neimeyer et al., 2008), therapists have noted that anxious children are likely to struggle with homework completion (Hudson & Kendall, 2002) primarily due to lack of therapeutic commitment or motivation (Houlding, Schmidt, & Walker, 2010). Unlike adults, who are often self-referred, children are usually brought to therapy by their parents or caregivers. As a result, children are often not voluntary participants in therapy and may view homework as unfavorable (Cummings, Kazantzis, & Kendall, 2014). One way to improve homework compliance is by providing positive reinforcement in the form of rewards (i.e., small toys, accessories or makeup, gift cards) for completing homework (Cummings et al., 2014; Kendall & Barmish, 2007). A similar approach can be applied to the system using gamification techniques. Gamification techniques, when appropriately implemented on an m-Health system, can potentially motivate and increase user activity and retention by improving the experience of doing routine tasks. Unlike games, which transform the tasks into powerful experiences, gamification techniques enhance the experience of performing the tasks by adding a gameful (rule-based and goal-oriented) experience. Principle 9: Gamification techniques (i.e. rewards, challenges, and recognition) should be used to provide reinforcement to anxious children in completing therapeutic homework delivered to the smartphone app.

Usage monitoring

As part of clinician-directed CBT treatment, the therapists are required to monitor youth adherence to treatment regimens and activities. The therapists utilize monitoring data to determine the treatment regimen for the following week. In addition, auxiliary data regarding usage patterns or behaviors of children when using the app, such as engagement (time spent on app, app utilization), app retention (app utilization per session), reminder adherence, and proximity was collected. The proximity was estimated by polling the smartphone's movement data (0=stationary and 1=shifting) and screen status (0=off and 1=on) every five minutes between 8AM and 11PM. *Principle 10: Usage monitoring feature is required to allow the therapist to determine anxious child's grasp of CBT skills and adherence to treatment regimens.*

In addition to the design ingredients, a graphical representation of the app's user using avatars was provided to allow customization. Several avatars were created and integrated into the app. The children would then be able to choose their own avatar from the app.

5.1.2 Iterative System Development

As illustrated in Figure 11, the iterative system development consists of four stages: (1) planning and analysis, (2) design, (3) implementation and testing, and (4) evaluation. In the planning and analysis stage, we defined functional requirements and the core components of the system using the design principles as our reference and developed methods for the implementation of gamification. In the design stage, the interconnection of the components was defined and translated into system architecture. During the implementation and testing stage, the core components and contents of the system were codified into operational source code implementation and then validated through unit testing. The evaluation stage involved assessing the appropriateness of the system's user interface (UI) and verifying the system's consistency with the design principles and completeness.

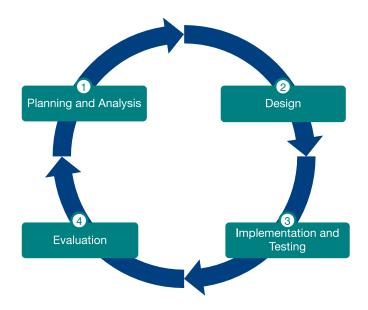


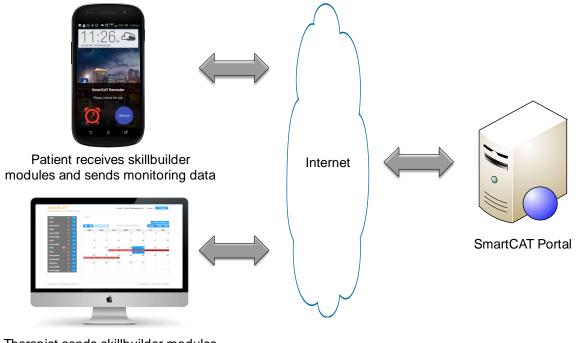
Figure 11. Iterative system development

5.1.2.1 Planning and Analysis

Functional requirements and system components

The design principles were implemented in the SmartCAT 2.0 system. Like the SmartCAT 1.0 system, the SmartCAT 2.0 system consists of a smartphone app, a therapist portal, and a form of two-way communication connecting them. As illustrated in Figure 12, the smartphone app cues the anxious child to initiate skill-building activities on the app (Table 2) during his/her daily activities. Unlike isolated local apps, this app can receive a treatment regimen as prepared by a therapist from a web-based portal and send monitoring data to the portal. Using the portal, the therapist can then monitor the child's compliance with the treatment regimen and also view summaries of the child's app usage. The data are then available to be discussed in the weekly CBT session. Therapists can use the portal to manage and track their patients' reward points. The system also allows patients and therapists to exchange messages securely without using text

messaging (virtually eliminating any potential threats to the security and confidentiality of the sensitive health data being exchanged).



Therapist sends skillbuilder modules and analyzes patient's data

Figure 12. Functional diagram of SmartCAT 2.0 system

The CBT components of the model were translated into several skillbuilder modules including an *in vivo* skills coach, a series of interactive games and activities to reinforce skill understanding, and a home challenge module to encourage home-based exposure (Table 2). Other skillbuilding activities such as viewing/practicing with a deep breathing techniques video, listening/practicing with a muscle relaxation audio file, or practicing a weekly task adapted from the Coping Cat workbook were provided. The number and types of skillbuilder modules can be adjusted in accordance with the children's progress during CBT treatment.

Module	Session	Description
Skills Coach	1, 2, 3, 4, 5, 6, 7	Guide the participant through developing a FEAR plan for a current or recent <i>in vivo</i> anxious experience.
What's the feeling? (game)	1, 2, 3, 4*, 5*, 6*, 7*	Ask the participant to identify emotional and somatic symptoms from various scenarios including anxiety, physical pain, hunger.
Chillax	1, 2*, 3*, 4*, 5*, 6*, 7*	View/practice with a video demonstrating deep breathing techniques. Listen/practice with an mp3 audio file for progressive muscle relaxation.
Thought-buster (game)	2, 3*, 4, 5, 6, 7	Ask the participant to identify anxious vs. non- anxious self-talk or coping vs. non-coping self-talk.
Thought-swapper (game)	3, 4, 5, 6, 7	Ask the participant to identify coping self-talk that work best in a given situation.
Problem-solver (game)	3, 4, 5, 6, 7	Generate and evaluate potential solutions to hypothetical problems.
Challenger	4, 5, 6, 7	Therapist selects personally relevant home challenges from a menu on the portal; patient is prompted to develop a FEAR plan and complete these challenges via the app.
STIC	1, 2, 3, 4, 5, 6, 7	Therapist selects weekly task (adapted from the Coping Cat workbook) from a menu on the portal; patient is prompted to complete the task via app.

Table 2. Skillbuilder modules

*=Optional

As part of the clinician-directed CBT treatment, the therapist was required to do several tasks on the clinician portal, which was accessible from a computer or a tablet (see Table 3). At the beginning of each session, the therapist would use the portal to review the data for the skills coach and other modules from the past week with the patient. Based on the subsequent discussion and app use, the therapist would select relevant modules and range of time that the reminders should go off for the upcoming week. This information would then be pushed to the app. If required, the therapist could also activate the location-aware feature of the app by entering the address of the anxiety-provoking location after discussing it with the patient. The

address would be geocoded into a latitude/longitude format by the portal and then sent to the app. To provide motivation and encouragement to the young patient, the therapist would integrate immediate rewards (i.e. points) into the treatment by managing the rewards directly from the portal. To support clinician-patient interaction, the therapist would use the portal to send/reply to messages to/from patients between sessions.

Tasks	Corresponding Portal Module	Start of Session	End of Session	Between Sessions
Enter custom locations	Geofence		*	
Select modules for upcoming week and times when app reminder should go off	Reminder/module		*	
Review skills coach or other module data from the week with child	Review	*		
Set target points for the following weeks	Reward	*		
Send/receive messages	Messaging			*

Table 3. Portal tasks and modules required by therapist

Method for implementation of gamification

In this study, the concept of gamification was integrated into the smartphone app to drive child engagement towards completing their skill building activities for the week. Although gamification can increase user motivation and engagement, it can also be ineffective when improperly designed (Mollick & Rothbard, 2013). For this reason, an iterative process of designing gamification, consisting of four steps, was conducted (see Figure 13).

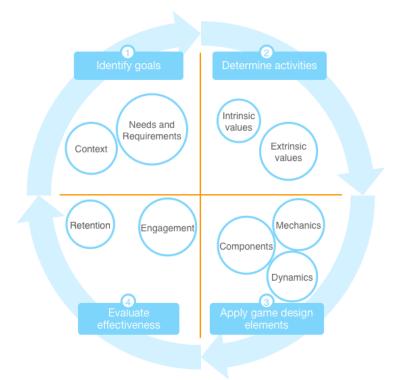


Figure 13. Iterative process of gamification on the m-Health system

- 1. Identify the end goals. Identify the desired goals (i.e., desired human behaviors). When defining the goals, the contexts of implementation (i.e., education, health) and the needs or requirements imposed by stakeholders (i.e., a policy of screen time reduction for children, smartphone use in class) need to be considered (Richards, Thompson, & Graham, 2014). Ideally, the goals should be specific —clear and well-defined—measurable, attainable, and intended to support and enhance the existing context. In this study, the goal was to maintain anxious children' therapeutic commitment or motivation in completing between-sessions skill building activities.
- 2. Determine interesting activities to move patient toward the end goals. Identify activities that are aligned with the goals. The activities should also capture the interest of the person. From a Self-Determination Theory (SDT) perspective, interest can be defined as an affect that occurs in the interaction between a person and an activity (Deci, 1992).

Interest organizes people's attention and activity. When people experience interest (being intrinsically motivated), the energy necessary for action is readily available. They are rewarded with spontaneous affective/cognitive experiences accompanying their behavior. Ryan and Deci (2000) explains that intrinsic motivation can be maintained by satisfying three psychological needs. These needs are:

Competence: the perceived necessity to gain mastery of tasks and learn different skills. Mastery is the process of becoming skilled at something. When people feel that they have skill or expertise at doing something, they will be more likely to continue doing it. Opportunities to learn different skills, being optimally challenged, or receiving positive feedback can also improve level of competency (Ryan, Rigby, & Przybylski, 2006).

Autonomy: the need to feel in control when performing activities or tasks. The core concept of autonomy is freedom. Providing people with opportunities to choose has been shown to improve a sense of autonomy and consequently, intrinsic motivation (Ryan et al., 2006).

Relatedness/connection: the need to feel connected to others. People tend to internalize and accept values and practices from those to whom they feel connected and from contexts in which they experience a sense of belonging. Providing a possibility of social connectedness that conveys security can strengthen intrinsic motivation (Deci & Ryan, 2000).

Although interest plays a central role in intrinsic motivation, it is not central to all motivated behavior. People often engage in instrumental activities for some desired outcome not related to the activity itself (being extrinsically motivated). External rewards

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such as points, money, gift cards, toys, or something else tangible can motivate people to do things. In order for gamification to truly motivate people, it has to target correct and intrinsically motivated activities as well as provide external rewards for completing these activities (Kappen & Nacke, 2013). When working with children who usually show little interest in a potentially useful activity, extrinsic rewards have been found to be the most appropriate way to motivate them (Williams & Stockdale, 2004). Table 4 shows intrinsic and extrinsic motivators that were added to the target activities.

Activities	Intrinsic Motivators	Extrinsic Motivators
Completing interactive	Specific modules are assigned	Tangible payoffs (i.e.,
skillbuilding modules ("What's	for a particular session. As the	accessories and makeup,
the feeling?", Thought-buster,	session progresses, different	small toys and games, gift
Thought-swapper, Problem-	modules with different	cards for older teens)
solver)	challenges will be assigned	
	(competence)	
	Each module can be initiated	
	independently (autonomy)	
Completing Skills Coach	As the session progresses,	
	children are asked to come up	
	with their own coping	
	strategies instead of choosing	
	from provided checklist	
	(competence and autonomy)	
Completing at-home challenges	At-home challenges are	
(Challenger), Chillax, and STIC	discussed with the therapist in	
(Show That I Can) task	face-to-face session. Children	
	can choose which challenges	
	they want to complete	
	(competence and autonomy).	
Sending/replying messages	Children can send messages to	Attention, praise
	their therapist to ask	
	therapeutic questions	
	(relatedness/connection)	

Table 4. Intrinsic and extrinsic motivators in target activities

3. **Apply game design elements to improve user experience.** Key elements of game design are applied on the activities to make them playful. The key elements can be identified by viewing game design elements as a hierarchy (Figure 14) that contains (1) components, (2) mechanics, and (3) dynamics (Werbach & Hunter, 2012).

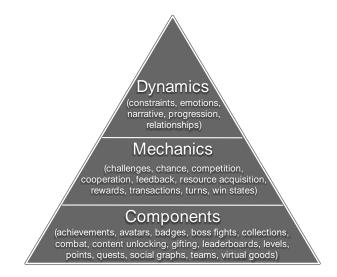


Figure 14. The game element hierarchy

Components represent the specific forms of mechanics and dynamics. Each component is tied to one or more higher-level elements. Mechanics refer to a distinct set of rules or basic processes that generate user engagement and drive the action forward. Dynamics represent the big-picture aspects of the gamified system that are indirectly managed by the system. Initially, actions that need to be monitored and rewarded are defined. Then, points, badges, and achievements (i.e., trophies and stars) are utilized to reward users when performing an action or a collection of actions. Points, levels, badges, and achievements part of the pyramid. To generate engagement, challenges and feedback (i.e., information about how the user is doing), which represent the mechanics part, are added. If the challenge is completed, the user can collect rewards (i.e., tangible payoffs as extrinsic motivators). Ultimately, the dynamics provided by the

system is the way the tangible payoffs relate to the number of points collected (bigger prizes require one to get a higher number of points). Table 5 shows the game design elements that were implemented in this study.

Actions	Components	Mechanics
Initiate and complete skillbuilder	1 point toward the	Collect certain number of
modules when required to do so by	target number of points	points. Therapists will assign
app alarm ("What's the feeling?",	(cumulative).	the target points needed to
Thought-buster, Thought-swapper,		redeem selected prize. A
Problem-solver, Skills Coach,		collection of stars and trophy
Challenger, STIC, Chillax).		will be displayed on home
Initiate and complete skillbuilder	2 points toward the	screen. Progress bar and
modules ("What's the feeling?",	target number of points	badges are displayed after
Thought-buster, Thought-swapper,	(cumulative).	completion of actions.
Problem-solver, Skills Coach,		
Challenger, STIC, Chillax) from		
within the app (on one's own		
initiative).		
Complete all required modules for	1 star.	Collect 1 star for each session.
a particular session.		
Complete all required modules for	Silver trophy.	Collect a silver trophy.
session 1, 2, 3, and 4.		
Complete all required modules for	Gold trophy.	Collect a gold trophy.
session 5, 6, and 7.		

4. **Evaluate effectiveness.** Depending on the goals defined in the initial step, the effectiveness of gamification can be assessed by gathering quantitative or qualitative data. Quantitative data that includes user engagement (time spent on app, app utilization) and app retention (app utilization between sessions) can be used to infer user behavior directly. Qualitative data such as user feedback, comments, concerns, frustrations, and suggestions can capture perceptions and attitudes toward gamified applications.

