

Enhancing Symptom Monitoring Using Mobile Technology for Children and
Adolescents with Life -Threatening Illness

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Dissertation submitted in partial
fulfillment of the requirements for the degree
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ABSTRACT

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Abstract

Background: Children and adolescents with life-threatening illness such as cancer or undergoing blood and marrow transplantation experience significant symptom distress. Intense debilitating symptoms are the result of the disease and its treatment. Symptoms are under-recognized, under-reported, and thus undertreated in children leading to a cycle of ongoing and escalating symptoms placing them at risk for overall poor outcomes and decreased quality of life. Most research to better understand symptom distress in children and adolescents with life-threatening illness has been cross-sectional. Little longitudinal research has been conducted to advance understanding of symptom dynamics (occurrences, clusters, and trajectories). Advanced understanding of symptom dynamics can lead to the development of targeted personalized symptom management strategies.

Mobile Health (mHealth) has the potential to revolutionize our understanding of illness and the associated symptom dynamics by providing dense streams of real-time patient generated health data that can be collected when and where it occurs. Having children track and report their symptoms daily not only provides longitudinal patient generated health data, but also gives their “voice” to their symptom experience. Given the prevalence of mHealth technologies and the strong developmental fit for children and adolescents, the patient generated health data they produce are likely to enhance

our understanding of symptom dynamics, address knowledge gaps, and importantly inform precision health symptom management strategies.

This dissertation work was framed conceptually by the Theory of Unpleasant Symptoms (TUS). The TUS developed by Lenz guides exploration and evaluation of symptom dynamics by examining symptom characteristics (timing, intensity, duration, distress, and quality). Mobile health technology offers a unique opportunity to gather these real-time patient generated data for this purpose.

The purpose of this dissertation was to advance understanding of symptom dynamics (occurrences, clusters, and trajectories) in children and adolescents with life-threatening illness through the use of data from mHealth, describe and visualize these symptom data in a meaningful way, and explore patient and parent caregiver perspectives on the use of mHealth technologies to monitor symptom distress.

Knowledge gained from this body of work will inform this under-researched area, address gaps in symptom research in children and adolescents, advance knowledge of symptom dynamics and importantly, lead to precision health symptom management strategies.

Methods: After reviewing the literature, a survey study was conducted to inform the design of the study mobile application (app) to be used as the one of the study data collection tools. Next a pilot study (n=10) was conducted to test the study design, procedures, mobile devices, and mobile device data transmission. Finally, the main

dissertation study used an exploratory longitudinal mixed methods approach to explore the feasibility of monitoring symptoms in children and adolescents (n = 20) with life-threatening illness using mobile health technology, and developed symptom data visualizations from this data. Interviews with both patients and a parent caregiver (once during the study) were conducted to obtain their perspectives on the mobile technology use and the data visualizations.

Results: We successfully designed the study app, Technology Recordings for better Understanding Pediatric Blood and Marrow Transplant (TRU-PBMT) and Technology Recordings to better Understand Oncology for use as one of the symptom data collection tools in the preliminary and dissertation studies. Findings from the pilot study demonstrated that it was feasible to collect longitudinal symptom data on children and adolescents with life-threatening illness using a wearable and a study app. We found it necessary to use a different wearable than the original one based on participant feedback and found our study approach and procedures to be sound. The dissertation study demonstrated feasibility and acceptability for the use of two mobile devices to collect symptom data in children and adolescent with life-threatening illness. We developed data visualizations to illustrate symptom dynamics and found patients and parents to be captivated by the symptom patterns and asking to learn more. Interviews with participants and parents led to a better understanding of the use of mHealth technology

in symptom management and how individuals perceive, interpret, and make meaning of data visualized from these technologies.

Conclusion: This dissertation established the feasibility and acceptability of using two mobile technologies for monitoring symptoms and further explored opportunities to visualize this data in an effective and useful manner for acutely ill children and adolescents. Knowledge generated from this work advances symptom science research and offers a framework to guide other study designs in the incorporation of mobile technologies to enhance symptom management, and improve patient outcomes. Using mobile health technologies presents new possibilities to develop precision health symptom management strategies for both acute and chronic conditions leading to improved health outcomes and quality of life.

Dedication

To Faith and Scottie who inspired this work, and to my family, friends, and mentors whose support and encouragement made this work possible.

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1. Introduction

1.1 Symptom Science

Patients with chronic illness experience significant symptoms that affect their well-being and quality of life (Cashion, Gill, Hawes, Henderson, & Saligan, 2016). Symptoms are complex phenomena and are defined as subjective experiences that reflects change in a person's physical, social, or cognitive functioning (Dodd, Miaskowski, & Paul, 2001; Lee, Vincent, & Finnegan, 2017). Each symptom experience is highly individualized and may be influenced by a variety of factors; biological, psychological, and/or environmental (Brant, Dudley, Beck, & Miaskowski, 2016; Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Linder, Al-Qaaydeh, & Donaldson, 2018). Additionally, patients' may experience multiple symptoms at one time, and these symptoms may interact and intensify each other (Erickson et al., 2013; Lenz et al., 1997). Symptoms can be caused by the underlying disease or the treatment, and can change over time (Barsevick et al., 2013; Miaskowski, Dodd, & Lee, 2004).

The National Institute of Nursing Research (NINR) has prioritized symptom science (identifying and alleviating symptoms) as a strategic goal for nursing practice and research (Miaskowski, Barsevick, et al., 2017) and managing symptoms has been described as one hallmark of nursing practice (Cashion et al., 2016; Corwin et al., 2014). Symptom science has advanced significantly over the past decades (Barsevick et al., 2013; Corwin et al., 2014; Redeker et al., 2015) beginning with evaluation and

characterization of individual symptoms, then advancing to the examination of co-occurring symptoms and symptom clusters. (Dodd et al., 2001; Erdem & Toruner, 2018; Lenz et al., 1997; Miaskowski et al., 2004) Symptom scientists seek to understand the multidimensional and complex nature of symptoms to better identify and treat patients. Guided by evidence based theories and models, researchers describe, explain, or predict symptoms and use this knowledge to develop interventions. At present, most symptom science research focuses on the symptom dynamics (occurrences, clusters, and trajectories) of adults with chronic illness (Zhukovsky et al., 2015). Much less research has focused the symptom dynamics of children with life-threatening illness (Baggott, Cooper, Marina, Matthay, & Miaskowski, 2012; Linder et al., 2018; Zhukovsky et al., 2015) thus many gaps exist in our understanding of the symptom experiences of children and adolescents with life-threatening illness. In addition, most pediatric symptom research has been cross-sectional in nature, (Baggott et al., 2010; Barsevick et al., 2013; Hockenberry et al., 2017) limiting what is known about longitudinal symptom complexity, patterning, and how and why these symptoms change over time (Baggott et al., 2010; Buckner et al., 2014; Hockenberry et al., 2017). Finally, limited research has been conducted to advance understanding of symptom dynamics to characterize symptom phenotypes and target personalized symptom management strategies in children and adolescents with life-threatening illness.

In addition to limited longitudinal research, another significant gap in our knowledge of the pediatric symptom experience is that symptoms in seriously ill children are often poorly recognized and often reliant on parents to identify and/or communicate them to clinicians (Brock, Wolfe, & Ullrich, 2018; Irwin et al., 2012; Sourkes, 2018; Zhukovsky et al., 2015). Evidence supports that patient report is considered the “gold standard” for symptom report (Ruland et al., 2013) and furthermore parent care-givers and clinicians tend to under-report symptoms (Irwin et al., 2012; Pinheiro et al., 2018). This proxy reporting leads to less than optimal symptom assessment. All of these factors contribute to inadequate treatment of symptoms (Pinheiro et al., 2018; Snaman et al., 2018) which leads to persistent ongoing and escalating symptom distress. Originally described by McCorkle and Young, symptom distress is characterized as “the degree of discomfort from specific symptoms as reported by the patient” (McCorkle & Young, 1978). Importantly, children who experience symptom distress are at risk for higher mortality, increased depression and anxiety (Buckner et al., 2014), decreased functional status (Buckner et al., 2014; Larsen, Nordstrom, Bjorkstrand, Ljungman, & Gardulf, 2003), decreased quality of life (Anderson et al., 2007; Cohen et al., 2012; Ilowite et al., 2018), and overall poorer outcomes (Larsen et al., 2003; Lopes-Junior, de Omena Bomfim, Nascimento, Pereira-da-Silva, & de Lima, 2015; Miaskowski, Barsevick, et al., 2017). Evidence shows patients with significant symptom distress are less apt to adhere to treatment (Cleeland et al.,

2000; Coughtrey et al., 2018; Ilowite et al., 2018), and more apt to delay treatment (Cleeland et al., 2000; E. Miller, Jacob, & Hockenberry, 2011). Thus optimizing symptom management must be a priority along with other treatment decisions.

1.1.2 Symptom Distress in Children with Life-threatening Illness

Children and adolescents with life-threatening illness are medically fragile, require intensive treatments, and depend on these treatments to survive (Docherty, Miles, & Brandon, 2007; Mooney-Doyle, Dos Santos, Szylit, & Deatruck, 2017).

Hospitalization for a life-threatening illness poses significant disruption in the physical, developmental and psychological health of a child (Wesley & Fizur, 2015). The severity of the diagnosis and treatment place these children at risk for significant symptom distress.

Two pediatric populations that experience significant symptom distress include children and adolescents with cancer (Baggott, Dodd, Kennedy, Marina, & Miaskowski, 2009; Hong, Blonquist, Halpenny, & Berry, 2016) and children and adolescents undergoing blood and marrow transplantation (Johnston et al., 2018). These children and adolescents undergo intense treatment regimens (chemotherapy, radiation, and possible surgery), experience prolonged and/or frequent hospitalizations, and require close monitoring of symptoms and side effects. Children and adolescents with life-threatening illness are at high risk for severe symptom distress related to the aggressive treatments they undergo (Erickson et al., 2013; Kestler & LoBiondo-Wood, 2012;

Rodgers, Hooke, Ward, & Linder, 2016; Wesley & Fizur, 2015). I first examined the literature, then explored innovative ways to improve understanding of the significant symptom distress they experience.