5.1.2.2 Design

The system architecture of SmartCAT 2.0 is illustrated in Figure 15. Like SmartCAT 1.0, the app consists of a user interface that interacts with the patient and a background service that maintains a real-time data connection with the portal when the smartphone is off. The background service was redesigned to accommodate unique features such as geofencing and gamification. It is also responsible for determining the proximity of the smartphone from the user (through use of the smartphone's accelerometer). Geofencing enables automatic detection of mobile objects as they enter or exit a geofence (a virtual boundary for a real-world area; Namiot & Sneps-Sneppe, 2013). This architecture allows the app to update its contents automatically (e.g., activities of the week, geofence sent by a therapist) or to alert patients as new data is pushed from the portal (e.g., secure message). The portal consists of a presentation layer, an application logic layer, and a persistence layer. The presentation layer provides the user interface that helps therapists complete tasks such as sending treatment regimens, monitoring treatment responses and rewards, and sending or replying to messages. The application logic layer provides services for data access and data synchronization, connecting both the portal's presentation layer and the app's background service with the persistence layer. This layer also provides an activity log service that captures therapist activities when interacting with the portal (i.e., login time, logout time, page accessed, time spent, and device type used for access). The persistence layer consists of relational database software that stores clinical data and Lightweight Directory Access Protocol (LDAP) software, which stores unique identifiers of the app and the therapists' account information. The portal's security works closely with the directory service to provide a unified authentication mechanism for all users.

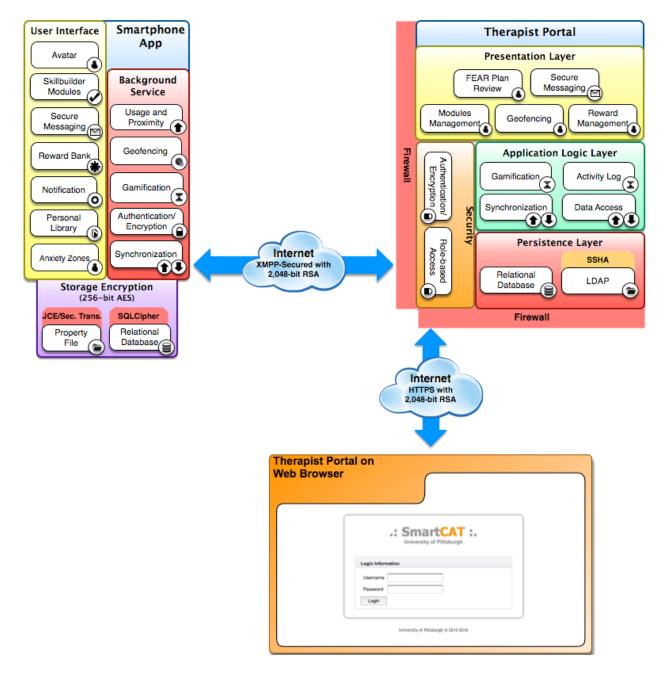


Figure 15. SmartCAT 2.0 system architecture

Maintaining privacy and security of information is the biggest challenge for m-Health systems (Whittaker, 2012). To address this challenge, the following features were incorporated:

1. **Seamless authentication and encryption:** the app requires a registration process using a portal interface. The process requires a user identifier and a password. The combination of user identifier and password are used to authenticate and establish a secure connection

to the portal. Upon successful authentication, the data transmission is encrypted using an RSA (Rivest, Shamir, and Adelman) algorithm with a 2048-bit key. This public-key cryptosystem with a 2048-bit key is currently being used as the standard cryptosystem in E-commerce to prevent man-in-the-middle attack¹.

- 2. Encrypted storage: The app's storage (both database and property files) was encrypted using Advanced Encryption Standard (AES) with a 256-bit key. AES is a private key and encryption algorithm developed by Joan Daemen and Vincent Rijmen. According to the National Institute of Standards and Technology (NIST), a 256-key length is sufficient to protect "Top Secret" level information. This measure also prevents malware access and reverse engineering efforts.
- 3. Password-protected online portal over Secure Socket Layer (SSL). Therapists must provide a username and a password to access the portal. The connection between the web browser and portal was also encrypted using RSA with a 2048-bit key.
- 4. Increased security by physically separating the web application and database via a threetier architecture. The connection between the web application and database is private and secured.

The data synchronization process for the app and portal data was conducted through the Internet using Extensible Messaging and Presence Protocol (XMPP). The protocol allows two or more network entities connected through the Internet to exchange data bi-directionally and asynchronously in near real-time. The platform's synchronization module is responsible for managing the connection between the app and the portal. Because network connectivity is not

¹ A man-in-the-middle attack (MITM) is an attack where the attacker secretly relays and possibly alters the communication between two network entities who believe they are directly communicating with each other.

guaranteed to be constantly available as patients move from one location to another, the app and the portal detect each other's connection information before exchanging data. In cases where the receiving end lacks an Internet connection, the sender will store data indefinitely and send it whenever the receiving end acquires a connection. This mechanism ensures successful data delivery even when the connection is not reliable.

5.1.2.3 Implementation and Testing

SmartCAT App

The app was developed using an Android Software Development Kit (SDK). To accommodate new features (i.e., low-power location monitoring, improved user interface), Android SDK version 4.2 was used. The games were developed using Unity, a cross-platform game engine developed by Unity Technologies. Unity allows the games to be run on top of Android or iOS devices.

Google's material design principles were used as the guideline for developing the app's main UI. User interface (UI) design is important as it can significantly impact perceived usefulness, ease of use, and enjoyment, which ultimately leads to user loyalty (Cyr, Head, & Ivanov, 2006). The main characteristic of material design is the increased use of grid-based layouts, responsive animations and transitions, bold hue colors, padding, and depth effects such as lighting and shadows (Google, 2014).

To help expedite the development process, a number of third-party software components were utilized. A third-party software component is a reusable software component developed by an entity other than the original developer of a product that provides more general functionality out of the box. These components can help developers to focus more on important details of design by alleviating the need to reinvent the wheel for common development needs. To provide user interface enhancement, security and encryption, and utility features for the app, several third-party software components were integrated.

Two levels of testing of the app were conducted. The first level was unit testing, aimed at ensuring the stability of the code basis. The unit testing was conducted using the Android JUnit library and involved testing the smallest possible unit of code (i.e., method, class, or component) without dependencies on system or network resources. The second level of testing was functional user interface (UI) testing. This was meant to verify that the UI of the app is functioning correctly and smoothly (running at a consistent 60 frames per second). For the UI testing, a human tester was assigned (a CBT therapist) to perform a set of user operations on the app.

SmartCAT Portal

The portal was developed using a combination of Java-based web application frameworks (i.e., Spring Model View Controller and Java Server Faces). A web application framework is a universal, reusable software environment that is designed to support the development of dynamic websites, web applications, web services, and web resources. The framework provides general and fundamental functionality that can be modified by additional user-written code to provide application-specific software. It may include libraries for database access and security, templating frameworks and session management, and application-programming interfaces (APIs). Web application frameworks allow developers to build and maintain a complex web application rapidly and efficiently.

As in the development of the app, a number of third-party software components were used. The components include user interface enhancement, security, communication, database abstraction, and utility. Unit testing using JUnit was conducted to verify the functionality of each component of the portal.

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5.1.2.4 Evaluation

The goal of the evaluation stage is three-fold. First, we wish to assess the appropriateness of the UI design (i.e., color schemes, layout, use of animations, and typeface). Next, we wish to verify the consistency and completeness of the implemented modules against the design principles. Finally, we wish to ensure formative usability study readiness. The therapists performed the evaluation stage and the input/feedback from the therapists were noted and then implemented in the next iteration.

5.1.3 Formative Usability Study

The formative usability study was conducted using non-anxious children to evaluate nontreatment features of the app including the skills coach, thought-buster, thought-swapper, problem-solver, and "What's the feeling?". The main goal of the formative usability study was two-fold: to discover and enumerate usability problems, and to measure initial usability of the app with respect to its effectiveness, efficiency, and user satisfaction. In this study, effectiveness is defined as the ability of a participant to complete a task; efficiency is defined as the ability of a participant to complete a task quickly and accurately. User satisfaction is the perceived enjoyment afforded to a participant when interacting with different components of the platform.

The evaluation of the app was conducted for one hour in a lab setting. In addition to this one-hour evaluation, the participant was asked to use the app for one week in a home setting. During the lab testing, a research staff member trained the participant to use the app. The participant was also given an opportunity to use the app to become more familiar with it while in the lab. To collect usability data, the research staff member asked the participant to complete a set of tasks using the app. The tasks were completing the skills coach, thought-buster, thought-

swapper, problem-solver, and "What's the feeling?". The tasks were repeated two times to collect more data points for quantitative data analysis. For each task, the staff member measured the time spent by the participant to complete a task and mark the task as failed or completed. If the participant encountered a usability problem that prevented him/her from completing a task, the task would be marked as failed. He/she would be asked to start over immediately. After completing a task, the staff member asked the participant to complete the post-task usability questionnaire (see Measures). The post-test usability questionnaire (see Measures) and qualitative data (e.g. participant's comments, concern, frustrations, and suggestions) was collected after the participant completed the one-week of home testing.

5.1.3.1 Participants

Participants comprised 5 non-anxious children ages 9-14. The sample size was estimated using a probabilistic model of problem discovery. According to Sauro and Lewis (2012b), the most commonly used formula to model the discovery of usability problems as a function of sample size is

$$P(x \ge 1) = 1 - (1 - p)^n$$

In this formula, p is the probability of problem occurrence (e.g. the probability of app's forced closed occurrence), n is the number of opportunities for the problem to occur (it represents the sample size), and $P(x \ge 1)$ is the probability of the problem occurring at least once in n tries (participants). To solve for n, the equation $P(x \ge 1) = 1 - (1 - p)^n$ can be converted to

$$(1-p)^{n} = 1 - P(x \ge 1)$$
$$n(\ln(1-p)) = \ln(1 - P(x \ge 1))$$
$$n = \frac{\ln(1 - P(x \ge 1))}{\ln(1-p)}$$

In this study, to have an 80% chance of observing at least one problem that has a probability of occurrence of 0.30, the number of participants required is

$$n = \frac{\ln(1 - 0.80)}{\ln(1 - 0.30)} = \frac{\ln(0.2)}{\ln(0.70)} = 4.5 \sim 5 \text{ participants}$$

5.1.3.2 Recruitments

Participants for this study were recruited via community advertisement posted on Facebook.

5.1.3.3 Measures

To measure usability, the following metrics were used:

- Time on task: usability can be reflected by the amount of time required by a participant to complete a task. Obtaining the average time on task can help measure participants' ability to efficiently complete tasks in a reasonable amount of time (Bailey, Wolfson, Nall, & Koyani, 2009).
- 2. Success rate: captures overall success, or simply whether or not a participant can successfully complete a task scenario (1=success, 0=failed). Completion rates on a task were determined by dividing the number of participants who successfully complete the task by the total number who attempted it.
- 3. Post-test usability ratings: the perceived ease-of-use, system satisfaction, usability, and learnability was assessed using the 10-item System Usability Scale (SUS) (Brooke, 1996). The SUS (see Appendix A) obtains quantitative feedback on a 0–100 scale. Although SUS was only intended to measure the perceived ease-of-use (a single dimension), it also provides a global measure of system satisfaction and sub-scales of usability and learnability (Lewis & Sauro, 2009). Items 4 and 10 provide the learnability

dimension and the other 8 items provide the usability dimension. These dimensions can be used to track and report both subscales and the global SUS score. Despite being described as a "quick-and-dirty" usability scale, the SUS has become a very popular questionnaire for post-test, subjective assessment of usability (Lewis, 2012; Zviran, Glezer, & Avni, 2006) and has been shown to be reliable when the sample size is small (Lewis & Sauro, 2009). To better understand usability, the average score can be translated into letter grade using Table 6 (Sauro & Lewis, 2012a). The letter grade table was derived from analysis of 446 surveys/usability studies (Sauro, 2011). As suggested by the literature, the SUS was modified to be more appealing by incorporating ageappropriate language and using visual scales (i.e., smiley icons) instead of numbers and words (Usability.gov, 2015). The modified SUS score is scored using the following steps:

- a. Subtract one from each user response
- b. Add up the converted responses for each user and multiply the total by 2.5

Usability subscale (items 1, 2, 3, 5, 6, 7, 8, 9) and learnability subscale (items 4 and 10) are scored similarly, except that the sum of the converted responses is multiplied by 3.125 and 12.5, respectively.

SUS Score Range	Grade	Percentile Range
84.1-100	A+	96-100
80.8-84	Α	90-95
78.9-80.7	A-	85-89
77.2-78.8	B+	80-84
74.1-77.1	В	70-79
72.6-74	В-	65-69
71.1-72.5	C+	60-64
65-71	С	41-59
62.7-64.9	C-	35-40
51.7-62.6	D	15-34
0-51.7	F	0-14

Table 6. Grading scale interpretation of SUS scores (Sauro & Lewis, 2012a)

4. Post-task usability ratings: the metric measures participants' effort when completing a task using the app (see Appendix B). Post-task questions can add additional diagnostic information that a post-test questionnaire does not provide with very little effort (Sauro & Dumas, 2009). Perceived mental effort of completing a task will be assessed using the Subjective Mental Effort Question (SMEQ; Zijlstra & Doorn, 1985). SMEQ is used because it is highly sensitive with a sample size above 10 (Sauro & Dumas, 2009); it is significantly correlated with SUS scores, time on task, success rates, and errors collected during the experiment (Sauro & Lewis, 2012a); and it is reliable and easy for participants to use (Sauro & Dumas, 2009). Using the paper version of the SMEQ, (Appendix C), participants can draw a line through the scale (which is 150 mm in length) to indicate the perceived mental effort of completing a task. The score is indicated by the number of millimeters the participant marked above the baseline of 0.

5. **Preferences**: this metric is a supplemental component to usability analysis that includes qualitative information such as participants' comments, concerns, frustrations, and suggestions for improvement.

5.1.3.4 Statistical Analyses

Descriptive analyses were used to examine time on task, success rate, perceived mental effort of completing a task as measured by SMEQ score, and post-test usability rating as measured by SUS score. The result of descriptive analyses was utilized to determine usability problems and to assess initial usability of certain features of the app with respect to its effectiveness, efficiency, and user satisfaction.

5.2 RESULTS

5.2.1 System Development Results

The app was developed using an Android[®] (Google, Mountainview, CA) Software Development Kit (SDK). To accommodate new features (i.e., low-power location monitoring, improved user interface), Android SDK version 4.2 or above was used. The mini-games were developed using Unity, a cross-platform game engine developed by Unity Technologies. Unity allows the games to be run on top of Android or iOS devices.

The following design principles were implemented during the iterative system development process.

1. Customizable and location-aware reminders

The reminder (see Figure 16) is designed to cue anxious children to initiate a skillbuilder activity for the day. The app automatically wakes the device, shows a notification dialog, and then plays a distinct sound to get the patient's attention. The dialog contains a customized message, a snooze button, and a shortcut button for initiating the module of

the day. If the time is inconvenient, the children can choose to reschedule the reminder later (i.e. 30 minutes, 1 hour, 2 hour), three times at the most. To increase the effectiveness of the reminders, the children are also allowed to set their own preprogrammed reminders, after completing a skillbuilder activity.



Figure 16. SmartCAT 2.0 time-based reminders (left and middle). The location-aware reminder is shown on the right-hand screen

Another issue that children who suffer from an anxiety disorder face is that they experience fear, nervousness, and shyness, and so they may start to avoid specific locations (e.g. school, doctor's offices, and dogs in the neighbors' house). Therefore, to complement time-based reminders, we also provided location-aware reminders using geofencing. Geofencing enables automatic detection of mobile objects as they enter or exit a geofence (a virtual boundary for a real-world area; Namiot & Sneps-Sneppe, 2013). These alert the children, as they enter locations that will cause them anxiety, to deal with the situation.

The reminders are integrated into a weekly plan for each patient that is pushed to the patient's app. As shown in Figure 17, the plan represents a calendar event consisting of four parts:

- 1. **Notes:** an instructional message appearing on the message part of the app's notification dialog;
- 2. **Time:** the length of the event and the two-hour window (i.e. 4-6pm, 5-7pm, 6-8pm, 7-9pm) of the day that a notification should pop up;
- 3. **Session:** each session is associated with a different set of skillbuilder modules;
- 4. **Optional module:** an indicator to include additional skillbuilder modules.

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Figure 17. SmartCAT 2.0 weekly plan

2. Game-/multimedia-based learning

Four mini-games (Figure 18) were developed to provide anxious children more interactive ways to learn important CBT skills such as emotion and somatic symptoms

identification, cognitive restructuring, and problem solving. To complement the games, the Chillax module (Figure 19) containing a video recording of deep breathing exercise and an audio recording for relaxation was included. The multimedia files are accessible by initiating the Chillax module, which is part of session-specific skillbuilder modules, or by accessing the Media Library, which is always available throughout the treatment.



Figure 18. "What's the feeling?", Thought-buster, Thought-swapper, and Problem-solver screens, respectively

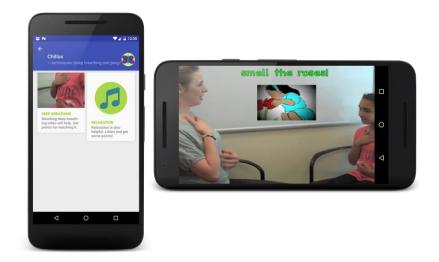


Figure 19. Chillax screens

3. Emotion and Somatic Symptoms Identification Skills

"What's the feeling?" module (Figure 20) helps anxious children learning skills to identify emotional and somatic symptoms from various scenarios (including anxiety, physical pain, hunger). The scenario consists of a character and a thought bubble describing the character's hypothetical situation. Depending on the situation, a bodily reaction is displayed. The child then needs to identify whether the character is experiencing anxiety or some other emotion. The child will lose a heart for identifying the incorrect emotion. To make the character feel better, the child needs to rub the part of the body on the screen.



Figure 20. "What's the feeling?" screens

4. Cognitive-restructuring

Two mini-games were developed to facilitate the learning of cognitive reframing techniques. Thought-buster module (Figure 21) helps the child in classifying self-talk as anxious or non-anxious. Thoughts are presented as balloons —randomized between screens— that can be popped by tapping the screen. The child needs to tap two correct self-talk balloons before moving on to the next screen. Tapping an incorrect balloon will cost the child a heart.



Figure 21. Thought-buster screens

The thought swapper module (Figure 22) allows the child to practice applying this skill to hypothetical situations. For each hypothetical situation, an anxious thought presented in a thought bubble on top of a character appears. The child then needs to pick the most appropriate coping thought to counter the presented anxious thoughts. As a coping thought is selected, the child can see changes in an anxiety thermometer as well as in the character's facial expression. The module offers two hypothetical situations in each game session. For each situation, the child needs to either counter the initial thought or intensify it. This way, the child can experiment and learn what coping thoughts will work best in a given situation and understand that thoughts can influence emotions.



Figure 22. Thought-swapper screens

5. Problem-solving

Problem-solver module (Figure 23) provides an interactive way for the children to get further out of session practice in the four steps of problem solving: define the problem, come up with as many solutions as you can think of, evaluate all of the options, and pick one or two of the best solutions. To familiarize the children with the steps, the module imitates a text message conversation between the child and his/her virtual friend who experiences a hypothetical problem that typically occurs in youth daily life (i.e., performing at the talent show after school, going to a friend's sleepover). The child's task is to help his/her virtual friend solving the problem that is randomly generated each time the module is initiated. To reduce the child's burden during the conversation, a predefined list of replies is provided. In the first step, the virtual friend describes her problem to the child (i.e. "I have a doctor's appointment and I have to get a shot"). In the second step, the child asks her to come up with several possible solutions including solutions that might not be great (to promote flexibility in generating solutions). The goal of the second step is to show the child that being able to generate a list of solutions is encouraged and important. The quantity of the solutions is more important than the quality, as brainstorming is a way to increase mental flexibility (Curry et al., 2000). In the third step, the child evaluates the "pros and cons" of each possible solution by selecting each solution. Solutions that generate positive consequence (i.e., "That's a good idea!" "That would help to relax me") and negative consequences (i.e., "I'd get into a lot of trouble", "I don't think that's a good solution") are highlighted in green and red, respectively. The module concludes by asking the child to pick the solutions colored in green that work best for his/her virtual friend.



Figure 23. Problem-solver screens

6. <u>Step-based plan for dealing with anxiety</u>

The skills coach module (Figure 24) provides a series of questions guiding the child in developing a FEAR plan for a current or recent *in vivo* anxious experience. To reduce the child's burden, checklists are provided, which include common responses to items (i.e. typical negative scenarios, automatic thoughts, coping thoughts) that were generated from therapists' input. As the session advances, the pre-populated responses from the checklist are replaced by text responses to encourage the child to generate his/her own response. FEAR plans are sent to the portal and stored locally on the app for later use when the child is feeling anxious.

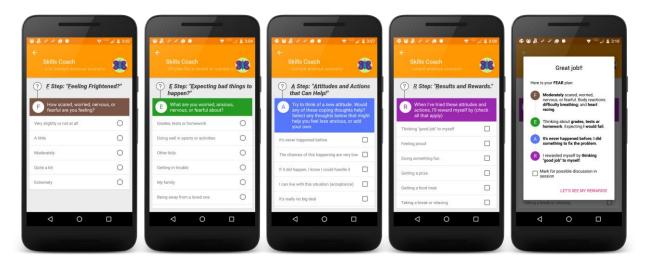


Figure 24. Skills Coach screens

As illustrated in Figure 25, the therapist can review FEAR plans created using the Skills Coach. The FEAR plans can be ordered by importance —set by the patient using the app before FEAR plan submission—session, or submission date. The FEAR plans that need to be discussed with the child have the title colored with a yellow background.

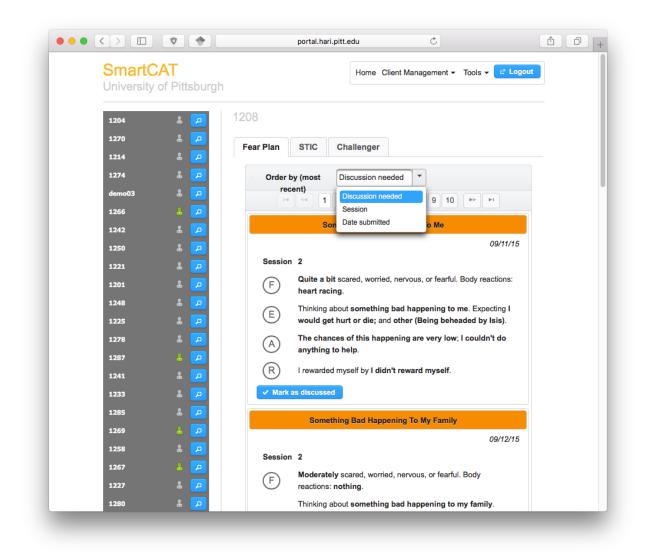


Figure 25. FEAR plans on the portal side

7. Exposure task

The therapist activates the Challenger module (Figure 26) from the portal during session four or higher. It provides a list of *in vivo* exposure tasks prepared by the therapist and the child during face-to-face sessions. For each exposure task, the child needs to describe how each task is conducted in the real-world situation and/or provide a photograph showing that he/she completed the task. The child's response will be sent to the portal for the therapist to see (Figure 27).

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Figure 26. The Challenger module screen showing in vivo exposure tasks (left) setup from the portal (right)

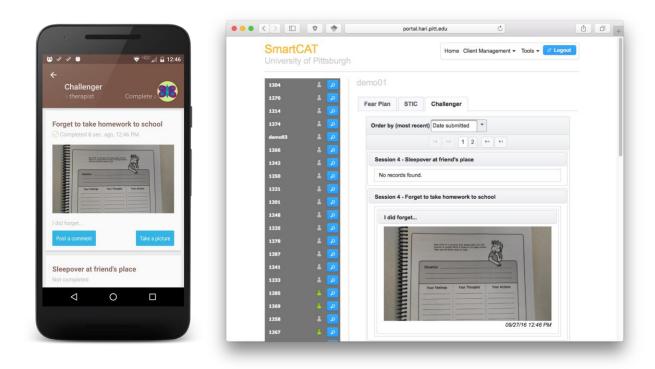


Figure 27. The Challenger module screen showing a completed in vivo exposure tasks (left). The right-hand screen

shows the corresponding task on the portal

8. Patient-therapist interaction

To support therapist-patient interaction, a secure messaging interface was developed (Figure 28). Using this interface, the child can compose a message on the phone, and the message will be sent to the portal rather than the therapist's private phone. The therapist may view these messages and/or send the patient a message at any time using the portal. Incoming/outgoing messages from/to the therapist were encrypted and stored in the phone's local storage using AES with a 256-bit key. During transmission, these messages were encrypted using RSA algorithm with a 2048-bit key to prevent man-in-the-middle attack. The portal is a secure portal protected by corporate firewall.

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Figure 28. Secure messaging interface

9. Reinforcement through gamification

Skillbuilder modules can be activated during acute anxiety by launching the app. From the app's home screen (Figure 29), the children can initiate skillbuilder activities that they find most useful. Each time they complete any of the skillbuilder modules, digital points

are awarded. The target points are associated with a prize (i.e., 50 digital points for a jigsaw puzzle) that the children can pick and are then assigned by the therapist using the portal. Depending on the target, the points are redeemed for the desired prize every two or three sessions. If the children acquire digital points beyond the target, the remaining digital points will be carried over to the following session. A star will be awarded when they complete all of the skillbuilder modules for the week. A maximum number of seven stars can be awarded. To maintain their motivation during treatment, the children are challenged to get silver trophy for collecting three stars and gold trophy for collecting the remaining four stars.



Figure 29. SmartCAT 2.0 home screen (left) indicating digital points, trophy, and stars awarded. The middle screen shows digital points from completing certain skillbuilder modules. The right-hand screen shows a star earned from completing all of the skillbuilder modules for the week

10. Usage monitoring

The portal allows therapists to monitor patients' progress and access their Skills Coach, STIC, and Challenger entries. The home screen of the portal is illustrated in Figure 30. After successful login, therapists can see a list of their patients and a summary of each

patient's progress. The list provides information about each patient's smartphone connectivity, a green mark indicating that a patient's phone is currently connected and a grey mark indicating no connection. An action button, next to the connectivity status, is used to initiate patient-related actions such as: reviewing skillbuilder modules' (Skills Coach, STIC, and Challenger) entries, managing treatment regimen and reminders for each session, sending/replying secure messages, managing geofences, and managing digital points. The summary contains the type of trophy and the number of stars collected by each patient. Therapists can also track how far each patient from the target points and the number and type of skillbuilder modules that have been completed.

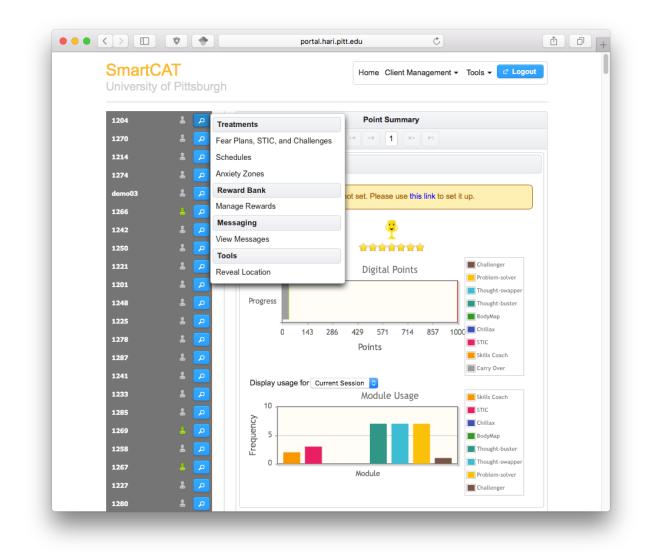


Figure 30. SmartCAT 2.0 Portal home screen

The STIC module (Figure 31) contains session-specific open discussion assignments adapted from the Coping Cat workbook. The child is asked to read through an instruction or a hypothetical situation and to provide a written response. As illustrated in Figure 32, the response is sent to the portal for review by the therapist. In the first session, the child needs to describe his/her situations, thoughts, and feelings when he/she felt really great as well as when he/she felt worried, scared, or nervous. In the second session, the child needs to brainstorm various thoughts experienced by different people in a hypothetical situation. The child also need to assess the feeling and action that a person will experience (i.e., "Jennifer is about to give a presentation in front of the class") based on his/her thoughts ("I'm going to mess up" vs. "I've done this before; I can do it again"). The goal is to understand that different people may have different thoughts and different thoughts can influence feelings and actions. In the third session, the child needs to list attitudes and actions that can help given a hypothetical situation and review the FEAR plan. In the fourth session or above, the child needs to develop a FEAR plan for various hypothetical situation.

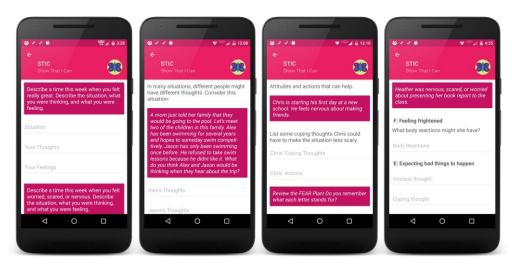


Figure 31. The content of STIC module from session 1 to session 4 (left to right)

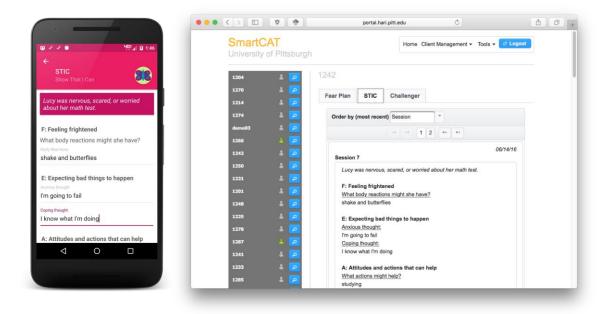


Figure 32. STIC entry is sent to the portal for review

5.2.2 Formative Usability Results

Participants were between the ages of 9 and 14 (M=11.40, SD=1.07). Three participants were male (60%) and two participants were female (40%). As shown in Table 7, all participants completed the tasks successfully. Among the tasks, participants rated Thought-buster as a bit hard to do (SMEQ=26.09; SD=16.18), perhaps, due to difficulties associated with reading a relatively fast moving text. Thought-buster (Figure 21) helps the child classifying self-talk as anxious vs. non-anxious. Thoughts are presented as moving balloons with thought descriptions inside. They can be popped by tapping the screen and are randomized between screens. Comments from the participants also indicated that sometimes when the balloons were too close, the wrong balloon might get popped. Thought-swapper was completed the longest, averaging 4.20 minutes (SD=1.04). Despite the longer completion time, the participants rated Thought-swapper not as hard as Thought-buster. Thought-swapper has four answers and the participants

can go to the next step by trying different combinations of the answers. Among the tasks, "What's the feeling?" was completed the quickest.