1.1.3 Symptom Distress in Children with Cancer

Over 15,000 children in the US are diagnosed each year with cancer (American Cancer Society, 2014). In the past 40 years, with the improvement in cancer treatments, overall childhood survival rates for all cancers have risen from 10% to nearly 90% (CureSearch, 2018). While cancer treatments have improved survival, these treatments are aggressive and create significant symptom distress that includes pain, fatigue, sleep disruption, nausea, and vomiting (American Cancer Society, 2014; Fortier, Chung, Martinez, Gago-Masague, & Sender, 2016; Kestler & LoBiondo-Wood, 2012; Wesley & Fizur, 2015). Symptoms can be attributed to the underlying disease, or treatments such as chemotherapy, radiation and/or surgery (Buckner et al., 2014; Fortier et al., 2016).

While much progress has been made in acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma treatment and survival, rarer and more aggressive pediatric cancers such as acute myeloid leukemia (AML) and bone cancers (osteosarcoma), have not seen the same advancements and successes for children. Children diagnosed with lymphoma, acute myeloid leukemia (AML) or osteosarcoma are treated with multiple courses of chemotherapy requiring prolonged hospitalizations (American Cancer Society, 2014; Getz et al., 2015; Hinds et al., 2009; Stokke, Sung, Gupta, Lindberg, &

Rosenberg, 2015). Severe symptom distress results from the intense chemotherapy regimen as well as the subsequent prolonged neutropenic phase (Getz et al., 2015; T. P. Miller et al., 2016).

1.1.4. Symptom Distress in Children Undergoing Blood and Marrow Transplantation

Pediatric blood and marrow transplantation (PBMT) also known as hematopoietic stem cell transplantation, is improving survival for patients with serious malignant and nonmalignant diseases including cancer, hematologic disorders, immune disorders, and metabolic diseases (Copelan, 2006; D'Souza & Fretham, 2017; Parsons, Tighiouart, & Terrin, 2013). More than 1,500 children in the US each year undergo the procedure (D'Souza & Fretham, 2017). Similar to pediatric cancer treatment, the PBMT procedure is characterized as an intense treatment which includes a pre-conditioning regimen of high dose chemotherapy and often total body irradiation, followed by a high risk immunocompromised recovery period filled with challenges and uncertainty (Majhail et al., 2013; Parsons et al., 2013). Like children diagnosed with cancer, these patients experience significant symptom distress including pain, fatigue, nausea and vomiting (Barker, Anderson, Sauve, & Butzner, 2005; Miaskowski et al., 2004; Vasquenza et al., 2015; S. L. West et al., 2014).

Symptom distress experienced by children undergoing a blood and marrow transplant is unique from other chronic diseases as it has multiple sources and a lengthy trajectory. The first source is the underlying primary disease and its treatment, which

often is relapsed cancer or a chronic progressively debilitating disease like sickle cell disease (Anderson et al., 2007; Larson, Viele, Coleman, Dibble, & Cebulski, 1993). The primary disease can cause both physical symptoms, such as pain and fatigue, as well as psychosocial symptoms such as anxiety and depression (Smith, Hobson, & Haig, 2016). Even before hospitalization for pre-conditioning and transplant, patients report significant symptoms related to their underlying disease (Anderson et al., 2007; Smith et al., 2016). The second source is the aggressive pre-conditioning treatment which typically includes an intensive myeloablative regimen consisting of high dose chemotherapy and total body irradiation (Anderson et al., 2007), both known to have multiple significant distressing symptoms such as pain, nausea, vomiting and fatigue (Baggott et al., 2010). Baggott and colleagues (2010) studied a group of pediatric patients and found the children rated these symptoms as moderate to severe. The final source of symptom distress is associated with the transplant procedure where patients are in a severely immunocompromised state and at high risk for infection, pain, mucositis, and severe nausea and vomiting (Rimkus, 2009; Rodgers, Krance, Street, & Hockenberry, 2014; Snaman et al., 2018).

Children who have undergone the blood and marrow transplant procedure report the worst part of the treatment was the severity of the symptoms they endured (Rodgers et al., 2014). Post-transplant symptom distress lasts for a prolonged period,

typically the first 100 days post-transplant (Hacker, Peters, Patel, & Rondelli, 2018; Parsons et al., 2013).

In summary, for children and adolescents with life-threatening illness, regardless of the primary disease or procedures needed for treatment, significant symptom distress is a reality. The dynamic nature of the underlying disease, the intensity of the treatment, and the prolonged recovery periods combined with the severity and volume of symptoms, render symptom management difficult for these children. Effective symptom assessment and monitoring are crucial for prevention, elimination, and/or prompt treatment distressing symptoms for children and adolescents with life-threatening illness (Dodd et al., 2001; Lewandowski, Palermo, Kirchner, & Drotar, 2009; Sourkes, 2018). Importantly, poor symptom management can result in decreased quality of life and poor short- and long-term health outcomes (Lopes-Junior et al., 2015; Miaskowski et al., 2004; Smith et al., 2016). Thus, advanced understanding of symptom dynamics (occurrences, clusters, and trajectories) is needed for children and adolescents with life-threatening illness to enhance symptom management strategies.

1.1.5 Mobile Health Technology and Precision Health

Rapid advances in mobile health (mHealth) technologies are reshaping healthcare delivery (Jo, Coronel, Coakes, & Mainous, 2019; M. MacPherson, Merry, Locke, & Jung, 2019; Riley et al., 2011; Wang, Wang, Greene, & Sun, 2020; White, Thomas, Ezeanochie, & Bull, 2016). mHealth technologies may offer new avenues to

enhance symptom monitoring and management by capturing symptom data in novel ways. For example, wearable mobile devices, such as the Apple Watch™ and Fitbit™ have advanced computing capabilities and are widely used to monitor and track data such as vital signs (heart rate, temperature), physical activity (step count, minutes of activity) and sleep (number of hours, quality of sleep) in a minimally burdensome way. (Heintzman, 2015; van der Veer, Aresi, & Gair, 2017) They are rapidly increasing in accuracy and predictive capabilities (Bai, Hibbing, Mantis, & Welk, 2018; Nelson & Allen, 2019; Thomson et al., 2019). Moreover, wearables capture patient generated health data (PGHD) at the *time* and *place* they occur (Heintzman, 2015; Shah, Jonassaint, & De Castro, 2014; Wood, Bennett, & Basch, 2015). Other mobile technologies such as smartphone mobile applications (apps) are capable of monitoring and tracking patient reported symptom data such as pain, sleep disturbance, and fatigue.

Precision health is a model of care that individualizes a patient's care based on multiple sources of information (genetic, biological, behavioral, and environmental). mHealth devices can benefit precision health by monitoring behaviors (diet, activity), detecting changes (heart rate, temperature), and intervening (sending reminders or prompts). Precision health symptom management strategies are personalized interventions, based on the patient's health data that target symptoms in effort to prevent, minimize, or eradicate them, thus giving the right treatment at the right time. Streams of real-time patient-generated health data from mHealth devices can illuminate

symptom characteristics that may lead to improved understanding of symptom dynamics and subsequently support effective precision health symptom management strategies (Heintzman, 2015; Jain, Powers, Hawkins, & Brownstein, 2015). Current studies shows using mHealth technology can improve chronic disease self-management for people with asthma (Cook, Modena, & Simon, 2016; Hui et al., 2017) and diabetes (Cafazzo, Casselman, Hamming, Katzman, & Palmert, 2012; Greenwood, Gee, Fatkin, & Peeples, 2017; Wu et al., 2017).

1.1.6 Mobile Technology in Children and Adolescents

The iGeneration (iGens) or Gen Z are defined as children and adolescents born between 1996 and present, are known for technological savvy and significant use of mobile technologies, electronic games, and the internet (Liew, 2019; Rosen, 2011). Given the prevalence of mHealth technologies and their strong developmental fit for these children and adolescents, researchers are examining ways to integrate mobile technology as a tool to facilitate disease management with this population. One study explored the use of “selfies” to encourage teens with sickle cell disease to take their medications (Leonard, Anderson, Jonassaint, Jonassaint, & Shah, 2017), another employed the use of avatars in a gaming platform to help children with cancer track their pain (Fortier et al., 2016). Still other researchers employed mobile apps to facilitate interventions to improve eating and nutrition in hospitalized children (Rodgers, Krance, Street, & Hockenberry, 2013). The use of mobile health technology for symptom

assessment and management holds potential for exploring new avenues of study for children and adolescents with life-threatening illness. Dense streams of real-time, in situ, patient generated data can be explored to foster deeper understanding of symptom distress by show a more comprehensive illustration of symptom dynamics (occurrences, clusters and trajectories). These devices and the patient-generated health data (PGHD) they produce are likely to enhance our understanding of symptom dynamics, address knowledge gaps (Greenwood et al., 2017; Hui et al., 2017; L. Miller, Schuz, Walters, & Walters, 2017) and lead to precision health, or personalized symptom management interventions. Further research incorporating these devices as symptom collection tools may improve recording and tracking symptom patterns and provide a novel and acceptable approach for advancing symptom research.

1.1.7 Future Research

New approaches using innovative research designs, data collection measures, and analyses need to be implemented and studied to see if we can better understand the complex and changing symptom dynamics children and adolescents with life-threatening illness experience. Longitudinal approaches that focus on examining real time, in situ, patient generated symptom data obtained from mHealth devices can provide rich data streams that will lead to more comprehensive understanding of symptom dynamics (Leahy, Feudtner, & Basch, 2018; Miaskowski, Cooper, et al., 2017). Further research opportunities using advanced data mining, statistical analyses, and

machine learning approaches may enhance understanding of symptom dynamics, lead to earlier detection of symptoms, improve predictive analytics, and foster the development of targeted precision health symptom management interventions.

1.2 Theoretical Framework: Theory of Unpleasant Symptoms

The Theory of Unpleasant Symptoms (TUS) has emerged as a prominent symptom theory in nursing research (Lenz et al., 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995; Lopes-Junior et al., 2015; Tyler & Pugh, 2009). Initially developed in 1995 by Lenz, Suppe, Gift, Pugh, and Milligan as a middle range theory, the TUS provides a foundational theoretical framework to facilitate exploration, description, and clarification of the complexity of the symptom distress problem, illuminate determinants of the problem, offer insight into the population experiencing the problem as well as guide intervention development (Lee et al., 2017; Lenz et al., 1995; Lopes-Junior et al., 2015). As a middle range theory, it is relevant for nurses in both the research and practice settings to foster better understanding of the symptom experience in patients (Lopes-Junior et al., 2015) and thus has been used extensively in research (Blakeman, 2019; Silva-Rodrigues, Hinds, & Nascimento, 2019; Tyler & Pugh, 2009). The theory was updated in 1997 to increase understanding that patients' experience multiple symptom and these symptoms occur simultaneously (Lee et al., 2017; Lenz et al., 1997).