Task	Measure	Minimum	Maximum	Mean (SD)
Skills coach	Time on task (minutes)	1.67	5.00	2.77 (.94)
	Trial #1	2.80	5.00	3.40 (.91)
	Trial #2	1.67	2.65	2.16 (.47)
	Success rate	100%	100%	100%
	Trial #1	100%	100%	100%
	Trial #2	100%	100%	100%
	SMEQ	0.00	36.00	16.97 (13.42)
	Trial #1	0.00	36.00	18.41 (14.00)
	Trial #2	0.00	33.00	15.53 (14.30)
Thought-buster	Time on task (minutes)	1.15	2.10	1.44 (.35)
	Trial #1	1.15	2.10	1.40 (.40)
	Trial #2	1.22	2.03	1.50 (.33)
	Success rate	100%	100%	100%
	Trial #1	100%	100%	100%
	Trial #2	100%	100%	100%
	SMEQ	0.00	44.39	26.09 (16.18)
	Trial #1	0.00	43.86	28.75 (17.87)
	Trial #2	0.00	44.39	23.43 (15.88)
Thought-swapper	Time on task (minutes)	1.87	5.08	4.20 (1.04)
	Trial #1	1.87	5.08	4.36 (1.40)
	Trial #2	3.37	4.95	4.02 (.65)
	Success rate	100%	100%	100%
	Trial #1	100%	100%	100%
	Trial #2	100%	100%	100%
	SMEQ	0.00	56.47	20.24 (16.79)
	Trial #1	0.00	28.02	17.61 (12.04)
	Trial #2	0.00	56.47	22.86 (21.73)
Problem-solver	Time on task (minutes)	1.07	3.17	2.06 (.79)
	Trial #1	1.65	3.17	2.67 (.61)
	Trial #2	1.07	1.70	1.44 (.24)
	Success rate	100%	100%	100%
	Trial #1	100%	100%	100%
	Trial #2	100%	100%	100%
	SMEQ	0.00	50.15	17.25 (19.13)

Table 7. Descriptive statistics of time on task, success rate, and SMEQ score

Trial #1	0.00	50.15	18.61 (20.83)
Trial #2	0.00	46.73	15.89 (19.61)
Time on task (minutes)	.85	1.83	1.16 (.32)
Trial #1	.92	1.47	1.22 (.22)
Trial #2	.85	1.83	1.11 (.41)
Success rate	100%	100%	100%
Trial #1	100%	100%	100%
Trial #2	100%	100%	100%
SMEQ	0.00	40.91	15.61 (18.13)
Trial #1	0.00	40.00	16.54 (19.97)
Trial #2	0.00	40.91	14.68 (18.41)
SUS Overall	62.50	95.00	78.25 (10.21)
Lab	70.00	92.50	78.5 (9.94)
Home	62.50	95.00	78.00 (11.65)
SUS Usability	62.50	93.75	77.75 (9.97)
Lab	68.75	90.63	77.75 (9.73)
Home	62.50	93.75	77.75 (11.35)
SUS Learnability	62.50	100.00	81.25 (12.15)
Lab	75.00	100.00	83.75 (10.29)
Home	62.50	100.00	80.00 (14.25)
	Trial #2 Time on task (minutes) Trial #1 Trial #2 Success rate Trial #1 Trial #2 SMEQ Trial #1 Trial #2 SUS Overall Lab Home SUS Usability Lab Home SUS Learnability	Trial #20.00Time on task (minutes).85Trial #1.92Trial #2.85Success rate100%Trial #1100%Trial #2100%SMEQ0.00Trial #10.00Trial #20.00SUS Overall62.50Lab70.00Home62.50SUS Usability62.50SUS Learnability62.50SUS Learnability62.50Lab75.00	Trial #20.0046.73Time on task (minutes).851.83Trial #1.921.47Trial #2.851.83Success rate100%100%Trial #1100%100%Trial #2100%100%SMEQ0.0040.91Trial #10.0040.00Trial #20.0040.91SUS Overall62.5095.00Lab70.0092.50Home62.5095.00SUS Usability62.5093.75Lab68.7590.63Home62.50100.00Lab75.00100.00

Table 7 (cont'd)

The participants rated the app as acceptable and easy to use (B+ grade), average SUS score of 78.25 (SD=10.21). This suggests that the app is more usable than 80% of the products in the Sauro (2011) database. The average usability subscale was 77.75 (SD=9.97) suggesting that the app is usable. The participants rated the app as easy to learn with average SUS Learnability score of 81.25 (SD=12.15).

5.3 DISCUSSION

A gamified m-Health system was developed, evaluated, and tested. Redesign efforts were performed based on feedback of SmartCAT 1.0 initial feasibility results and the use of the UCD approach. The design principles were implemented correctly and completely. SmartCAT 2.0 offers: (1) more interactive and diverse home-based CBT skills practice; (2) gamification to maintain patient motivation and engagement during the treatment; (3) modern user interface; and (4) the ability to capture usage patterns or behaviors of anxious children when using the app.

Results from the formative usability study suggested that the participants were satisfied with the app. They stated that the app would be useful to anxious children when learning and practicing CBT skills at home. The results also suggest that interactive features of the app were not too hard but not that easy. Despite experiencing several usability problems —animation speed, touch accuracy— the participants could complete all the tasks using the app. The usability problems were corrected prior to clinical implementation.

6.0 CLINICAL IMPLEMENTATION

The objective was to support BCBT treatment in an open clinical trial while collecting required data for:

- 1. Assessing the effectiveness of gamification in improving user engagement at post-treatment (Aim 2).
- 2. Identifying usage patterns or behaviors of children who benefit the most from the treatment (Aim 3).
- Identifying demographic and clinical characteristics of children who benefit the most from the BCBT + m-Health treatment (Aim 4).
- 4. Identifying therapists' technology-related efforts from the BCBT + m-Health treatment (Aim 5).

Prior to implementation, beta testing was conducted. The goal of the beta testing was to explore the limitations of the system in the "real world" before conducting the pilot clinical trial, and to capture usability problems revealed in real-world usage. Revisions and bug fixes were incorporated before actual implementation. The data collected from beta testing was also included for analysis. Participants enrolled in beta testing went through similar implementation procedures (Section 6.1) and were given similar CBT treatment (Section 6.5) to those enrolled in actual implementation.

6.1 IMPLEMENTATION PROCEDURES

As shown in Figure 33, after completing a phone pre-screen, potential participants for the implementation phase were required to complete a clinical intake interview. Clinical information was obtained from parents and children by a trained independent evaluator (IE) blind to the CBT therapist providing treatment. To establish anxiety and exclusionary diagnoses, the KSADS-PL (Kaufman et al., 1997b) for DSM-V was used. Participants that met the study criteria were scheduled for a CBT pre-test a week prior to the first therapy session. The CBT pre-test was conducted to measure their CBT related skills before treatment. For example, how equipped they were at problem solving, cognitive restructuring, and emotion identification before treatment. The child and a parent attended an orientation prior to the first therapy session to learn how to use the smartphone app. Participants were provided with an Android smartphone for the duration of the study (or if the child already had an Android phone, the app would be installed on the participant's phone).

Participants were required to attend 1-hour weekly therapy sessions with a therapist. At the beginning of each session, the therapist used the portal to review the data for the skills coach and other modules from the past week with the patient. Based on the subsequent discussion and level of patient improvement, the therapist would select relevant modules and time ranges that the reminders should be activated during the upcoming week. When the patient reached the target points, the therapist would redeem the points, and if required, set new target points. This information would then be pushed to the app.

After completing therapy, the presence of anxiety diagnoses was re-assessed using the KSADS-PL (Kaufman et al., 1997b) for DSM-V to establish the remission or non-remission of anxiety. Additionally, SUS scores were obtained to quantitatively measure the usability of the

system. SUS scores for the app and the portal were obtained from the participant and the therapist respectively at post-treatment.

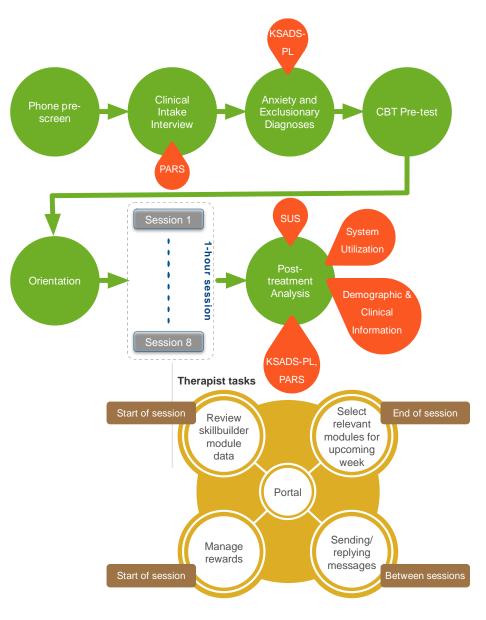


Figure 33. Clinical implementation procedures

6.2 PARTICIPANTS

Participants included 24 children —5 in beta testing and 19 in implementation— ages 9-14 with a DSM-V diagnosis of GAD, social anxiety disorder, and/or SAD. These diagnoses are common in children, frequently co-occur, have a similar presentation, and respond to the same treatment approaches (Albano, Chorpita, & Barlow, 2003; Collins, Westra, Dozois, & Burns, 2004; Lahey et al., 2008). A lower limit of age 9 and an upper limit of 14 were chosen based on the reading level requirements for the app and the age-appropriateness of the materials.

6.3 **RECRUITMENTS**

Participants for the implementation phase were recruited from referrals from the Services for Teens at Risk clinic at WPIC, local schools, pediatrician's offices, and also via community advertising over television, radio, internet, print publications, and Facebook.

6.4 INCLUSION AND EXCLUSION CRITERIA

Participants were anxious children aged 9-14 with a DSM-V diagnosis of GAD, social anxiety disorder, and/or SAD as identified by KSADS-PL. Participants with the following criteria were excluded: (1) a current comorbid diagnosis that would require alternative treatment or interfere with treatment (major depressive disorder, obsessive-compulsive disorder, posttraumatic stress disorder, conduct disorder, or substance abuse or dependence), (2) a lifetime diagnosis of autism

spectrum disorder, bipolar disorder, or psychotic disorder, (3) a prior trial of \geq 7 sessions of CBT (4) IQ below 70 as assessed by the Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999) or reading level below 80 on the Wide Range Achievement Test-4 (WRAT-4; Wilkinson & Robertson, 2006), (5) concurrent psychotherapy or treatment with anxiolytic or antidepressant medication (may be on medication for ADHD if dose has been stable for at least 4 weeks), and (6) acute suicidality or risk for harm to self or others.

6.5 CBT TREATMENT

Children were treated using the Brief Coping Cat manual and workbook (Kendall, Beidas, et al., 2012; Kendall, Crawley, et al., 2012), implemented in 8 sessions. The treatment includes two key components: (1) CBT skills training, including emotion identification and labeling, breathing and progressive muscle relaxation, cognitive reframing, and problem solving, and (2) CBT skills practice through graded exposure to feared stimuli. Skills are made more accessible to children with the acronym "FEAR," (Feeling frightened?; Expecting bad things to happen?; Attitudes and actions that can help; Results and rewards). As part of the treatment, children were asked to complete homework consisting of specific modules assigned at the end of each session using the app at home. Treatment was delivered by two Master-level therapists trained in CBT for child anxiety.

6.6 MEASURES

To achieve the research aims, the following measures were collected:

- 1. Demographics characteristics, namely the age and gender of the participants.
- 2. System Usability, defined as the extent to which a system can be used by specified end-users (i.e., anxious children, therapists) to achieve desired objectives with effectiveness, efficiency, and satisfaction. System usability was assessed using the 10-item SUS (Brooke, 1996). In this dissertation, the participants and therapists assessed the system's usability for the app and the portal respectively.
- 3. User engagement was defined as an indicator of the extent to which the participants interact with the app. User engagement data was reported using indications such as how much time the participants spent on the app (time spent), and the total number of features completed during treatment (app use).
- 4. App retention was defined as the extent to which the participants retain their willingness in completing skillbuilder modules between sessions. App retention data was reported using app utilization between sessions.
- 5. Reminder adherence was defined as the extent to which the participants responded to reminders in accordance with prescribed reminder regime during treatment. A reminder was represented internally within the system as a binary value (0=shown; 1=responded). If a reminder is displayed on the smartphone screen, its value will be set to 0. When a child responds to the reminder, the value will be updated to 1. The reminder adherence was calculated by averaging the reminder values.
- 6. Proximity was defined as the extent to which the smartphone is within the participant's arm's reach, measured in hour units per day. To determine proximity, the smartphone's

accelerometer and screen status (on/off) was utilized. The smartphone's accelerometer was utilized to detect the smartphone's movement while placed in a pocket or a backpack. To complement the accelerometer, the screen status was also utilized to detect smartphone use. Proximity's sample value was represented as binary value (0=beyond arm's reach; 1=within arm's reach). When a movement is detected or the screen is on, the value is set to 1. The value is 0 when the smartphone is stationary (the smartphone is placed on a table) and the screen is off. During clinical implementation, the value was sampled every 5 minutes for 15 hours (8:00AM-11:00PM) daily. Proximity per day was estimated using the following formula:

$$Proximity = \left(\sum_{i=1}^{n} v_i\right) * \frac{sampling frequency}{days in session * number of sessions}$$

where *n* is the number of samples, v_i is the sample value (where i = 1, 2, 3, ..., n), *sampling frequency* is the number of samples per hour (in this study, the sampling frequency is 5 minutes divided by 60 minutes), *days in session* is the number of days in one session (in this study, it was assumed that one session is seven days), and *number of sessions* is the number of sessions during which the samples were collected (in this study, although the treatment was conducted in eight sessions, the number of sessions is seven because the samples were collected after the first session).

- 7. Therapist-patient interaction was defined as the extent to which the participants exchanged secure messages during the treatment. Therapist-patient interaction was reported using the number of secure messages exchanged with the therapist.
- 8. The therapists' technology-related efforts were defined as any efforts beyond those efforts exerted by a therapist in delivering traditional BCBT treatment. The efforts were determined using several metrics such as the time spent on the portal per week, the

number of portal visits per week, and the number of patients reviewed per week. A Portal visit was defined as an act of logging in, using different features of the portal, and finally logging out of the portal. Time spent on the portal was calculated by subtracting the amount of "idle" time from the total time spent on the portal. Idle time is defined as the amount of time the therapist spent after logging in but not interacting actively with the system (i.e., reading information from a page, interacting with a patient). The portal is equipped with an idle time counter that is automatically active when the computer's input devices (keyboard and mouse) being used by the therapist are inactive for three minutes. Due to delayed implementation of the logging system, the data was not available at the start of the clinical implementation. The data reported in this dissertation is from June 24, 2016 to February 8, 2017.

Additionally, the following clinical measures were also collected:

- 1. Remission was defined as the absence of DSM-V diagnoses of GAD, SAD, and social anxiety disorder identified by KSAD-PL at post-treatment.
- 2. Anxiety severity was measured using PARS score (The Research Units On Pediatric Psychopharmacology Anxiety Study Group, 2002). The score was computed by summing six items, assessing severity, frequency, distress, avoidance, and interference items. Each item will be assigned a score ranging from 0 (none) to 5 (extreme). Anxiety severity was measured pre- and post-treatment.
- 3. Comorbidity was defined as the presence of more than one anxiety diagnosis (comorbid anxiety) or the presence of a primary anxiety disorder (i.e., GAD, SAD, social anxiety disorder) and an externalizing disorder (i.e., attention-deficit/hyperactivity disorder,

conduct disorder, oppositional defiant disorder) occurring in an individual at the same time.

 Anxiety subtype was defined as the presence of GAD or social anxiety disorder diagnoses at pre-treatment.

6.7 STATISTICAL ANALYSES

Descriptive analyses were used to examine demographics, system usability as measured by SUS, user engagement, app retention, reminder adherence, proximity, and therapists' technological efforts. Boxplots were created using IBM SPSS Statistics version 24 to visually examine app use between sessions. User engagement, app retention, reminder adherence, and proximity were also examined with respect to gender. To assess patients' willingness to learn different skills sets, the distribution of skillbuilder module usage between sessions was examined. The average amount of time spent on the portal was utilized to determine therapists' technology-related efforts when delivering CBT + m-Health treatment. The number of portal visits per week, and the number of patients reviewed per visit were examined to determine therapists' behaviors when using the portal.

The objective of Aim 2 was to evaluate the effectiveness of gamification by comparing engagement data at post-treatment with the previous version of SmartCAT without gamification. In this study, it was expected that gamification would increase participants' involvement in CBT treatment. A Mann-Whitney U-test was conducted to test whether the gamified system has a higher user engagement rate than the previous version of SmartCAT. An alpha level of .10 was used for the test due to the exploratory nature of the study. The Mann-Whitney U-test was

preferred due to a questionable normality of the data given the small sample size and possible extreme outliers among participants. Prior to the Mann-Whitney U-test, descriptive analyses were conducted to examine user engagement data. The data was examined to determine if the four basic assumptions of Mann-Whitney U-test had been met. These assumptions are: non-normal distributions, equal variance, that the data collected follows a continuous or ordinal scale, and independence of observations. The assumption of equal variance based on the median was examined using Levene's test. To indicate the amount of different in user engagement between the previous and the gamified version, *Cohen's r* was calculated and reported. *Cohen's r* was calculated using the following formula:

$$Cohen's r = \frac{Z}{\sqrt{N}}$$

where Z is the Z score of the test, and N is the total number of subjects. Cohen's guidelines for r are that a large effect is .5, a medium effect is .3, and a small effect is .1 (Fritz, Morris, & Richler, 2012).

To satisfy Aim 3 and Aim 4, logistic regression analyses were conducted to develop a multiple regression model that explains the remission of anxiety diagnoses at post-treatment (dependent variable) using a set of explanatory variables for each aim. Logistic regression compares the null model —the regression model with a constant only— with a model including all explanatory variables to determine whether the latter model is more appropriate. Logistic regression is regularly used when there are only two categories of the dependent variable. Like ordinary regression, logistic regression provides a coefficient 'b', which measures each explanatory variable's partial contribution to variations in the dependent variable. Since the dependent variable (Y) can only take one of the two binary values 0 or 1, the outcome of the

regression is not a prediction of a Y value —as in linear regression— but a probability of belonging to one of two conditions of Y (any value between 0 and 1 rather than just 0 and 1).

The form of the logistic regression equation is:

$$ln\left(\frac{p(x)}{1-p(x)}\right) = a + b_1 x_1 + b_2 x_2 + \cdots$$

p can then be calculated with the following formula:

$$p = \frac{e^{a+b_1x_1+b_2x_2+\cdots}}{1+e^{a+b_1x_1+b_2x_2+\cdots}}$$

where:

p = the probability that a case is in a particular category

e = the base of natural logarithms

a = the constant of the equation and,

b = the coefficient of the independent variables.

The assumptions of logistic regression include the following (Burns & Burns, 2008):

- 1. A linear relationship between the dependent and explanatory variables is not required.
- 2. The dependent variable must have two categories (dichotomous).
- 3. The explanatory variables do not need to be interval, normally distributed, linearly related, or of equal variance within each group.
- 4. A case can only be in one group (mutually exclusive) and every case must be a member of one of the groups (exhaustive).
- Larger samples are needed (compared to linear regression) because maximum likelihood coefficients are large sample estimates. A minimum of 50 cases per predictor is recommended.

Although the sample size in this study was well below the recommended minimum, it was considered sufficient due to the exploratory nature of these aims. Additionally, the results should be interpreted with caution. Prior to regression model development, descriptive and correlation analyses were conducted to examine and identify potential explanatory variables that could explain remission of anxiety diagnoses. If the explanatory variables were not normally distributed, Spearman's rank-order correlation was utilized rather than Pearson's correlation (Mukaka, 2012). Highly correlated explanatory variables were excluded from logistic regression analysis to avoid multicollinearity², which can lead to an inaccurate estimation of model parameters and erroneous interpretation of odds ratios (Aguilera, Escabias, & Valderrama, 2006). Among highly correlated explanatory variables, only one explanatory variable was selected.

The logistic regression model development process was conducted iteratively to determine the most appropriate model. Explanatory variables that were not able to contribute in explaining remission of anxiety diagnoses were incrementally removed from the current model based on their respective p-value (the explanatory variable with largest p-value was removed first). The process was concluded when there was no remaining explanatory variable for analysis or a statistically significant model was found. IBM SPSS Statistics software version 24 was used to conduct logistic regression analyses.

For Aim 3, the goal was to identify usage patterns or behaviors of children who were free from anxiety diagnoses at post-treatment. The explanatory variables to satisfy Aim 3 include app use, time spent, Skills Coach use, reminder adherence, and proximity. The data type for the

 $^{^2}$ In statistics, multicollinearity is a phenomenon in which two or more predictor variables in multiple regression model are highly correlated.

variables for Aim 3 was continuous. For Aim 4, the goal was to identify demographics and clinical characteristics of children who were in remission at post-treatment. The explanatory variables for Aim 4 include age, gender, comorbidity, anxiety severity, and anxiety subtype. Among these variables, the data type for age and anxiety severity was continuous. The data type for gender, comorbidity, and anxiety subtype was categorical and coded as 0, 1, or 2 (0=male, 1=female; 0=primary anxiety only, 1=comorbid anxiety, 2=comorbid externalizing disorder; 0=absent, 1=present; respectively).

6.8 **RESULTS**

Informed consent was obtained from 39 participants. Among consented participants, two participants had consent withdrawal. Among 37 participants eligible for CBT treatment, two participants dropped out of treatment, and two participants had incomplete data. In this study, the data from 24 participants that completed CBT treatment were analyzed, including the five participants enrolled in beta testing and excluding the data from nine participants who are still in the treatment.

Participants at pre-treatment were between the ages of 9 and 14 (M=11.02, SD=1.62). Thirteen participants were male (54.2%) and 11 participants were female (45.8%). As shown in Table 8, among 24 participants, 33.33% participants (n = 8) had primary anxiety disorder only, 54.17% participants (n = 13) had primary anxiety disorder with comorbid anxiety, and 12.5% participants (n = 3) had primary anxiety disorder with comorbid externalizing disorder.

Variable	ANX	ANX/COM	ANX/EXT
Gender (n)			
Male	2	9	2
Female	6	4	1
Age (Mean; Standard Deviation)	M = 11.51,	M = 10.66,	M = 11.41,
	SD = 1.66	SD = 1.39	SD = 2.41
Severity (Mean; Standard Deviation)	M = 11.88,	M = 14.93,	M = 13.67,
	SD = 3.52	SD = 4.51	SD = 3.51

Table 8. Distribution of comorbid diagnoses and anxiety severity at pre-treatment

Note: ANX = primary anxiety disorder only (i.e., SAD, GAD, social anxiety disorder); ANX/

COM = primary anxiety disorder, and comorbid anxiety; ANX/EXT = primary anxiety disorder, and comorbid externalizing disorder.

Table 9. Descriptive statistics of SUS score, user engagement, app retention, reminder adherence, and proximity

Measure	Minimum	Maximum	Mean (SD)
SUS Score (App)	45	100	86.15 (13.87)
User Engagement (across duration of tre	eatment)		
App Use	12	385	96.63 (78.99)
Male	24	251	89.54 (16.86)
Female	12	385	105 (29.81)
Time Spent (minutes)	34.00	2012.08	282.41 (388.85)
Male	62.79	538.61	221.27 (38.86)
Female	34.00	2012.08	354.67 (168.85)
App Retention (per session)			
App Use	1.71	55	13.93 (11.23)
Male	3.43	35.86	12.81 (2.41)
Female	1.71	55.00	15.26 (4.22)
Time Spent (minutes)	4.86	287.44	40.43 (55.51)
Male	8.97	76.94	31.61 (5.55)
Female	4.86	287.44	50.67 (24.12)
Reminder Adherence	15%	71%	40.21% (15.9%)
Male	17%	50%	36% (3%)
Female	15%	71%	45.45% (6%)
Proximity per day (hour)	0.22	11.34	2.11 (2.35)
Male	0.45	11.34	2.45 (0.80)
Female	0.22	4.45	1.71 (0.46)
Therapist-patient interaction	0	35	8.29 (7.64)

Table 9 (cont'd)	Tał	ole 9	(con	ťd)
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Male	2	10	6.08 (2.33)
Female	0	35	10.91 (10.66)

The participants rated the app as acceptable with an average SUS score of 86.15 (SD = 13.87). Using Table 6 as a reference, the app received an A+ grade, suggesting that the app is more usable than 96% of the products in the Sauro (2011) database.

As shown in Table 9, on average, the participants spent 282.41 (SD=388.85) minutes on the app (about 4 hours and 42 minutes) completing 96.63 (SD=78.99) skillbuilder modules throughout the duration of CBT treatment. Between sessions, they completed 13.93 skillbuilder modules (SD=11.23) spending 40.43 (SD=55.51) minutes on the app. These data suggest that they were sufficiently involved in the treatment. Although the participants were sufficiently involved in the treatment, keeping their smartphone within arm's reach for 2.11 (SD=2.35) hours per day (about two hours and 11 minutes per day), their adherence to reminders averaged 40.21% (SD=15.9%) across the duration of treatment. The participants could communicate with their therapists beyond office visits, exchanging an average of 8.29 (SD=7.64) messages with their therapists.

The average (represented by the wide horizontal line on each boxplot) and the median of app use were higher during the first week and started to level off towards the end (Figure 34). App use above 60 was considered an outlier and was not included. The high usage frequency during the first week might indicate that the participants were excited about the app, although after session 5, several participants were using the app more extensively.

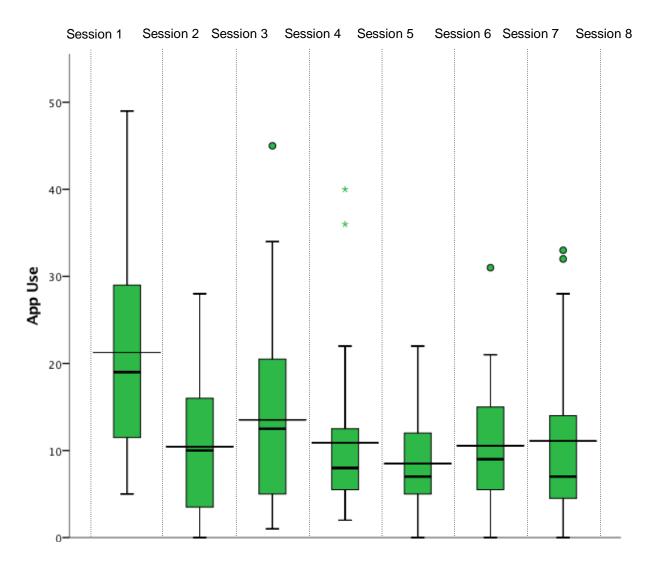


Figure 34. SmartCAT 2.0 usage frequency. Usage data were collected after Session 1 and calculated at the end of Session 8

The participants were using a different set of skillbuilder modules between sessions suggesting their willingness to learn different set of skills. As illustrated in Figure 35, the interactive skillbuilder modules (i.e., "What's the feeling?", Thought-buster, Thought-swapper, and Problem-solver) were completed more frequently than the other modules between sessions. This suggests that children are more motivated and likely to engage in learning CBT skills using an interactive and fun learning environment such as games.

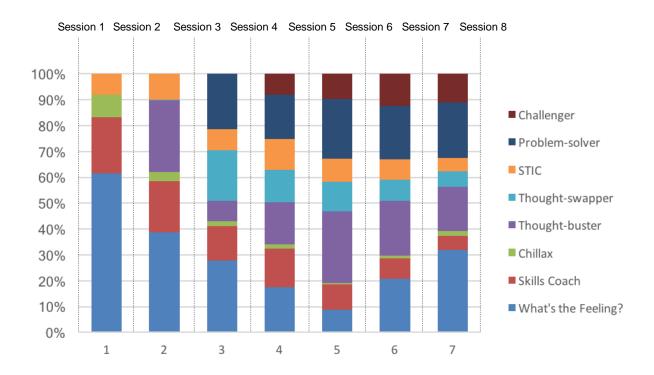
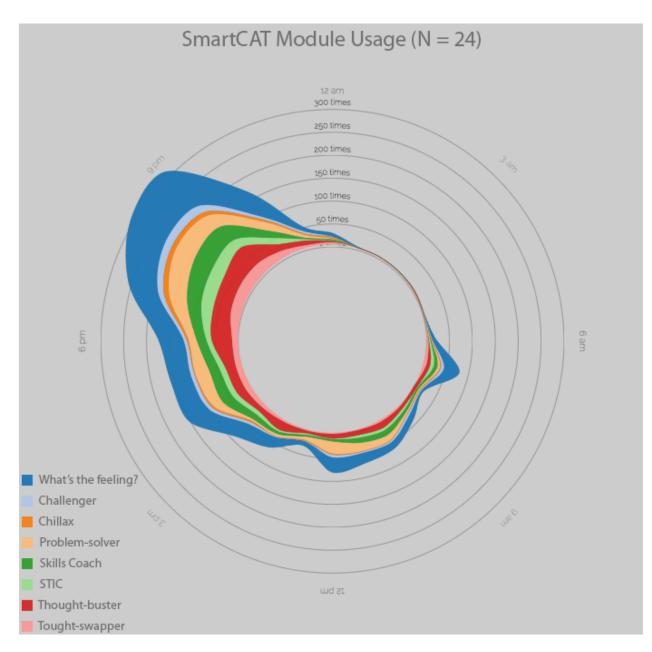
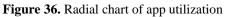


Figure 35. Skillbuilder module usage between sessions

As can be seen in Figure 36, the app was generally being used beyond school time (before 8AM or after 3PM). Some of the participants who were enrolled in the study during summer however could use the app during school time. App utilization reached its peak between 7PM-9PM, despite most reminders being scheduled by therapists around 6PM-8PM (Figure 37). During this time range, the "What's the feeling?" module was completed the most, followed by Thought-buster, Skills Coach, and Problem-solver. The figure also indicates that the lowest app utilization was around midnight, breakfast time (8AM), or lunchtime (1PM).