The TUS was developed initially to explore the symptoms of fatigue and dyspnea in the clinical area, but has been expanded to study symptoms in many

contexts (Brant, Beck, & Miaskowski, 2010; Lopes-Junior et al., 2015). The strength of the TUS is reflected in its broad and comprehensive use in empirical studies to explore and describe symptoms, highlight factors that predispose patients, and guide interventions for treatment or prevention. The theory focuses on the symptom experience and takes into consideration that multiple symptoms may occur together (Lenz et al., 1997). The theory has been used to study symptoms relevant to bariatric surgery (Tyler & Pugh, 2009), childhood cancer (Lopes-Junior et al., 2015), cancer related cognitive impairment (Myers, 2009), childbearing (Pugh, Milligan, Parks, Lenz, & Kitzman, 1999), and dementia related to Alzheimer's disease (Hutchinson & Wilson, 1998).

1.2.1 Theory of Unpleasant Symptoms Assertions

The Theory of Unpleasant Symptoms posits six assertions: 1) Symptoms are fluid and multidimensional, and symptom characteristics include: timing, intensity, quality, and distress (Lenz et al., 1997); 2) Symptoms may be experienced individually or in combinations and when they are combined, the results are multiplicative and thus are more intensified (Lenz et al., 1997); 3) Concurrent symptom presentation results in one symptom amplifying the other and these symptoms are more powerful than when experienced individually (Lenz et al., 1997); 4) Outcomes of the symptom experience include health related quality of life elements, both functional and cognitive (Lenz et al., 1997); 5) Influencing factors can be physiologic, genomic, psychologic, or situational and can interact to influence the symptom experience (Lenz et al., 1997); 6) Relationships

exist between the symptom experience, influencing factors, and outcomes and these relationships are reciprocal in nature (Lenz et al., 1997).

1.2.2 Theory of Unpleasant Symptoms Concepts

The TUS has three major concepts: 1) the symptoms the patient experiences, 2) the influencing factors, and 3) the performance outcomes (Figure 1). The first key concept, and most central to the theory, is the symptom(s) the patient experiences (Lenz et al., 1997; Lopes-Junior et al., 2015). The theory operationalizes symptoms as “perceived indicators of change in normal functioning as experienced by patients” (Lenz et al., 1997). The theory states symptoms are multidimensional and include intensity, timing, and distress, duration, and quality. These dimensions, or characteristics, are separate but interrelate (Lenz et al., 1997; Tyler & Pugh, 2009). Intensity is reflected by the severity, strength, or amount of the symptom experienced (Lenz et al., 1997; Lopes-Junior et al., 2015; Tyler & Pugh, 2009). Timing includes the frequency of a symptom’s occurrence, duration, or a combination of the two (Lenz et al., 1997; Myers, 2009). Distress is defined as to the degree to which the person is bothered by the symptom (Myers, 2009). Quality is the patient’s vocal expression used to describe what the symptom actually feels like (Lenz et al., 1997; Myers, 2009).

The second key concept the TUS highlights is the impact of a patient’s physiological, psychological, and situational factors on the symptom experience (Lenz et al., 1997). These factors are the influencing factors or antecedents (Figure 1).

Physiological factors that act as moderators include the patient's underlying disease, age, genetic make-up, body system function, side effects or complications that result from the disease, curative therapies, or medications (Myers, 2009). Psychological factors include the patient's developmental level, state of mind, mood, understanding of the disease and treatment, anxiety, depression, fear, and can be influenced by family and social support (Myers, 2009). Situational factors for these patients include the physical environment, school level, family support, social support, peer support, isolation, changes in routine, and even stressors on the family such as parental employment status or impact on siblings.

The final key concept addressed by the TUS includes the performance factors or outcomes of the symptom experience (Figure 1). Outcomes focus on health related quality of life, physical activity levels, return to baseline functioning (if possible) (Lenz et al., 1997). The model shows the reciprocal relationship between the outcomes and the symptom experience. Poor outcomes or decreased levels of performance can create a negative feedback loop on the influential factors.

1.2.3 Theory of Unpleasant Symptoms in the Child with Life-Threatening Illness

The experience of children and adolescents with life-threatening illness is unique and challenging and the TUS is a useful framework to examine, describe, and plan interventions to target symptom distress. The "Symptom Experience" portion of the TUS (Figure 1) (highlighted in green) was an adaptation of Lenz's model and used in this

dissertation to guide the research, formation of the research question, and the selection of variables. The integration of mobile health technologies facilitates patient generated symptom data collected in real-time that support examination of the timing, intensity, distress, duration, and quality of symptoms. Examining symptom dynamics using the TUS we can begin to gain insight into the complex symptom dynamics including the characteristics, patterns, interactions, and trajectories. Outcomes from children and adolescents with life-threatening illness focus on health related quality of life, physical activity levels, return to baseline functioning (if possible) (Lenz et al., 1997), decreased symptom distress such as pain and fatigue levels and improved overall sleep quality (Graef et al., 2016; Myers, 2009)

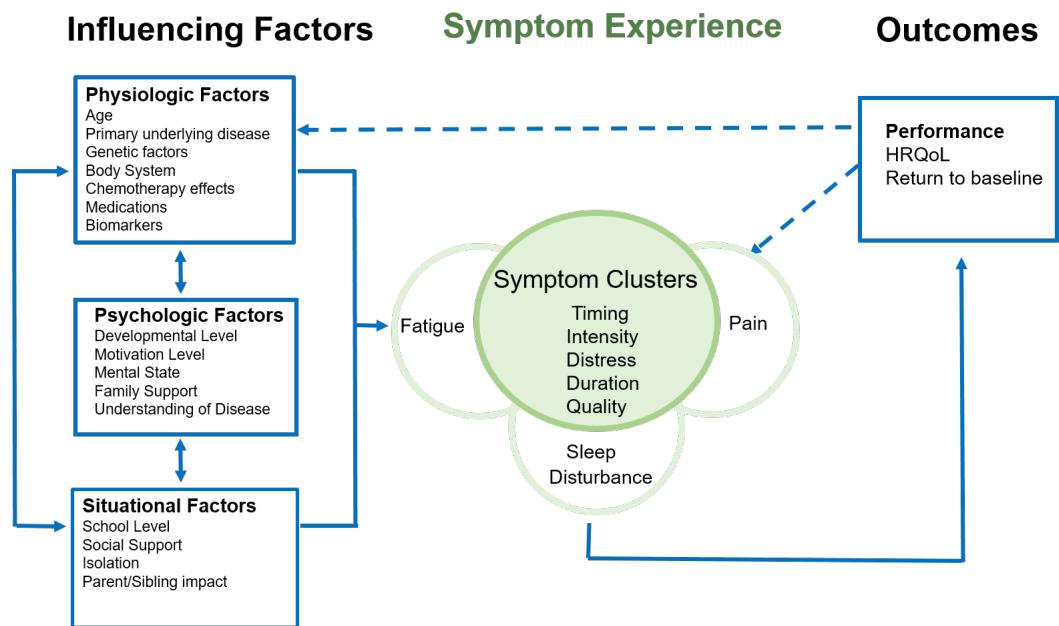


Figure 1: Adaptation of the Theory of Unpleasant Symptoms Model in Children with Life-Threatening Illness.

In summary, the TUS offers a comprehensive approach to examine the complex symptom distress that occurs during a life-threatening illness for a child. The theory provides a framework to support their complex interactions between biologic, psychological, and social processes and their influence on symptom characteristics. As a middle range theory, it has relevance for nurses in the clinical setting and research environments to foster clearer understanding of symptom characteristics, interactions, and patterns. Our model focuses on the specific symptom distress children experience in the context of cancer treatment or blood and marrow transplantation (Figure 1). Using mobile technologies to target the Symptom Experience section of the model fosters understanding of the timing, intensity, distress, and quality of symptoms and illuminates relationships between these concepts that can guide interventions targeted to prevent, minimize, or eradicate the distressing symptoms experienced by children and adolescents with life-threatening illness.

1.3 Dissertation Purpose and Research Aims

The purpose of this dissertation was to advance understanding of symptom dynamics (occurrences, clusters, and trajectories) in children and adolescents with life-threatening illness. This goal was achieved through a series of studies that used mHealth technologies designed to collect physiologic and self-reported symptom data. I then described and visualized these symptom data in a meaningful way, and explored

patient and parent caregiver perspectives on the use of mHealth technologies to monitor symptom distress. This dissertation study was among the first to explore the feasibility of using two mobile technologies in children and adolescents with life-threatening illness to obtain longitudinal patient generated symptom data that describe and visualize symptoms dynamics. Knowledge gained through this dissertation study adds to the body of symptom science research by enhancing our understanding of symptom occurrences, clusters, and trajectories that contribute to the significant symptom distress these children endure. These findings inform this under-researched area and enhance our understanding of symptom dynamics, address knowledge gaps, and importantly contribute to the development of precision health interventions and strategies to enhance symptom management for children and adolescents with life-threatening illness. The purpose of this dissertation was achieved through the following aims:

1.3.1 Aim one

Introduce the problem, background, and significance of symptom distress in children and adolescents with life-threatening illness. Explore how the use of patient generated health data (PGHD) from mobile technologies' can advance understanding of symptom dynamics and inform precision health symptom management strategies.

(Chapter 1).

1.3.2 Aim two

Describe the development of a mobile application (app), called the Technology Recording to better Understand Pediatric Blood and Marrow Transplant (TRU-PBMT). This app was developed as a data collection tool for the symptoms specifically experienced by the PBMT patient. (Chapter 2).

1.3.3 Aim three

Conduct a pilot study to 1) determine the feasibility of integrating a mobile app and wearable tracking device to collect and transmit PBMT patient-generated symptom data, and 2) test the study design and procedures, and 3) explore children's perspectives on the feasibility of using the mobile devices (Chapter 3).