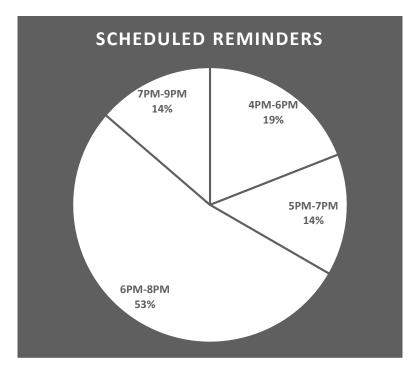


Figure 37. Reminders scheduled by therapists

6.8.1 The Effectiveness of Gamification

Table 10 presents the summary of user engagement of the previous (SmartCAT 1.0) and the gamified (SmartCAT 2.0) version, respectively. The assumption of equal variance based on the median was examined using Levene's test. The assumption was satisfied (p=.268 for time spent; p=.091 for app use). A two-tailed Mann-Whitney U-test (α = .10) was conducted to test whether SmartCAT 2.0 has higher user engagement rate than SmartCAT 1.0. The test indicated that participants were using SmartCAT 2.0 more frequently (*Median* = 82.5) than SmartCAT 1.0 (*Median* = 39), U = 34.00, p < .01, with a large effect size, *Cohen's* r = .52. The test also indicated that the participants spent time longer using SmartCAT 2.0 (*Median* = 184.97) than SmartCAT 1.0 (*Median* = 106.03), U = 64.00, p = .075, with a medium effect size, *Cohen's* r = .31.

Table 10.	User	engagement	by	system
-----------	------	------------	----	--------

System	Number of Participants	Engagement (across duration of treatment)						
		Time Spent in Minutes Features Complete		mpleted				
		Mean (SD)	Median	Mean (SD)	Median			
SmartCAT 1.0	9	125.03 (12.76)	106.03	37.56 (15.40)	39			
SmartCAT 2.0	24	282.41 (388.85)	184.97	96.63 (78.99)	82.5			

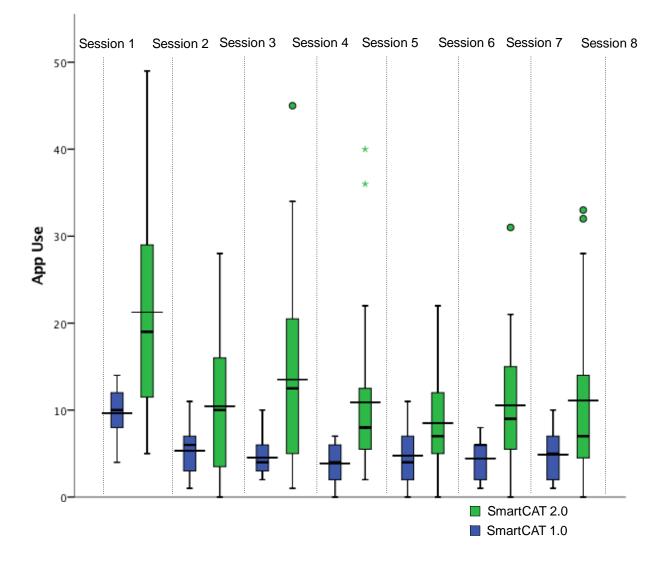


Figure 38. SmartCAT 1.0 vs. SmartCAT 2.0 usage frequency. Usage data were collected after Session 1 and calculated at the end of Session 8

Figure 38 shows the app retention of SmartCAT 1.0 compared to that of SmartCAT 2.0. App use above 60 was considered an outlier and was not included. SmartCAT 2.0 was used more often than SmartCAT 1.0 between sessions. The pattern of use between the two systems however was arguably consistent. In other words, both systems were highly utilized earlier in the session but then leveled off towards the end.

6.8.2 Usage Pattern and User Behaviors as Explanatory Variables that Explain Remission of Anxiety

The initial step in developing the logistic regression model was to avoid multicollinearity between explanatory variables using correlation analysis. Prior to correlation analysis, the Shapiro-Wilk test of normality of variables (i.e., app use, Skills Coach use, time spent, reminder adherence, proximity) was conducted to determine the appropriate correlation coefficient (Pearson's product-moment coefficient vs. Spearman's rank-order coefficient). All explanatory variables, except reminder adherence, violated the assumption of normality. Therefore, Spearman's rank-order correlation was utilized. Table 11 shows the correlation among the variables. There was a relatively strong, positive correlation between app use and Skills Coach use, which was statistically significant ($\rho = .638$, p < .01). There was a moderately positive correlation between reminder adherence and proximity ($\rho = .400$, p = .053), suggesting that participants who kept their smartphone within arm's reach longer were more adherent to reminders. App use and time spent was highly correlated, which was statistically significant ($\rho = .943$, p < .01). For this reason, the time spent variable was excluded for analyses.

		App Use	Skills Coach Use	Time Spent	Reminder Adherence	
App Use	Spearman's p	1.000				
	Sig. (2-tailed)					

Table 11. Correlation matrix of usage patterns and user behaviors

Table 11	(cont'd)
----------	----------

	N	24				
Skills Coach	Spearman's p	.638**	1.000			
Use	Sig. (2-tailed)	.001	•			
	N	24	24			
Time Spent	Spearman's p	.943**	.638**	1.000		
	Sig. (2-tailed)	.000	.001	•		
	N	24	24	24		
Reminder	Spearman's p	.205	136	.270	1.000	
Adherence	Sig. (2-tailed)	.335	.527	.202		
	N	24	24	24	24	
Proximity per	Spearman's p	.181	010	.217	.400	1.000
day	Sig. (2-tailed)	.397	.963	.309	.053	
	N	24	24	24	24	24

**. Correlation is significant at the 0.01 level (2-tailed).

A logistic regression analysis was conducted to explain remission of anxiety at posttreatment for 24 participants using app use, Skills Coach use, reminder adherence, and proximity as explanatory variables. As shown in Table 12, the Score test was conducted to measure the contribution of each explanatory variable in explaining remission. The test indicates that app use, Skills Coach use, reminder adherence, and proximity are not useful in classifying remission.

Table 12. Score test of app use, Skills Coach use, reminder adherence, and proximity

Explanatory Variable	Score	P-value	df
App use	2.655	.103	1
Skills Coach use	.254	.614	1
Reminder adherence	2.366	.124	1
Proximity	1.389	.239	1

As shown in Table 13, a test of the full model against a constant only model was not statistically significant, indicating that the variables as a set did not reliably distinguish between remitters and non-remitters of BCBT + m-Health treatment ($\chi^2 = 7.614$, p = .107 with df = 4).

Follow up analyses were also conducted with a combination of explanatory variables in the set. The tests were not statistically significant.

							95% C.I.fe	or EXP(B)
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
App Use	032	.023	1.944	1	.163	.969	.926	1.013
Skills Coach Use	.125	.099	1.575	1	.209	1.133	.932	1.377
Reminder Adherence	-1.807	3.593	.253	1	.615	.164	.000	187.976
Proximity per day	145	.211	.467	1	.494	.865	.572	1.310
Constant	3.148	1.814	3.013	1	.083	23.292		

Table 13. Usage pattern and user behaviors variables in the equation

6.8.3 Demographic and Clinical Characteristics as Explanatory Variables that Explain

Remission of Anxiety

Similarly, the initial step in developing a logistic regression model was to avoid multicollinearity between explanatory variables using correlation analysis. The variables consisted of a mix between continuous (age, anxiety severity) and categorical (gender, anxiety subtype, and comorbidity) data types. For this reason, the Shapiro-Wilk test of normality on anxiety severity and age was conducted prior to correlation analysis to determine the appropriate correlation coefficient (Pearson's product-moment coefficient vs. Spearman's rank-order coefficient). The assumption of normality was violated. Therefore, Spearman's rank-order correlation was utilized. Table 14 shows the correlation among the variables. Highly correlated variables were not found, indicating that all explanatory variables could be included for analyses.

		Age	Gender	Comorbidity	Anxiety Severity	Anxiety Subtype
Age	Spearman's p	1.000				
	Sig. (2-tailed)					
	N	24				
Gender	Spearman's p	.217	1.000			
	Sig. (2-tailed)	.307				
	N	24	24			
Comorbidity	Spearman's p	151	371	1.000		
	Sig. (2-tailed)	.481	.075			
	N	24	24	24		
Anxiety	Spearman's p	.165	170	.270	1.000	
Severity	Sig. (2-tailed)	.442	.428	.202		
	N	24	24	24	24	
Anxiety	Spearman's p	007	048	.132	.028	1.000
Subtype	Sig. (2-tailed)	.974	.823	.539	.897	
	N	24	24	24	24	24

Table 14. Correlation matrix of demographic and clinical characteristics

*. Correlation is significant at the 0.05 level (2-tailed).

A logistic regression analysis was conducted to explain remission of anxiety at posttreatment for 24 participants using age, gender, anxiety severity, anxiety subtype, and comorbidity as explanatory variables. As shown in Table 15, the Score test was conducted to measure the contribution of each explanatory variable in explaining remission. The test indicates that age, gender, anxiety severity, anxiety subtype, and comorbidity are not useful in classifying remission.

Explanatory Variable	Score	P-value	df
Age	.035	.852	1
Gender	1.343	.247	1
Anxiety severity	3.794	.051	1
Anxiety subtype	.00	1.000	1
Comorbidity	2.524	.283	2

Table 15. Score test of age, gender, anxiety severity, anxiety subtype, and comorbidity

As shown in Table 16, a test of the full model against a constant only model was not statistically significant, indicating that the variables as a set did not reliably distinguish between remitters and non-remitters of CBT + m-Health treatment ($\chi^2 = 9.111$, p = .167 with df = 6). Follow up analyses were also conducted with a combination of explanatory variables in the set. The tests were not statistically significant.

							95% C.I.for EXP(B)	
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age	.004	.403	.000	1	.992	1.004	.456	2.211
Gender(1)	-2.271	1.364	2.773	1	.096	.103	.007	1.495
Anxiety Severity PARS	198	.187	1.120	1	.290	.821	.569	1.184
Comorbidity			2.218	2	.330			
Comorbidity(1)	-2.590	1.744	2.206	1	.137	.075	.002	2.288
Comorbidity(2)	-1.876	1.869	1.007	1	.316	.153	.004	5.980
Anxiety Subtype(1)	.574	1.188	.234	1	.629	1.776	.173	18.221
Constant	5.707	4.914	1.349	1	.245	300.949		

 Table 16. Demographic and clinical characteristics in the equation

6.8.4 Therapists' Technology-related Efforts

To determine therapists' technological efforts when delivering BCBT + m-Health treatment, the portal was equipped with a logging system that records therapists' activities on the portal. This includes login time, logout time, device used by the therapists (computer vs. mobile device), different type of pages accessed by the therapists (i.e., home page, reminder/module management page, review page, messaging page, and reward management page), and the length of time the therapists spent on a page.

The therapists rated the portal as acceptable with an average SUS score of 86.56 (SD = 15.48). Using Table 6 as a reference, the portal received an A+ grade, a similar grade received by

the app. As shown in Table 17, the therapists provided CBT treatment to an average of four patients every week, spending an average of 44.35 minutes (SD = 24.56 minutes) interacting with the portal. Portal visits were averaged 10.35 times (SD = 5.27), suggesting that the therapists might visit the portal at least twice per week when delivering treatment to one patient. Each portal visit took an average of 5.5 minutes. The number of secure messages received by the therapists varied from one per week to six per week (M=2.03, SD=1.56).

Table 17. Descriptive statistics of SUS score, weekly number of visits, weekly time spent, and the number of

Measure	Minimum	Maximum	Mean (SD)
SUS Score (Portal)	47.5	100	86.56 (15.48)
Number of visits (per week)	1	23	10.35 (5.27)
Therapist #1	1	17	9.4 (4.96)
Therapist #2	1	23	11.30 (5.59)
Time spent in minutes (per week)	.3	107.47	44.35 (24.56)
Therapist #1	.3	91	43.62 (25.30)
Therapist #2	3.42	107.47	45.07 (23.82)
Number of patients reviewed (per week)	1	6	$3.45(.98) \approx 4$
Therapist #1	1	5	$3.32(1.16) \approx 3$
Therapist #2	2	6	$3.60(.81) \approx 4$
Number of messages sent (per week)	1	3	1.21 (.52)
Therapist #1	1	2	1.16 (.37)
Therapist #2	1	3	1.27 (.57)
Number of messages received (per	1	6	2.03 (1.56)
week)			
Therapist #1	1	4	1.50 (1.07)
Therapist #2	1	6	2.55 (1.81)

patients reviewed per week

Figure 39 and Figure 40 illustrate different features of the portal accessed by the therapists at different times. Often, the portal was being accessed during office hours (9AM-5PM), although on some occasions the therapists could access the portal during the night or early in the morning beyond their conventional office hours. The home page of the portal, which is the

default landing page after successful authentication, was the only page accessed the most by the therapists (see Figure 41). One therapist (Therapist #2) accessed the messaging feature more frequently suggesting that the therapist received more electronic messages from his/her patients.