1.3.4 Aim four

The overall goals of this study were the following: 1) Examine the feasibility of children and adolescents with life-threatening illness to record and transmit symptom-related data daily up to 4 months via a wearable activity tracker (HR, step count) and a mobile app for symptom recording (fatigue, pain, sleep quality) of children and adolescents with life-threatening illness and to identify symptom dynamics; 2) Describe and visualize the symptom(s) occurrences, patterns, and trajectories that enhanced understanding of symptom distress for each participant including timing, intensity, distress, duration, and quality using mHealth technology; and 3) Explore patient and parent perceptions of facilitators and barriers to symptom management using mobile

health devices and how to best visualize this data through patient and parent interviews. This was achieved through a longitudinal mixed methods analysis that examined children and adolescents with life-threatening illness who had received treatment for cancer or blood and marrow transplantation. (Chapter 4).

1.3.5 Aim five

Chapter 5 summarizes the dissertation work, synthesizes the findings, describes implications for nursing, and suggests future directions for research. (Chapter 5).

2. Customization of the TRU-PBMT App (Technology Resources to better Understand Pediatric Blood and Marrow Transplant)

*(Vaughn, J., Jonassaint, J., Summers-Goeckerman, E., Shaw, R. J., & Shah, N. (2018). Customization of the TRU-PBMT App (Technology Recordings to better Understand Pediatric Blood and Marrow Transplant). *Journal of Pediatric Nursing*, 42, 86-91.)

2.1 Introduction

More than 1,500 children undergo blood and marrow transplants each year in the United States to treat life-threatening diseases (D'Souza & Fretham, 2017). While this procedure is improving survival of oncologic, hematologic, immunologic, and metabolic diseases (Copelan, 2006; D'Souza & Fretham, 2017; Dietz et al., 2017; Khandelwal et al., 2017; McGrady, Williams, Davies, & Pai, 2014), the post-transplant period is filled with significant symptom distress. Symptoms include profound fatigue, extreme sleep disturbances, constant nausea and/or vomiting, decreased physical activity, and severe pain (Rodgers et al., 2014; Vasquenza et al., 2015). The dynamic nature of the disease combined with the severity and number of adverse effects make symptom management difficult for pediatric blood and marrow transplant (PBMT) patients and caregivers. Symptoms often remain underdiagnosed and undertreated in children (Baggott, Baird, Hinds, Ruland, & Miaskowski, 2015; Fortier et al., 2016). Better assessment and monitoring will foster precision health strategies, leading to improved symptom management and patient outcomes.

Emerging mobile health (mHealth) technologies are increasingly evaluated to improve self-management, care delivery, and health outcomes by capturing patient-generated health data and providing real-time feedback to patients, caregivers, and clinicians. (Siminerio, 2010; Steinhubl, Muse, & Topol, 2013) Increased access to wireless handheld technologies, such as smart phones and tablets, has facilitated the use of mobile applications (apps) for managing chronic illnesses (Shah et al., 2014). Current studies show mHealth technologies have improved self-management of blood glucose in diabetes (Cafazzo et al., 2012; Padman et al., 2013), weight loss in overweight and obese people (Napolitano et al., 2013), and pain management for sickle cell disease (Jonassaint, Shah, Jonassaint, & De Castro, 2015). Findings from these studies show that patients, particularly younger patients, find these devices accessible, acceptable, and usable (Rodgers et al., 2014). Mobile apps make it relatively easy for patients to keep track of their symptoms and for clinicians to identify symptom clusters, which leads to better symptom management.

Our investigative team is examining the integration of mobile health technologies and wearable technology into symptom monitoring for PBMT patients. While there are numerous health-related apps, none address the symptoms of the PBMT patient. Our team decided to customize an existing app to address these specific symptoms. Team members had previously designed an app for patients with sickle cell disease (Technology Recording to better Understand Pain, 'TRU-Pain'). We chose to

modify this app since it focuses on pain symptoms for patients with sickle cell disease thus it served as a good template for designing the PBMT app. In addition, the TRU-Pain app is currently being employed successfully in other clinical studies (Johnson, Gollarahalli, Abrams, Jonassaint, & Shah, 2017; Narine, Yang, Banerjee, Jonassaint, & Shah, 2017). This article describes development of the app, called the Technology Recording to better Understand Pediatric Blood and Marrow Transplant (TRU-PBMT) app. The aims for this project were two-fold: to obtain input from patients, caregivers, and clinicians with knowledge of PBMT symptoms and incorporate that feedback into the design and development of a PBMT-specific app; and to build a child-friendly interface to engage the pediatric population. The authors are currently conducting a pilot study investigating the feasibility, usability, and acceptability of the TRU-PBMT app.

2.2 Design and Methods

Following Institutional Review Board approval, a convenience sample of volunteer participants (N = 32) were recruited over a two-week period of time. This time period was sufficient to obtain substantial feedback for the app. Data collection ended when no new information was being provided. Our project employed a multi-step approach that included information sessions, demonstrations with hands-on user sessions and survey data collection (Figure 2).

The project consisted of a multi-phase approach which included the following: a brief session that included a large clinician group presentation (phase I); followed by small group sessions of clinicians, patients, and caregivers that included detailed app description, an interactive session, and survey data collection (phase II); and finally, final production of the TRU-PBMT mobile application (phase III).

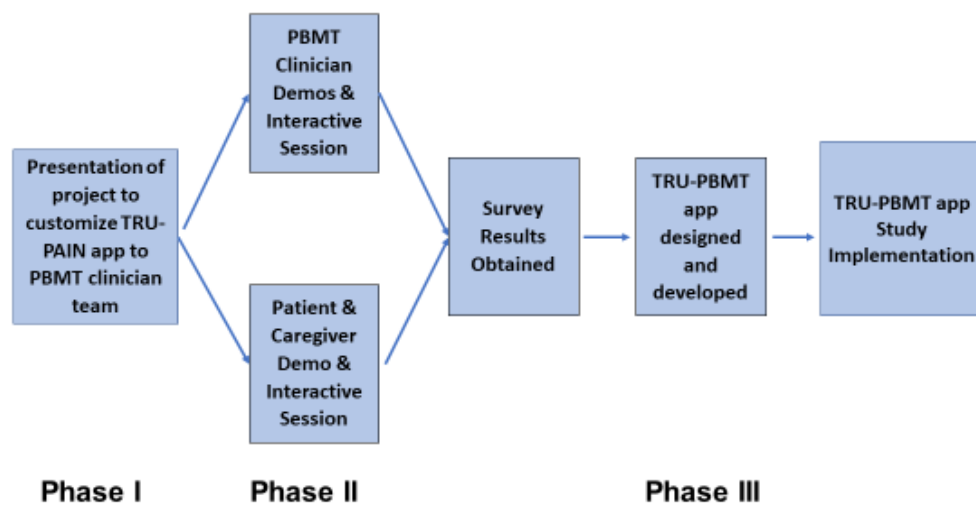


Figure 2: Illustration of the study phases for the development of TRU-PBMT.

Phase I: The investigative team presented the app project to the PBMT clinical team in the clinic setting. The goal was to introduce the project and obtain initial input for the app design and development. A short presentation using the initial TRU-Pain sickle cell app was presented to the PBMT team to serve as a visual example of how the PBMT app could be used to benefit their patients. Clinicians were asked to provide specific feedback on the utility and revisions needed to the app.

Phase II: Following development of the first version of TRU-PBMT app, we targeted both participant groups, the clinician group, and the PBMT outpatients and caregiver group

to obtain detailed feedback and solicit additional suggestions. The study coordinator provided information sessions in the clinic setting for clinicians during the routine work day. Unit based educational sessions were presented for inpatient nurses. Individual sessions for caregivers and PBMT patients were offered while they attended the outpatient day hospital. The study coordinator conducted a demo of the TRU-PBMT app prototype followed by an interactive hands-on session where participants were asked to experiment with the app and ask questions. These ten-minute sessions ran over a two-weeks and targeted both inpatient and outpatient clinicians as well as PBMT outpatients and caregivers.

At the end of the sessions, each participant completed a 19-question survey the team has previously used to obtain information on demographics, current ownership of devices, and his or her experience with the app regarding usability, acceptability, and usefulness (Jonassaint et al., 2015; Shah et al., 2014). Both open-ended and closed questions were used. Participants were asked to rate the ease of use and learning related to the app using a five-point Likert scale ranging (1= Strongly Disagree, 5= Strongly Agree). Survey questions included asking participants their age, gender, if they owned a smart phone or tablet and if so, how often they use it. Open-ended survey questions included free text responses for features or information that should/should not be included in the TRU-PBMT app. Data collection ended when we noticed no new information was being provided.

Phase III: The team worked with the mobile app developer to address results and comments from Phase II. The new version of the TRU-PBMT app was presented to the clinical team, uploaded to iTunes for easier download, and is available for prospective studies. The app can be downloaded to a smart phone or iPad which when connected to Wi-Fi or a cellular signal transmits data to the secure HIPAA compliant server.

Data Analyses: Data were analyzed using SAS 9.4 (Cary, NC). Descriptive statistics were completed, including means and standard deviations to summarize participant characteristics and survey responses. The research team analyzed the open-ended responses with content analysis to identify themes related to PBMT symptoms and care activities (Hsieh & Shannon, 2005). Open-ended responses were grouped by themes the findings were discussed until agreement was reached on the definitions of the final themes.

2.3 Results

Demographic data for PBMT patients, caregivers and health care clinicians is listed is listed in Table 1.

Table 1: Demographic Statistics

Participant ^a			Male		Female	
	n	%	n	%	n	%
PBMT Outpatient	4	12.5%	1	3%	3	9%
PBMT Caregiver	5	15.6	2	6%	3	9%
Medical Doctor	3	9.5%	3	9%	0	0%
Nurse Practitioner	4	12.5%	1	3%	3	9%
Registered Nurse	11	34%	1	3%	10	31%
Dietician	2	6.2%	0	0%	2	6%
Pharmacist	1	3%	0	0%	1	3%
Social Worker	2	6.2%	0	0%	2	6%

^a n=32

Phase I: The initial clinician response to the app was positive. Clinicians responded to researchers' questions about security, infection cleaning, and specific PBMT-related symptoms. Clinicians provided initial suggestions for specific symptoms and care needs to include in the app design. A prototype TRU-PBMT app was designed by the study team mobile app developer, based on this initial feedback, to be used in Phase II. The TRU-PBMT prototype app was developed, and the demo with interactive sessions began.

Phase II: The total sample was divided into two groups of participants (Table 2): one group consisted of a convenience sample of four PBMT outpatients and five caregivers, and a second group consisted of a convenience sample of 23 health care clinicians (MDs,

nurse practitioners, inpatient nurses, outpatient nurses, social workers, dieticians, and caseworkers). We chose an inter-disciplinary group of clinicians to obtain broad and comprehensive feedback. Clinician participants were randomly recruited from the inpatient and outpatient PBMT program and patient and caregiver participants were recruited from the outpatient program. Surveys were disseminated to clinicians (n=23), caregivers (n=5), and PBMT outpatients (n=4) ages 6-18 years old, who volunteered to evaluate the app.

Overall, our initial version of the app was well received, and all agreed that the proposed app would be acceptable and useful to this patient population. The modal responses for the *ease of use* and *helpfulness for tracking symptoms* was “Strongly Agree” from the respondents. Feedback also included that the app was easy to learn and use (Table 2). Patients and their caregivers were more likely to strongly agree with the statements than the clinicians.

One question designed to collect information for future app features asked about taking “selfies.” Selfies are self-portrait photographs typically taken with a smartphone. The patients and caregivers responded positively to adding a feature to take a picture (selfie) of themselves taking their daily medications and sending it to their clinicians. Of the participants who responded to the question related to owning a smart phone or tablet, 100% percent indicated they owned a device and used mobile applications multiple times per day.

The survey also included two open-ended questions designed to elicit suggestions from participants for additional TRU-PBMT app features (Tables 3 & 4). Suggestions included adding symptoms such as “mouth pain” (oral mucositis) and “bleeding” along with the source (vomit, stool, urine or other places) and making the language more “child-friendly.” Both clinicians and caregivers suggested a visual stool chart to facilitate the description of bowel movements and ability to report an accurate stool count. In addition to symptoms, clinicians expressed interest in recording important care needs (mouth care, daily bath, linen change, and laps walked on the inpatient unit). Both groups requested a medication record to facilitate med adherence when the PBMT patient becomes an outpatient.

Table 2: Usability and Acceptability of the TRU-PBMT app

Question	PBMT Clinicians ^a M (SD)	Patients & Caregivers ^b M (SD)
TRU-PBMT was easy to use	4.3 (1.1)	4.8 (0.4)
I think most people could learn to use TRU-PBMT quickly	4.4 (1.2)	4.8 (0.4)
I felt confident using TRU-PBMT	4.6 (0.6)	5.0 (0.0)
I think using the application and wearable device daily would be helpful for tracking symptoms and pain	4.9 (0.4)	4.9 (0.4)

Another feature we are planning to add to TRU-PBMT is designed to help patients remember to take their medication as directed. This feature would have patients taking a picture of themselves (Selfie) taking their medicine and send the picture to their doctor. How likely would you be to send your doctor a picture of yourself taking your medication every day? N/A 3.8 (1.3)

^a n=23 ^b n=9

Table 3: Clinician Open Ended survey responses

Question	n	%	PBMT Clinicians^a
What features or information should we include in the TRU-PBMT app to help BMT patients and their doctors	10	43%	Add medication record
	6	26%	Add the Bristol Stool Chart.
	6	26%	Add incentives for kids. Add incentives to get kids moving
	5	22%	Add fever, rash, sore throat, fatigue, and bleeding as symptoms
	3	13%	Make the Pain Scale Kid-friendly (smiley faces).
	3	13%	Add Daily care goals: laps walked, mouth care, bath and linen change
	3	13%	Add kid-friendly language
	2	8%	Add mucositis and fatigue scales

^a n=23

Table 4: Child & Caregiver Open Ended survey responses

Question	n	%	Patients & Caregivers ^b
What features or information should we include in the TRU-PBMT app to help BMT patients and their doctors	6	66%	Make it more fun, add better pictures, or games as incentive to use the app
	4	44%	Add avatars, emoticons and smiley faces
	4	44%	Add alerts to remind us of medication times and missed doses
	3	33%	Use child-friendly language
	2	22%	Add the discharge information (currently in paper and binder format) such as "Important numbers to call, Follow-up appointments etc."
	2	22%	Add stool record with pictures
	1	11%	Add more color to the screens

^b n=9

Phase III: Feedback, comments, and survey results were reviewed for modifications to the TRU-PBMT app. As a result, we changed language to be more child-friendly; created an initial home page with patient icon that changes to a star when the patient completes his or her daily care goals; added symptoms including mouth pain, sore throat, tingling, vomiting, and bleeding; and included the Bristol Stool chart.

Throughout the study, themes were identified within each group. Clinicians' suggestions for app features focused on expanding the list of symptoms and setting patient-specific care goals (mouth care, laps, daily bath) to allow patients to record and

track these essential activities. Most clinicians agreed that the app's language needed to be simplified so young patients could understand it and adding incentives such as badges, rewards, and icons was important to motivate the patients to increase physical activity and promote other care goals.

Caregivers agreed with clinicians on child-friendly language, but their themes centered on app features that would help them better manage their child's care.

Caregivers requested medication records, discharge planning information, instructions about managing symptoms once they are outpatient, and important medical related phone numbers.

The children who gave input on this project provided valuable first-hand information about the challenges and needs of PBMT patients. Their suggestions included designing a more personalized, fun, and interactive app. The children suggested adding a race track or similar gaming feature to encourage ambulation and track their steps. The children also suggested graphic additions such as avatars, emoticons, smiley and sad faces.

2.4 Discussion

The significant symptoms children experience following a blood and marrow transplant present constant management challenges for patients, caregivers, and clinicians. We found key stakeholders agreed to the need for a PBMT mobile app, provided critical insight and suggestions to improve an initial version, and resulted in

TRU-PBMT specifically customized for this patient population. The TRU-PBMT app was designed to be child-friendly to encourage consistent data entry and for access on a tablet or smart phone. Importantly, the app serves as a repository of patient-generated health data similar to a diary, which can be analyzed by providers and integrated into patient care. The app can be used intermittently throughout the day, which is helpful to reflect changes in symptoms. Obtaining data this way can increase understanding of symptom patterns over time, clusters, and trajectories, and facilitate personalized health strategies to manage these symptoms.

Patients, caregivers, and clinicians were eager to participate in the project and give feedback on the TRU-PBMT symptom app design. Our first objective was to add symptoms specific to the PBMT population for data collection based on feedback from patients, caregivers, and clinicians. Capturing the onset, location, duration, and characteristics of symptoms is important for symptom management. Thus, a “Symptom Tracker” section was designed to do just that (Figure 3). The Symptom Tracker allows the user to enter a symptom, record its intensity on a visual analog scale numbering 1-10, record the symptom status (new, resolved, better, same, or worse), and address any interventions (medication, relaxation, skin cream, etc.). The specific symptoms added to the TRU-PBMT app included mouth pain, sore throat, rash, bleeding, fever, headache, burning, tingling.

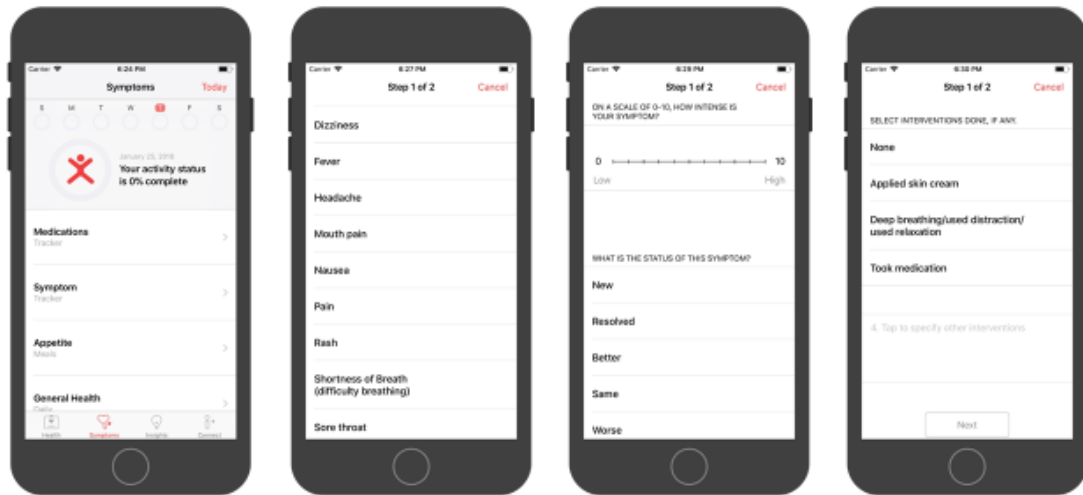


Figure 3: The TRU-PBMT app Symptom Tracker screens

The addition of the Bristol Stool chart was another feature added. Tracking stool characteristics and output is important in the care for PBMT patients, yet patients of all ages are typically reluctant to share their bowel habits with their clinicians.

The second objective of this project was to design a child-friendly and appealing app (Figure 4). Today's children and adolescents are known as the "iGeneration" or "iGens." They were born after 1995, are described as technologically savvy individuals who spend significant periods of time connected to the internet, and they are highly engaged with mobile technology (Rosen, 2011). We chose to use the app as a data collection tool and incorporated child-friendly language and graphics to improve children's understanding of symptom terminology and to encourage use of the TRU-PBMT app. Children are also more likely to use a device when it is interesting to them (Bendixen, Fairman, Karavolis, Sullivan, & Parmanto, 2017; Cafazzo et al., 2012; Rodgers et al., 2014).