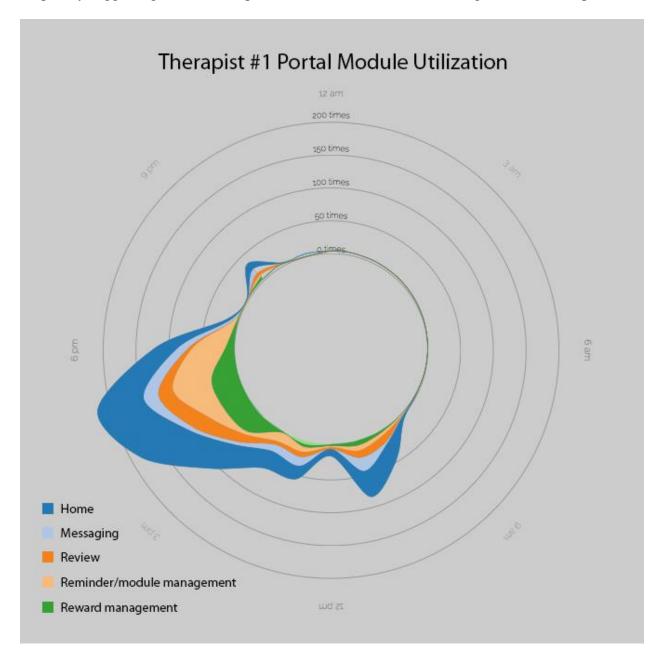


Figure 39. Therapist #1 portal page utilization

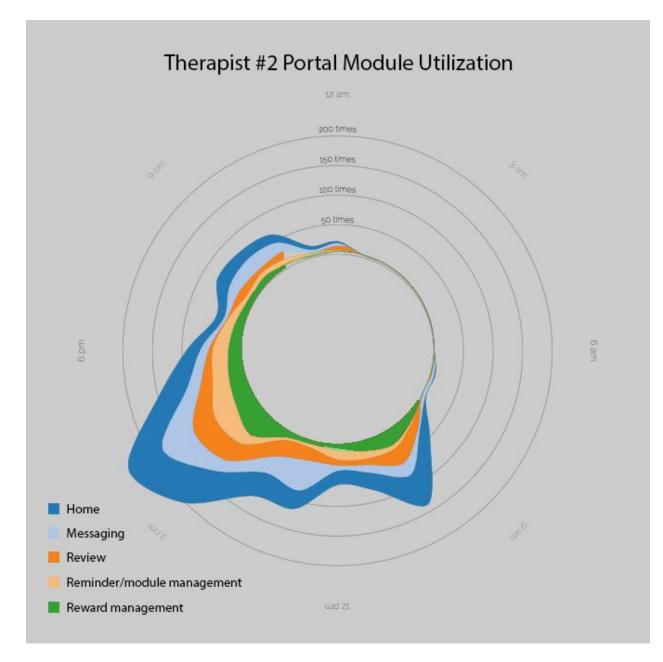


Figure 40. Therapist #2 portal page utilization

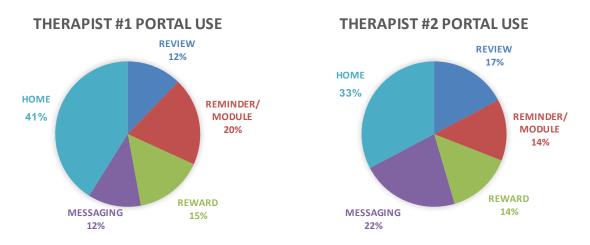


Figure 41. Portal page utilization by therapists

On the home page, the therapists spent approximately a minute examining the summaries of each patient's progress, or any incoming messages from patients. Although frequently accessed, the home page of the portal was not the page that the therapists spent most of their time on. As shown in Figure 42, on average, they spent two minutes of their time on the review page reviewing Skills Coach, STIC, or Challenger module entries from the past week with their patient. It is worth mentioning that the amount of time spent on this page depends on the number of entries sent by the patients. Based on the subsequent discussion with their patient, the therapists selected relevant modules and ranges of time that the reminders should go off for the upcoming week using the reminder/module page, which took approximately a minute to complete. Every two or three weeks, the therapists were also required to setup new target points for their patient using the reward page. They could complete the task in under a minute. In addition, they spent approximately one minute on the messaging page when sending/replying messages to/from their patients.

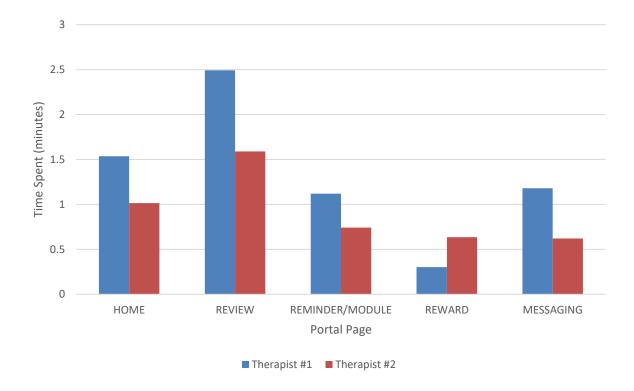


Figure 42. Average time spent on different portal pages

6.9 **DISCUSSION**

The participants were satisfied with the visual appearance of the app, and felt comfortable using the app and making it a part of their daily routines. They stated that the app was easy to use and found it helpful when they were experiencing anxiety. On average, the app was used twice a day. The participants used the secure messaging feature of the app to communicate with their therapist when they encountered problems with the app, wanted to share their enjoyment when receiving in-app rewards (i.e., a star, a trophy), wanted to share their worries and asked for guidance, or wanted to ask treatment related question (i.e., what does FEAR plan stand for, difficulties conducting exposure tasks). The therapists used the portal to deliver CBT treatment accordingly. The therapists were satisfied with the visual appearance of the portal and were comfortable using the portal and making it a part of their therapy session routines. The portal allowed therapists to track patients' weekly progress and could provide verbal reinforcements to patients when necessary. To treat a patient, the therapist visited the portal twice a week —potentially one visit during therapy session, and another visit beyond therapy session— spending about four to five minutes per visit. When delivering CBT treatment, the therapists also received an average of two messages per week. Although the use of the portal and the ability to communicate beyond office visits may introduce an additional burden for CBT therapists, they were willing to visit the portal beyond office hours and viewed communicating with their patients by electronic messages very favorably.

Overall, the results of clinical implementation indicate that the gamified SmartCAT system has been used as expected. SmartCAT 2.0 was used twice as much as SmartCAT 1.0, suggesting that the inclusion of gamification effectively increased user engagement and app retention.

Although effective, the effects of gamification were not uniformly experienced by all participants. During the clinical implementation, one patient did not use the app often, completing only 12 skillbuilder modules throughout the treatment. The patient was not motivated to use the app and was diagnosed and referred for depression treatment at post-treatment, suggesting that depressive symptoms may interfere with engagement. Five other patients used the app more often but less than an average of seven times between sessions (less than 49 times across the duration of treatment). Despite using the app less often, four of them were free from anxiety diagnoses at post-treatment. As they got better, they might view the app as less useful,

thus initiating the app less often. This also suggests that the implementation of gamification does not always lead to significant increases in user engagement. As previous studies on player motivations suggest, intrinsic (psychological needs) and extrinsic (i.e., desired outcome, expectations) motivators can differentially influence the way people interact with game-like systems (Bostan & Barbaros, 2009; Yee, 2006). Thus, user experience created by gamifying motivational affordances are likely to differ (Huotari & Hamari, 2012).

Post-treatment analysis revealed that remission of anxiety was not associated with app utilization or behaviors of the children when using the app. The four patients mentioned above, for example, recovered from their anxiety diagnoses at post-treatment despite using the app less often. One patient who used the app the most, completing 385 modules across duration of treatment, however did not recover from anxiety at post-treatment. Consistent with findings from several studies (Berman, Weems, Silverman, & Kurtines, 2000; Kendall et al., 1997; Shortt, Barrett, & Fox, 2001; Silverman et al., 1999a), demographic characteristics (i.e., age, gender) and comorbidity were not associated with a remission of anxiety at post-treatment. Although a recent meta-analysis (Compton et al., 2014) reported that anxiety severity, and principal diagnosis of social anxiety disorder were associated with less favorable treatment outcomes, the results of logistic regression analyses failed to detect such association.

At post-treatment, 16 out of 24 participants were free from DSM-V diagnoses of GAD, SAD, and social anxiety disorder (remission rate = 66.67%). Compared to the 60% remission rate of full-length CBT (Kendall, 1994; Kendall et al., 1997; Rapee, 2000; Walkup et al., 2008), the remission rate reported in this study was very encouraging.

7.0 CONCLUSION

An m-Health system can be successfully integrated into CBT for children with anxiety disorders but can also be exhausting and tedious for children. Integrating gamification techniques and interactive features to the system increase children's involvement in CBT treatment and facilitate CBT skills practice beyond the clinic.

The integration of m-Health into CBT may introduce additional burdens to CBT therapists in the community. This includes the requirement to interact with the portal when preparing for sessions and to interact with patients between sessions via secure text messaging. This technology-related burden however is minimal, as the portal allows the therapists to view patient's progress and data with the patient at the beginning of the session (similar to viewing patient's homework during session in standard CBT), Furthermore, the therapist can assign predefined weekly activities/modules for the upcoming session at the end of the session (which takes a minute or less to perform). It is also becoming increasingly common for insurance companies to offer "eVisit reimbursement" for interactions with patients via electronic methods such as text messaging (Tang, Black, & Young, 2006).

There are several obstacles that may prevent anxious children from receiving CBT treatment in the community. First, most CBT programs for childhood anxiety require a significant time commitment from families. Many families may be unable to commit to a 4-5 month treatment due to scheduling and transportation difficulties (Collins et al., 2004). Second,

in most communities, the availability of CBT therapists is limited (Collins et al., 2004; Crits-Christoph, Frank, Chambless, Brody, & Karp, 1995), meaning that existing CBT therapists tend to have lengthy waitlists. Third, costs associated with longer treatment present challenges to healthcare consumers and providers (Nelson, Steele, & Mize, 2006). The integration of m-Health gamification with CBT appears to be a promising avenue to provide effective treatments in a shorter period of time, potentially improving dissemination, faster amelioration of symptoms, and promoting healthcare affordability.

7.1 LIMITATIONS

One limitation of this dissertation is the relatively small sample size used in clinical implementation. Although the number of participants was more than sufficient to assess general usability of the system and determine its utilization in an uncontrolled clinical trial, it may not be sufficient to detect the relationships and strengths among the variables in Aim 3 and Aim 4. As described by Burns & Burns (2008) and Peduzzi et al. (1996), logistic regression recommends a minimum of 50 cases per independent variable due to its use of maximum likelihood estimation.

The second limitation is that the usage patterns observed at post-treatment may not reflect realistic usage patterns, as the patients who already have iPhones or Windows phones were not able to use the app on their own smartphones.

The third limitation is the assumption that the actual users of the app were the children enrolled in clinical implementation. It was not possible to verify that the children were the ones who completed the app and not somebody else.

7.2 FUTURE DIRECTIONS

As the results showed good acceptability and usefulness not only among anxious youth receiving m-Health with BCBT treatment but also among CBT therapists, the next step would include conducting larger randomized clinical trials (RCTs) to compare the effects of BCBT vs. m-Health with BCBT on treatment outcomes. This can better assess whether the integration of m-Health systems within BCBT can improve treatment outcomes.

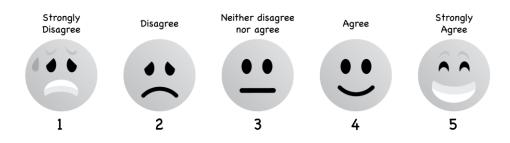
Future works may also include exploring the effectiveness of delivering m-Health with BCBT treatment in community settings. CBT for child anxiety remained underutilized (Kendall, Settipani, & Cummings, 2012) in the community. The integration of an m-Health system can facilitate dissemination given the rapid rise of smartphone ownership (Torous, Friedman, & Keshavan, 2014) and the large amount of time the children spend with technology (Madden et al., 2013). To support this effort, the app should be adapted to other operating systems (i.e. iOS), as Android and iOS are currently dominating the smartphone market share (International Data Corporation, 2016).

APPENDIX A

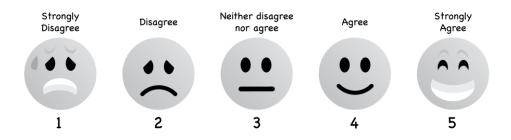
SYSTEM USABILITY SCALE (APP)

Modified from: The System Usability Scale (SUS) © Digital Equipment Corporation, 1986. **Instructions:** Please tick the box that most closely describes your level of agreement with the following ten statements about the smartphone app. A response of "1" indicates that you strongly disagree with the statement. A response of "5" indicates that you strongly agree with the statement. A response of "3" indicates that you neither disagree nor agree with the statement.

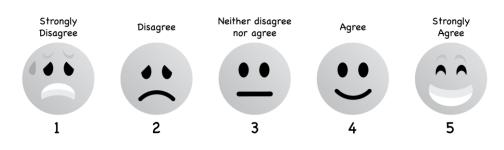
1. I think that I would like to use this app often.



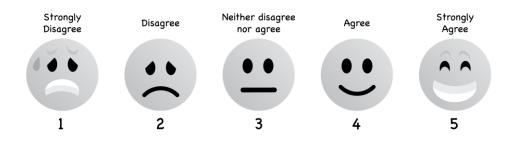
2. I found the app to be simple.



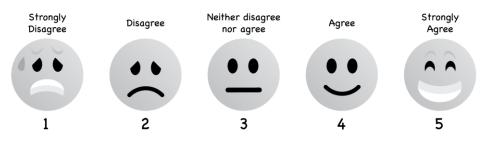
3. I thought the app was easy to use.



4. I think that I could use the app without help from someone who is an expert at using technology.

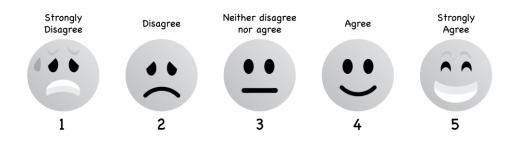


5. I found that the different games and activities in the app worked well together.

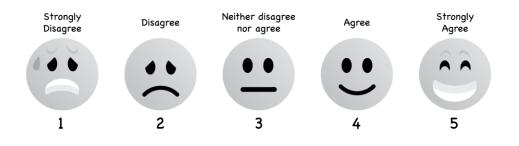


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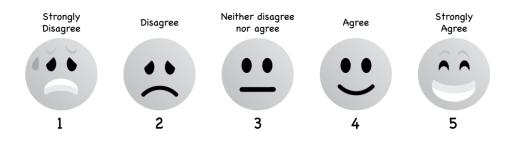
6. I thought that parts of the app (such as title and "next" button) were in the same places throughout the activities and games, making them easy to find.



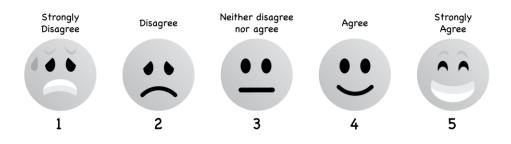
7. I would imagine that most people would learn to use this app very quickly.



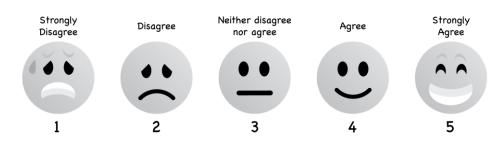
8. I figured out how to use the app very easily without needing help.



9. I felt sure that I knew what I was doing while using the app.



10. I could use the app without having to learn anything new.



APPENDIX B

SYSTEM USABILITY SCALE (PORTAL)

Modified from: The System Usability Scale (SUS) © Digital Equipment Corporation, 1986. Instructions: Please tick the box that most closely describes your level of agreement with the following ten statements about the clinician portal. A response of "1" indicates that you strongly disagree with the statement. A response of "5" indicates that you strongly agree with the statement. A response of "3" indicates that you neither disagree nor agree with the statement.

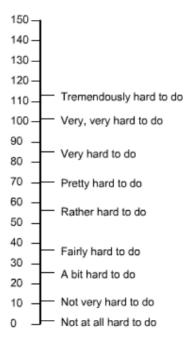
- 1. I think that I would like to use this portal frequently
- 2. I found the portal to be simple
- 3. I thought the portal was easy to use
- 4. I think that I could use the portal without the support of a technical person
- 5. I found the various functions in this portal were well integrated
- 6. I thought there was a lot of consistency in this portal
- 7. I would imagine that most people would learn to use this portal very quickly
- 8. I found the portal very intuitive
- 9. I felt very confident using the portal
- 10. I could use the portal without having to learn anything new

Strongly disagree				Strongly agree
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

APPENDIX C

SUBJECTIVE MENTAL EFFORT QUESTIONNAIRE

Instructions: Using web browser, go to the online version at <u>www.usablesurveys.com</u>. Once the web page is loaded, please slide the red slider with a mouse to the point in scale that represents your judgment of difficulty. Please remember to click the submit button to reveal the actual score.