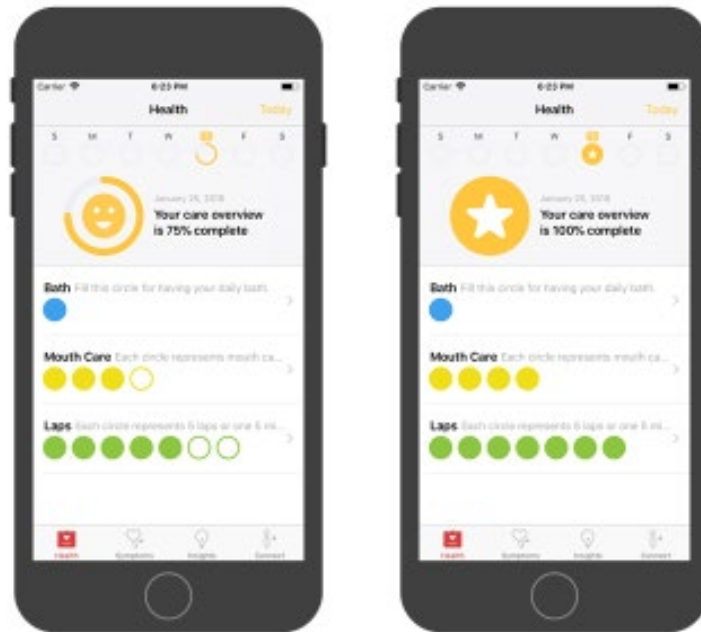


Figure 4: Pediatric-friendly TRU-PBMT app additions

2.5 Conclusion

The TRU-PBMT app project idea and prototype were well received by patients, caregivers, and clinicians. They provided valuable input into the initial design of the PBMT-specific app. The investigative team is conducting a study to examine the feasibility and usability of the app for continued to improvement for implementation. At present, clinicians are not using real time data from the app, however, participants are recording and tracking symptoms and using the app as a tool to discuss the symptoms with clinicians. The initial version is available on the iTunes mobile app store to outside investigators. Additional suggestions under consideration for when patients become outpatients include a medication record with push prompts or alert notifications for medication administration as well as discharge instructions, scheduling information,

and important team phone numbers. In addition, pictures of skin rashes may be added to help patients monitor rashes related to graft vs host disease. Selfies or avatars have also been considered to be added to engage children further with the app. The advances in mobile technologies make projects such as this one real possibilities for providing innovative ways to improve and personalize patient care. Next steps include continued development and real world clinical application.

3. Mobile Health Technology for Pediatric Symptom Monitoring: A Feasibility Study

*(Vaughn, J., Gollarahalli, S., Shaw, R. J., Docherty, S., Yang, Q., Malhotra, C., Shah, N. (2020). Mobile Health Technology for Pediatric Symptom Monitoring: A Feasibility Study. *Nursing Research*. doi:10.1097/nnr.0000000000000403)

3.1 Background

Over 1,500 children undergo a pediatric blood and marrow transplant (PBMT) each year in the United States (D'Souza & Fretham, 2017). PBMT is an intense treatment and children undergoing the procedure experience significant symptom distress (Johnston et al., 2018). Symptom distress is characterized as “the degree of discomfort from specific symptom(s) as reported by the patient” (McCorkle & Young, 1978). The symptom distress PBMT patients experience is different from other chronic illnesses as it has multiple contributing factors and a lengthy trajectory. The underlying primary disease and its treatment, which often is relapsed cancer or a progressively debilitating disease, create bothersome symptoms (pain, fatigue, anxiety, depression) that exist before hospitalization for transplant (Anderson et al., 2007; Johnston et al., 2018). In addition, the aggressive pre-transplant conditioning treatment, typically a myeloablative regimen (high dose chemotherapy and total body irradiation), contributes to symptom distress (Rodgers et al., 2013). These treatments have significant associated symptoms including risk for pain, fatigue, potential organ toxicity, infection, and bleeding (Parsons et al., 2013; Rimkus, 2009). Finally, factors related to the transplant procedure contribute

to symptom distress. During this phase, children are severely neutropenic, anemic, and thrombocytopenic putting them at risk for infection, debilitating fatigue, persistent pain, bleeding, and enteritis with nausea and vomiting (Rimkus, 2009; Vasquenza et al., 2015). Children typically experience multiple symptoms that persist for a prolonged period and report the distressing symptoms as the worst part of their illness and treatment (Rodgers et al., 2014).

Accurate symptom assessment is crucial for optimal symptom management (Baggott, Gibson, et al., 2012; Hochstenbach, Zwakhalen, Courtens, van Kleef, & de Witte, 2016), however, it can be challenging for clinicians to obtain accurate symptom data during the post-transplant phase (Snaman et al., 2018; Vasquenza et al., 2015). Acquiring meaningful symptom data is complicated for many reasons, including the child's developmental level and ability to articulate the symptom experience, and children are frequently too ill to accurately communicate their symptoms (Irwin et al., 2012). Moreover, research suggests parent caregiver and clinician reports (proxy reports), which are commonly used, frequently under-report both the prevalence and severity of children's symptoms in acute diseases (Irwin et al., 2012; Pinheiro et al., 2018). This presents a significant threat to symptom management for this at-risk population.

Advances in mobile health (mHealth) technologies are reshaping chronic disease management (Kaplan et al., 2017). These technologies are popular, accessible, and can

unobtrusively collect, monitor, and transmit near real-time patient-generated health data (Munos et al., 2016; Wesley & Fizur, 2015). Wearable devices such as the Apple Watch™ and Fitbit™, can passively collect real-time physiologic data (heart rate, (HR), step count) (Heintzman, 2015), while smart phone mobile applications (apps) can record and track real-time patient self-reported outcomes (Leahy et al., 2018).

The literature shows using mHealth technology can improve disease self-management for people with asthma (Hui et al., 2017) and diabetes (Greenwood et al., 2017; Wu et al., 2017). In light of these findings, mHealth may offer new avenues to enhance symptom monitoring and management by capturing symptom data in novel ways. Dense streams of real-time patient-generated health data from these devices can illuminate symptom characteristics that may lead to improved understanding of symptom dynamics and subsequently support effective symptom management strategies (Heintzman, 2015; Jain et al., 2015).

mHealth technology offers a possible solution to symptom management challenges for children undergoing a PMBT, however, research in this area is limited. While a few studies report feasibility results with mHealth symptom tools in pediatric cancer patients (Baggott, Gibson, et al., 2012; C. F. Macpherson et al., 2014), only one study by Rodgers, et al., (2013) explored the feasibility of using an app for eating-related issues in PBMT outpatients (Rodgers et al., 2013). Thus, our team designed a study using two mHealth devices, a wearable tracker and a smart phone app, to collect longitudinal

symptom data (pre-transplant through the post-transplant period). We conducted a pilot study: 1) to examine the feasibility of using mHealth technologies to monitor, record, and transmit symptom data in children undergoing a PBMT, 8-18 years of age; and 2) to identify and address design or procedural issues before conducting a larger study.

Theoretical Framework

The Theory of Unpleasant symptoms (TUS) guided our exploration and evaluation of the symptom experience and will guide future intervention development (Lenz et al., 1997). Mobile technologies offer a unique opportunity to collect real-time symptom data (timing, intensity, distress, and duration) for this exploration and evaluation.

3.2 Design and Methods

This study used a single-site longitudinal exploratory design.

Participants and Setting: The study protocol was approved by the medical center Institutional Review Board. We recruited a convenience sample of ten children, 10-17 years of age at a major medical center in the southeastern United States. We chose a sample size of 10, which is supported by human factors testing that determined a minimum of five users are sufficient to assess usability benefits (Nielsen & Landauer, 1993). Our sample size was consistent with other studies testing the feasibility of mobile devices for adolescents with chronic disease (Baggott, Gibson, et al., 2012; Cafazzo et al., 2012). Although children and adolescents differ developmentally, we chose to combine

the age ranges for this pilot study due to the sample size and our feasibility objective. Eligible participants were children, aged 8-17 undergoing their first PBMT and able to read English. All children were enrolled prior to transplant and could remain in the study up to 120 days, which could include inpatient and outpatient days. A PBMT clinical team member initially approached the child and parent to elicit interest in the study. If interested, a study nurse obtained parental consent and child assent, enrolled the child in the study, and set up and explained the study devices.

Study Measures: Children were loaned two study devices; 1) a wearable tracker, initially the Microsoft Band II™, later changed to the series 1 Apple Watch™, and 2) an iPhone 6™ downloaded with an app, the Technology Recordings to better Understand PBMT (TRU-PBMT). This app was designed as a pediatric-friendly tool to collect symptom and health data (Vaughn, Jonassaint, Summers-Goeckerman, Shaw, & Shah, 2018). The app has a “symptom tracker” page where children can record symptoms, the intensity (using a visual analogue scale), the time they occur, and any interventions. The app also has a “Health” page where children can record daily care goals such as mouth care and bathing as well as a “Food Diary” page to track food intake and the Bristol stool chart to track stools. Children were asked to record in the app daily.

Feasibility data was collected using; 1) a wearable tracker to obtain daily physiologic data (HR, step count) as indicators of symptom distress; 2) a smart phone app to collect daily self-reported symptom data; 3) monthly structured interviews with

children focused on their experiences and satisfaction with technology; and 4) a 23-question survey developed by the study team designed to evaluate feasibility. The survey was given at study completion and contained items addressing perceived technical capability, ease of use, satisfaction, and acceptability. Survey scores for technical capability ranged from 0 (problems using device) to 4 (no problems using device); ease of use ranged from 0 (very hard) to 4 (very easy); and satisfaction/acceptability ranged from 0 (very dissatisfied) to 4 (very satisfied).

Data Collection: At study enrollment, patient demographic and clinical characteristics were extracted from the electronic health record. Feasibility was assessed as mobile device acceptability and usability, and by an end-of-study feasibility survey.

Acceptability: Acceptability was measured by enrollment and attrition rates. Interview data was used to ascertain elements that led to sustained participation in or attrition from the study.

Usability: Wearable and app usability was measured as the proportion of missing device data and percentage of device use. Interview data regarding device use was also used to assess usability.

Data Analysis: SAS 9.4 (Cary, NC) statistical software was used for quantitative data analysis. The heat map visualization was generated in RStudio (Version 3.5.0 – © 2009-2018). Descriptive statistics were used to summarize children’s characteristics, calculate the proportion of missing data for each device, calculate the percentage of

device use throughout the study, and obtain enrollment and attrition rates. We also plotted the proportion of missing data with standard error across different time points to explore trends. All interview data was recorded in real time using written notes, then transcribed. We analyzed the data by organizing it according to each interview question and developing common themes within each question category.

3.3 Results

Children (N=10) were between 10-17 years of age (Mean = 14.4 years) and 60% female (Table 5).

Table 5: Patient Demographics

Participant	Gender	Race	Age	Days in Study
1	Female	Black	15	116
2	Female	White	10	2
3	Female	Black	12	92
4	Female	Black	15	118
5	Female	Hispanic	17	88
6	Male	White	14	10
7	Male	Black	15	40
8	Male	White	17	77
9	Male	White	17	2
10	Female	Black	12	76

Acceptability: Of 12 children and their parents approached, 10 enrolled in the study (enrollment rate 83%). Seven (70%) remained in the study for at least 40 days. Two children withdrew from the study within 48 hours and a third withdrew on day 10 (attrition rate 30%). One child withdrew on day 40, the other six stayed in the study from 76-118 days. Acceptability was also evaluated using the structured interview data with 6 children who remained in the study for more than 40 days. All 6 who were interviewed responded (n = 6) that they were satisfied using the mobile devices.

Usability: We evaluated usability for the seven children who used the devices (n=7). Usability was measured using wearable device and app usage and missing data from the wearable device and app. Figures 5 and 6 illustrate group mean empirical summary plots for proportion of weekly missing heart rate (wearable) (Figure 5) and missing chart (app) (Figure 6) data throughout the study weeks. The proportion of missing data increased overall for both devices during the study.

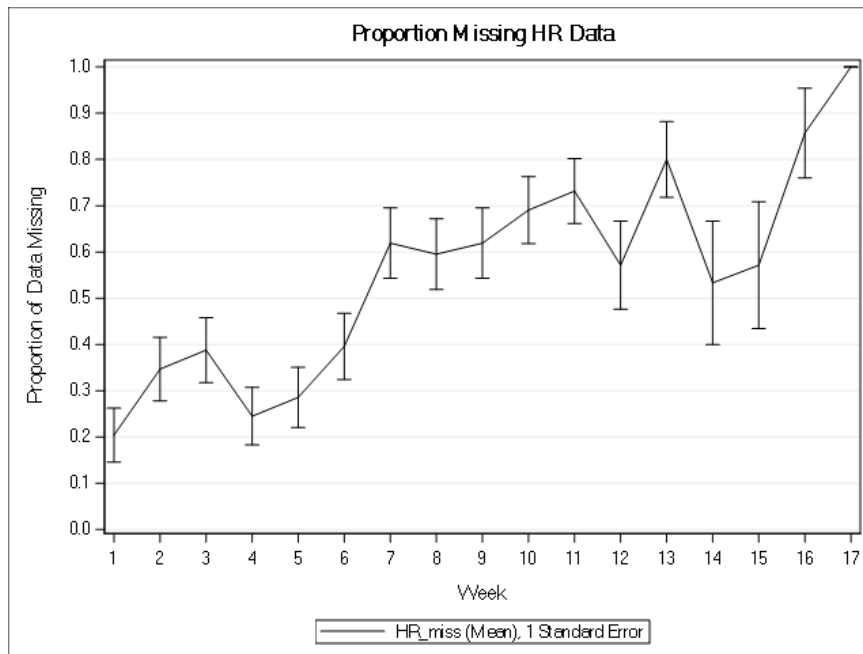


Figure 5: Empirical Summary Plot Missing HR Data

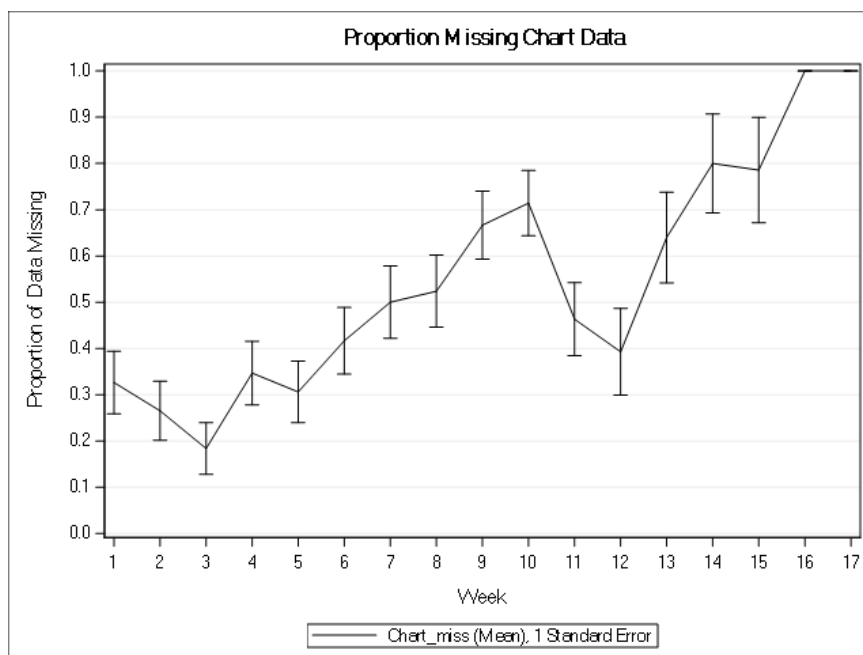


Figure 6: Empirical Summary Plot Missing Chart Data

Table 6 shows the number of days each child (n=7) used the devices during the study and group mean of use for each device. Wearable usage was defined as using the wearable for more than 3 hours per day. Recording in the app usage was defined as charting in the app at least once per day. On average, children wore the wearable device 51% of their total days in the study and recorded data in the app an average of 56% of their days in the study.

Table 6: Number of days children (n=7) wore or used mHealth tools while in study

	Pt 1	Pt 3	Pt 4	Pt 5	Pt 7	Pt 8	Pt 10
Days wearable was worn/Days in study	70/116	69/92	40/118	42/88	21/40	46/77	19/76
Days recorded in app/Days in study	77/116	17/92	41/118	79/99	31/40	25/77	54/76

Another indicator of app usability is illustrated in the heat map (Figure 7). The dark gray shaded regions represent each day a child recorded in the app. The heat map also depicts symptom data recorded by the children (each child is listed on the right). It is a 2-dimensional chronological visualization of symptom occurrences and intensity. The x-axis shows the study day and the y-axis shows symptoms. The colors represent symptom intensity on a scale of 0-10 ranging from blue (low intensity) to red (high intensity).

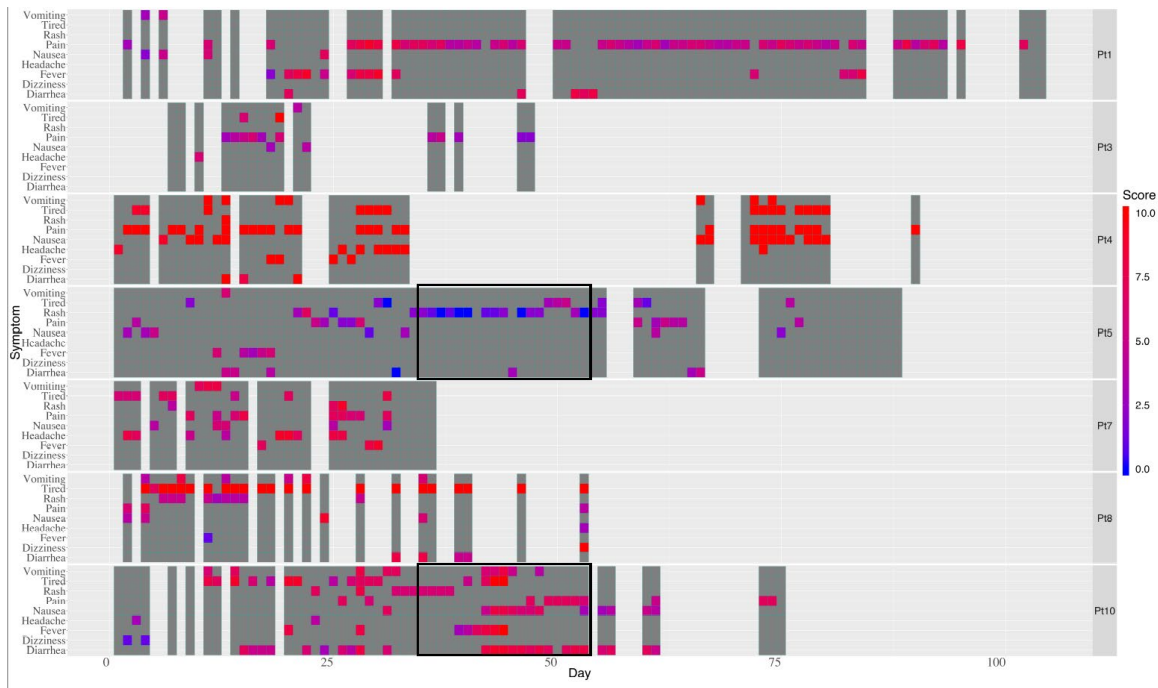


Figure 7: Symptom Heat Map

Interview data: Children (n = 6) reported missing data from the wearable was due to forgetfulness (forgetting to wear and/or charge the device), feeling too ill to wear the device, or rashes or pain that prevented wear. For the app, children (n = 5) reported missing data was due to forgetfulness, pain, and fatigue. Children (n = 6) reported that overall the devices were easy to use and they encountered no technical difficulties. The three children who left the study within 10 days reported that it was too difficult to keep up with the device maintenance.

Feasibility survey results are summarized in Table 7. Scores ranged from 0-4. Children rated technical capability in terms of problems using the devices; scores ranged from 0 (problems using the device) to 4 (no problems using the device) with an average

score of 3.18. They also rated ease of use in terms of 0 (very hard) to 4 (very easy) with an average score of 3.76. Children rated satisfaction/acceptability with scores between 0 (very dissatisfied) to 4 (very satisfied) with an average score of 2.52.

Table 7: Feasibility Survey Responses

Feasibility Survey Questions	Average Score
Technical Capability	3.18
Ease of Use	3.76
Satisfaction/Acceptability	2.52

Design and Procedural issues: One design issue with the wearable tracker was identified by the first two children enrolled, who complained about the stiffness of the Microsoft Band II. In response we changed to the Apple Watch, which addressed the comfort issue, but did not collect sleep data. We added a sleep app to obtain this data. In addition, the Apple Watch had a shorter battery life (18-20 hours) than the Microsoft Band II (48 hours) and children reported difficulty in keeping up with charging the wearable. Of the four children who continued in the study as outpatients, three reported this as the main challenge of remaining in the study. Two children withdrew from the study once outpatient; one found device management too burdensome and the second lost the wearable. The third child did not wear the device due to a persistent rash and the fourth wore the device inconsistently until the 120-day timeline was reached.