APPENDIX D

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

[Please see the next page]



3137 Sennott Square 210 South Bouquet Street Pittsburgh, PA 15260 412-624-4500

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY TITLE: Using Smartphones to Enhance Treatment of Childhood Anxiety (Smart-CAT)

PRINCIPAL INVESTIGATOR:

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CO-INVESTIGATORS: Neal D Ryan, MD Western Psychiatric Institute and Clinic University of Pittsburgh School of Medicine 3811 O'Hara Street, Pittsburgh, PA 15213 Telephone: 412-383-5477

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SOURCE OF SUPPORT: National Institute of Mental Health

What is informed consent?

Federal regulations require that you are informed about research studies that you and your child have volunteered for before your child participates in them. The follow Page 1 of 10

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information explains the aims, procedures, risks, benefits, restrictions, and requirements of this research study. Signing this form will indicate that this study has been explained to you and your child, and that you agree to allow your child to participate in the study.

Why is this research being done?

Your child is being asked to participate in a study examining how smartphones may be used to enhance treatment for children who have anxiety disorders. We hope to learn whether smartphones can be used to increase the benefit that children receive from treatment of childhood anxiety disorders. This could benefit individuals who suffer from anxiety and the professionals who help them.

Who is being asked to take part in this research study?

Your child is being asked to participate in this study to test a smartphone app that is designed to help other children like him/her. The study will take place at the Families, Emotion, Neuroscience, and Development (FEND) Lab as well as in your child's home environment. 30-35

What is a smartphone?

A smartphone is a handheld device that lets you make telephone calls, but also lets you perform actions that you might find on a personal digital assistant or a computer. A smartphone has wireless access to the internet and can run "apps". Apps are pieces of software which help you to perform a specific task like check the weather, set a reminder to take a medication or receive a message from someone.

What procedures will be performed for research purposes?

If you decide to take part in this research study, your child will undergo the following procedures. If a person decides to withdraw from the study, they will need to turn in their smartphone at the time of withdrawal.

Screening Procedures and Questionnaires:

During this visit, you and your child will be interviewed by an experienced clinician about your child's psychiatric history, mood and other problems he or she may have experienced. You and your child will also be asked to fill out other questionnaires about his or her moods, feelings and behaviors. We expect that it will take both you and your child 2-3 hours to complete the activities in this visit. A member of our research staff will be available to answer any questions you or your child may have about the questionnaires. The interviews may also be videotaped and reviewed by research staff and their supervisors to ensure that interviews are being conducted consistently. After this interview, your child will be told whether or not he or she qualifies to continue in the study.

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Pre-Treatment Measures:

Families who are deemed eligible to participate in this study based on the initial interview will be invited to the lab to complete a series of questionnaires and tasks in which your child will hear stories depicting social situations and asked to rate how they would handle the situations. Stories will be played through audio recordings or read by a research staff member. You and your child will also be asked to complete questionnaires rating his/her moods and behaviors. This visit will last approximately 1 hour.

Therapy Sessions and Smartphone Protocol:

Upon completing the procedures described above in the first visit, your child will begin an 8 week course of talk therapy called Cognitive Behavioral Therapy (CBT), which is an empirically validated treatment for anxiety disorders in children and adolescents. CBT is an intervention that follows a specific step by step program to decrease symptoms of anxiety. This intervention will be supplemented with a home-based protocol in which your child will be asked to answer questions about his/her moods and daily experiences using a study-provided smartphone, described below. Your child will receive an electronic notification once per day that will alert him/her that they should complete these questions using the smartphone app. The smartphone app will also contain interactive games and activities designed to help your child practice skills he/she will learn during CBT sessions in his/her daily life. The games and activities may be launched at your child's discretion or the app may be programmed to launch during times or locations that you or your child identify as the times and locations where he/she typically experiences increased worries, fears or anxiety using the GPS function on the smartphone. You or your child may turn this feature on or off as desired. Each week, your child's therapist will review his/her responses to the questions and provide feedback during therapy. The therapist assigned to your child will video tape all sessions. The only people that will view these tapes are the therapist's supervisors and authorized research personnel. Therapy supervision is provided by investigators or co-Investigators who are working on this research center's studies. This way the supervisors can rate the therapists and provide feedback to therapists to ensure that they are providing optimal therapy for your child. Any information collected on video tape will be coded with an identification number only. These videos will be saved on DVDs. The DVDs will be in no way linked to your child by name. These DVDs will be stored in a locked file cabinet to which only authorized research members have access.

If your child's anxiety worsens or if he/she begins to exhibit more serious psychiatric symptoms during the course of the assessments or interventions, you will be offered a referral for appropriate treatment. If more intensive treatment is needed, a referral will be made for your child to the Department of Child and Adolescent Psychiatry at WPIC, or other appropriate sites, as determined by the research staff, all of whom will be familiar with mental health resources in the community. In that event, your child would not be able to remain in the study. In addition, if your child indicates that he/she wants to harm him/herself, the interviewer or therapist will assess the severity of your child's intent and Page 3 of 10

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will consult with the study psychiatrists/psychologists. With written permission from you, they will consult with your child's other care providers. Appropriate intervention or follow up care will be arranged by the child's study therapist. If it seems as though hospitalization may be required, the study therapist will refer the subject to the Diagnostic Evaluation Center at WPIC. Also, if following study provided treatment, you feel that your child needs an alternative form of intervention, research staff will help to arrange treatment for your child with your own provider.

During CBT, your child might be asked to talk with other children and adolescents or adults in order to practice managing his/her anxiety. Your child might also be asked to leave the building with their therapist. This is to allow your child to become more comfortable in situations that make them feel anxious by gradually exposing them to the specific situation. He/she may be asked to wear a small electrode on the palm of his/her hand during one or more of these occasions. This is to measure his/her level of physiological activation by measuring skin conductance through sweat on the skin. The electrode contains an adhesive backing and is applied in the same way one might apply a sticker or small bandage.

Smartphone Protocol:

During a home-based protocol, your child will be asked to answer questions about his/her moods and daily experiences or complete interactive games on the phone once per day throughout the course of CBT. Your child will be given a pre-programmed smartphone on which they will enter their responses to a series of questions about moods and daily experiences and complete games using an app developed for this study. Your child will receive an electronic notification similar to the sound they would hear when receiving a text message, and will be prompted through a series of questions about what he/she is doing, who he/she is with, how he/she is feeling, worries or stressful events, and how he/she coped with these events. We expect it should take your child approximately 5 minutes each time to complete the questions. Your child will only be prompted to answer these questions and complete the games outside of school hours and on weekends. Before each therapy session, your child's trained therapist will view the responses to these questions and use this information to tailor your child's treatment session to his/her real life experiences each week. The information from the week will also be summarized and displayed for your child to help him or her identify patterns in his/her thoughts, feelings, and ways of coping.

Daily Diary:

Parents will be asked to complete an online diary to keep track of what skills their child uses during the week. After completion of the initial interview visit, you will be asked to complete this diary once per day for seven days. After this seven day period, you will be asked to complete an entry in the diary twice per week throughout treatment. At the end of treatment, subjects will again be asked to complete the diary once per day for

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another seven days. Parents will be asked to complete the diary once per day for another seven days following the two-month follow-up interview. You will receive links to the online diary and instructions for completion via email. Diaries should take no longer than 10 min per day to complete. The data will be encrypted and stored securely through an online survey system. After all entries have been completed, you will be notified of your completion of the diaries.

Follow-Up Interview and Questionnaires:

After completing CBT therapy and the smartphone protocol, you and your child will be scheduled for a second visit to the FEND lab in Oakland to repeat the interviews about your child's psychiatric history, moods, and other problems he or she may have experienced. You and your child will also be asked to complete the same questionnaires about your child's moods and behaviors and your child will be asked to repeat the same skills measures that were completed prior to the start of their treatment. We expect that it will take approximately 2-3 hours to complete these activities. Two months later, you and your child will be scheduled for a third visit to the lab to repeat these interviews, questionnaires, and skills measures.

What are the possible risks, side effects, and discomforts of this research study?

While completing the interviews, questionnaires and smartphone questions, you and your child may become aware of feelings of happiness, sadness, or other mood states that he or she had not considered before. It is also possible that the questionnaires, interviews or smartphone questions or activities may make your child uncomfortable or embarrassed. You and your child may also become tired or bored during the questionnaires, interviews, or smartphone questions. If your child shows undue distress or discomfort at any time, the procedures will be stopped. You and your child will be encouraged to express any concerns and ask questions throughout the study. Further, if you have any questions, concerns, or discomfort arising from these procedures, you are encouraged to contact Dr. Silk or any of the Co-Investigators listed on the first page of this document.

The study provided smartphone will have internet and SMS text messaging services enabled. These services are necessary to signal your child to complete the daily questionnaire and activities in the app, as well as to communicate with his/her therapist. We have taken precautions to restrict app and content use of the phone; however we cannot guarantee that your child will not receive text messages or phone calls from unknown contacts. Complete control over internet and SMS text messaging services cannot be guaranteed. Therefore your child's use of the smartphone is at your discretion.

In any study, there is a minimal risk of breach of confidentiality. However, all records related to your involvement in this research study will be stored in a locked file cabinet.

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All database records related to you or your child's involvement in this research study will be stored with password protection. Information collected using the smartphone will be transferred using a secure two-way communication channel and no information will be accessible on the smartphone by phone companies. Additionally, in the event that the smartphone is lost, records may be remotely erased from the phone by research staff while being preserved on a secure study server.

What are possible benefits from taking part in this study?

Your child will receive a diagnostic evaluation and an empirically supported treatment for child anxiety. Knowledge gained from the study may also contribute to improvements in the prevention and treatment of anxiety for children.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study. The smartphone and the CBT treatment will be paid for by the study sponsor and therapy, will be provided by study therapists. You, or your insurance provider will be billed for routine care services, or services **not connected** with the study, and will be responsible for any associated co-pays, co-insurances, and deductibles.

Will I be paid if I take place in this research study?

You and your child will be paid a total of \$508 for completing all parts of this study (\$240 for your child and \$268 for you). If you and your child complete only part of the study, for any reason, you will be paid as follows:

Interview Only: If your child is not eligible after completing the initial screening interview, you will be paid a total of \$50, \$25 for your child and \$25 for you.

<u>Interview + Questionnaires:</u> You and your child will be paid a total of \$80 for completing the screening interview and questionnaires,\$25 for you and \$25 for your child for completing the interview, plus \$15 for you and \$15 for your child for completing questionnaires.

<u>Pre-Treatment Measures</u>: Your child will be paid a total of \$40 for completing the pre-treatment measures.

<u>Daily Diary</u>: Parents will be compensated up to a total of \$148 for completing the internet skills diaries throughout 8 weeks of treatment and the seven internet skills diaries at follow up. Parents are compensated \$4.00 per diary entry for up to 37 entries.

<u>Post-treatment Interview + Questionnaires:</u> You and your child will be paid a total of \$120 for completing the follow-up interview, questionnaires, and skills measures. (\$25 for you and \$25 for your child for completing the interviews, \$40 for your child for

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completing skills measures, \$15 for you and \$15 for your child for completing questionnaires.)

<u>Two Month Follow-Up Interview + Questionnaires</u>: You and your child will be paid a total of \$120 for completing the follow-up interview, questionnaires, and two month skills measures (\$25 for you and \$25 for your child for completing the interviews, \$40 for your child for completing two-month skills measures, and \$15 for you and \$15 for your child for completing questionnaires.

Who will know about my participation in this research study?

Any information about your child obtained from this research will be kept as confidential (private) as possible. All records related to your child's involvement in this research study will be stored in a locked file cabinet. All database records related to your child's involvement in this research study will be stored with password protection. Your child's identity on these records will be indicated by a case number rather than by his or her name, and the information linking these case numbers with your identity will be kept separate from the research records. Your child will not be identified by name in any publication of the research results unless you and your child sign a separate consent form giving you and your child's permission (release).

An exception to confidentiality is information on child abuse and neglect that is obtained during research. The investigator will report such information to the appropriate local (i.e., Children, Youth and Families [CYF]) or state agency as required by Commonwealth of Pennsylvania law. If information about abuse comes up that must be reported, or if a court order to release reports is received, an attempt will be made to inform you before CYF or any other agency is consulted. Within these bounds of confidentiality permitted by law, no information about you will be shared with any individual or agency without your prior consent.

If you have consented or do consent for your child to participate in a research study where an investigator is the same as an investigator listed on this protocol, the data from the studies may be joined.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will not involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to you or your child's participation in this research study:

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Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your child's identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your child's participation in this research study in response to an order from a court of law. If the investigators learn that you, your child, or someone with whom you or your child are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use, for the purposes described above, identifiable information related to your child's participation in this research study for a minimum of 7 years and for as long (indefinite) as it may take to complete this research study. No identifiable research data will be disclosed to those who are not members of this research team.

Is my child's participation in this research study voluntary?

Your child's participation in this study is completely voluntary. You may decide not to permit your child to participate, and your child may stop participating at any time, even after you sign this form. Your decision will not affect the care your child receives from WPIC or the University of Pittsburgh Medical Center, and will not affect yours or your child's current and future relationship with those facilities or with the University of Pittsburgh.

May I withdraw, at a future date, my consent for participation in this research study?

Yes. To do so, you must contact the investigators who are listed on the first page of this consent form. If you withdraw your child from this study, any research information that was collected prior to your withdrawal will continue to be used.

PARENT'S VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant	's (Parent's) Signature		Date		
•		Page 8 of 10			
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INTEREST IN PARTICIPATING IN FUTURE RESE	
Participant's (Parent's) Signature PARENT'S PERMISSION FOR CHILD'S PARTICII	Date PATION
Participant's (Child's) Name (Print)	
I understand that, as a minor (age less than 18 yea to participate in this research study without my con- my consent for his/her participation in this research	sent. Therefore, by signing this form, I give
Parent's or Guardian's Name (Print)	Relationship to Participant (Child)
Parent's or Guardian's Signature	Date
PERMISSION TO RELEASE INFORMATION TO C By signing this form, I request to have information r psychiatric evaluation and treatment progress to be understand that this information may be placed in r may withdraw my consent for the disclosure of my treatment progress to his/her health care provider a child's participation in this research study or other h	related to my child's research-related e disclosed to his/her health care provider. I ny child's medical record. I understand that I child's research related evaluation and and that doing so will not affect my or my
Parent's or Guardian's Signature	Date
Name of Practice:	
Name of Health Care Provider:	
Address of Practice or Health Care Provider:	
Street	City
Page 9 of 1	0
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State	Zip
Phone Number of Practice or Healthcare Provide	r: ()
CHILD'S ASSENT TO PARTICIPATE (for children ages 14-17, and less than 14 when a This research has been explained to me, and I ag	<i>developmentally appropriate)</i> gree to participate.
Participant's (Child's) Name (Print)	
Participant's (Child's) Signature	Date
*****	*****************
VERIFICATION OF EXPLANATION: I certify that I have carefully explained the purpos named child in age appropriate language. She or me in detail. I have answered all of his or her que agreement (i.e., assent) to participate in this rese	he has had an opportunity to discuss it with stions and she or he has provided affirmative arch study.
Investigator/Research Staff Member Signature	Date
*****	*************
CERTIFICATION OF INFORMED CONSENT I certify that I have explained the nature and purp individual(s), and I have discussed the potential b participation. Any questions the individual(s) have we will always be available to address future que research aspect of this protocol was begun until a	penefits and possible risks of study a about this study have been answered, and stions as they arise. I further certify that no
Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date

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