3.4 Discussion

The use of mobile technology to collect continuous real-time patient data presents a unique opportunity to examine symptoms in novel ways. These real-time patient-generated health data may play an important role in understanding children's symptom experiences and add to the body of symptom science knowledge. This study is the first to our knowledge to examine the feasibility of integrating two mHealth technologies to collect longitudinal PBMT patient symptom data.

Children, with the consent of their parents, were eager to enroll in the study and 70% stayed in the study for 40 days or more, indicating high levels of acceptability. Their rate of daily wearable use during the study averaged 51%, which we found encouraging when compared to other studies. Recent data from a study using a wearable tracker with children with juvenile idiopathic arthritis averaged 72% for logged activity over a 28-day period (Heale et al., 2018). Our findings were slightly lower, likely due to the children in our study being acutely ill, hospitalized for most of the study, and using the device over a longer period of time.

The heat map demonstrates app usability, and importantly, illustrates symptom intensities, patterns, and changes over time. Presenting data in this manner is a valuable approach that gives clinicians and researchers the opportunity to assess patient-reported symptoms each day and facilitate improved understanding of symptoms. The overall percentage of days children (n=7) used the app over the course of the study was 56%.

This level of reporting is encouraging and suggests that mobile technology can be a useful method to collect patient-reported symptom data for children. App usage showed a decreasing trend over time and our app usage rates are similar to other studies. One study found a 27% app reporting rate for adult medication adherence over an 84 day time period (Becker et al., 2013) and a second study found a 45% app reporting rate for women reporting sleep disturbances over a 90 day time-period (Min et al., 2014).

The three children who withdrew within 10 days found the study demands too rigorous for how sick they were feeling. Two had already completed their pre-transplant conditioning and were experiencing significant symptom distress upon study enrollment. The other seven children began pre-transplant conditioning at the time of study enrollment, which may have provided an acclimation period to the technologies prior to the onset of intense symptoms thus improving device engagement. Six of these children reported a high level of satisfaction with the study and the devices, and reported that the devices were easy to use.

To ease participant burden, a study nurse assisted children with device maintenance (charging and software updates), suggested “scheduled” times to charge the wearable (i.e., during daily shower time and meal times), and encouraged parent caregivers to remind the children to use the devices. This level of device support, particularly the parent caregiver engagement, will be necessary for a larger study to optimize data collection and minimize participant burden. Other studies have had

success with children with chronic diseases managing mobile devices more independently (Fortier et al., 2016), however, children in our study sample were acutely ill. We saw study engagement decrease once children were discharged to outpatient management. As outpatients, they came to the clinic each day for treatment, but had difficulty remembering to use the wearable and chart in the app. When asked, children reported the increased self-management responsibilities (frequent medications, central line care) superseded study involvement.

Future development will include a re-designed app that uses gamification and rewards to increase satisfaction and adherence to daily recording. The literature shows these features increase engagement and compliance with devices (A. S. Miller, Cafazzo, & Seto, 2016; Taylor, Ferguson, Peng, Schoeneich, & Picard, 2019). We may also incorporate a response button in the symptom tracking list for children to document “don’t feel well enough to chart”. This feature may improve understanding of missing data by identifying times when symptom distress prevents children from charting symptoms. We will also investigate a waterproof wearable that would decrease the number of times it is removed, thus decreasing the likelihood of children forgetting to put it back on after their daily shower.

Our approach had several strengths. This study demonstrated that it is feasible to collect patient-generated real-time longitudinal symptom data in acutely ill children using two mobile devices. Combining physiologic data from the wearable with child-

reported symptom data from the app will enhance understanding of their symptom experience as it changes over time and contribute to the growing body of pediatric symptom science research.

Limitations of the study include that study engagement may have been influenced by the novelty of the mobile devices we provided, particularly if children did not already own these devices. We also measured feasibility based on device missing data, however, the limited battery life of the wearable plus the child's level of health may underrepresent the child's engagement. Final limitations were the limited sample size and use of a single institution for the study both of which may affect the generalizability of our findings.

3.5 Conclusion

Despite the proliferation of mHealth technologies, few studies have evaluated their role in symptom monitoring in children undergoing PBMT. Conducting a feasibility study with acutely ill children at the start of their hospitalization using mobile devices to obtain symptom data was an important first step in designing a larger study. Our ability to collect time-dense longitudinal symptom data from children and demonstrate acceptability of using mobile technology indicates that it is feasible. In addition, our findings uniquely highlight how mobile technologies can be used to obtain symptom data to enhance understanding and lead to symptom management strategies.

4. Symptom Monitoring using Mobile Technology for Children with Life-Threatening Illness

4.1 Introduction

Children and adolescents with life-threatening illness such as cancer or those undergoing blood and marrow transplantation, experience significant symptom distress (Baggott et al., 2010; Brock et al., 2018; Johnston et al., 2018). Intense, debilitating symptoms come from the underlying disease and treatment and include severe pain, fatigue, nausea, vomiting, and sleep disturbances (Beyer, Simmons, Woods, & Woods, 1999; Brock et al., 2018; Cohen et al., 2012; Erickson et al., 2013; Panepinto et al., 2013; Sourkes, 2018). Symptoms are poorly recognized, under-reported, and thus inadequately treated in children and adolescents with life-threatening illness (Brock et al., 2018; Fortier et al., 2016; Pinheiro et al., 2018; Snaman et al., 2018) leading to a cycle of ongoing and escalating symptoms placing them at risk for overall poor outcomes (Larsen et al., 2003; Lopes-Junior et al., 2015; Miaskowski, Barsevick, et al., 2017). In addition, children with significant symptom distress are less likely to adhere to treatment, (Coughtrey et al., 2018; Ilowite et al., 2018) and more likely to delay treatment (E. Miller et al., 2011). Distressing symptoms have been reported by these children and adolescents as the worst part of their illness (Hong et al., 2016; Rodgers et al., 2014).

Most research to better understand symptom dynamics (occurrences, clusters, trajectories) in children and adolescents with life-threatening illness has been cross-sectional, giving a snapshot view, and often relies on patient recall at the time of data

collection. Thus, knowledge gaps exist about ongoing symptom complexity, patterning, and how and why these symptoms change over time (Baggott et al., 2010; Buckner et al., 2014; Hockenberry et al., 2017). Longitudinal research has the potential to give deeper insight into the ongoing, dynamic, and changing nature of the symptom experience. Yet limited longitudinal research has been conducted for this age group. Longitudinal research can advance understanding of symptom dynamics and ultimately lead to the clinical application of personalized symptom management interventions that target symptom distress (Anderson et al., 2007; Baggott et al., 2010; Hockenberry et al., 2017).

Reliable symptom assessment and monitoring are crucial for prevention, alleviation, and/or prompt treatment of unpleasant symptoms experienced by children and adolescents with life-threatening illness (E. Miller et al., 2011; Sourkes, 2018). Recent advancements in mobile health technology (mHealth) have improved our ability to capture real-time patient-generated health data (PGHD) and thus holds the potential to revolutionize our understanding of illness and the associated symptom dynamics (Boodoo et al., 2017; Heintzman, 2015; Nowell, 2019; Shah et al., 2014; van der Veer et al., 2017; Wood et al., 2015). These dense streams of PGHD can illuminate a comprehensive real-time picture of a patient's health and symptom dynamics (van der Veer et al., 2017; Wood et al., 2015). For example, wearable devices such as the Apple Watch™ and Fitbit™, can passively collect real-time physiologic data (heart rate (HR), step count, sleep hours and quality), (Heintzman, 2015) have advanced computing capabilities, and

are widely used to monitor and track health data (Heintzman, 2015; Nowell, 2019; van der Veer et al., 2017). These devices are rapidly increasing in accuracy, reliability, and predictive capabilities (Bai et al., 2018; Khushhal, 2017; Nelson & Allen, 2019; Thomson et al., 2019).

Other mHealth technologies such as smartphone applications (apps) are capable of tracking PGHD (Leahy et al., 2018; Nowell, 2019). Having children track and report their symptoms daily in an app not only provides longitudinal PGHD, but also gives their “voice” to their symptom experience. Importantly, there is increasing evidence that children and adolescents prefer using technological approaches, such as mHealth for self-management (Baggott, Gibson, et al., 2012; Estep et al., 2014; Fortier et al., 2016).

Advances in precision health, which individualizes patient care based on multiple sources of information (genetic, biological, behavioral, and environmental) can be aided through data obtained from mobile technologies to address symptom management. Given the prevalence of mHealth technologies and the strong developmental fit for children and adolescents, these devices and the PGHD they produce are likely to enhance our understanding of symptom dynamics (Greenwood et al., 2017; Hui et al., 2017; L. Miller et al., 2017) and importantly inform precision health symptom management strategies (Heintzman, 2015; Jain et al., 2015; Nowell, 2019).

Purpose: The purpose of this study was to advance understanding of symptom dynamics, address knowledge gaps, and inform precision health symptom management

strategies. Our aims to achieve this were; 1) to explore the feasibility of using mobile devices to obtain child/adolescent generated symptom data in children and adolescents with life-threatening illness; 2) to visualize these data and develop personalized symptom profiles and explore symptom dynamics (occurrences, clusters, and trajectories); and 3) through interviews, explore child, adolescent, and parent perceptions of facilitators and barriers to symptom management using mobile health devices and how to best visualize these data.

Theoretical Framework

The methodologic design and analysis for this study were framed by an adaptation of the Theory of Unpleasant Symptoms (TUS) combined with an adaptation of the NIH Symptom Science Model (NIH SSM) (Figure 8). This framework guided our research using mobile technology data to advance understanding of the complex symptom distress experienced by children and adolescents with life-threatening illness. The TUS broadly guides symptom science research by identifying symptoms, examining the influencing factors, illuminating determinants of the problem, and offering insight into the population experiencing the problem as well as guiding intervention development (Lee et al., 2017; Lenz et al., 1995; Lopes-Junior et al., 2015). We explored the theory's key components of the symptom experience (timing, intensity, duration, distress, and quality) using mHealth technologies to better understand the symptom dynamics children and adolescents with life-threatening illness experience (Figure 8).

The theory guided the symptom assessment, evaluation, and the development of symptom data visualizations. The NIH SSM outlines a systematic progression for symptom science research for identifying complex symptoms, characterizing symptom phenotypes, investigating biomarkers that will lead to the development of precision health symptom management strategies (Cashion et al., 2016). Our study used the model's first two steps, identifying complex symptoms and exploring possible phenotypes using data from mHealth technologies.

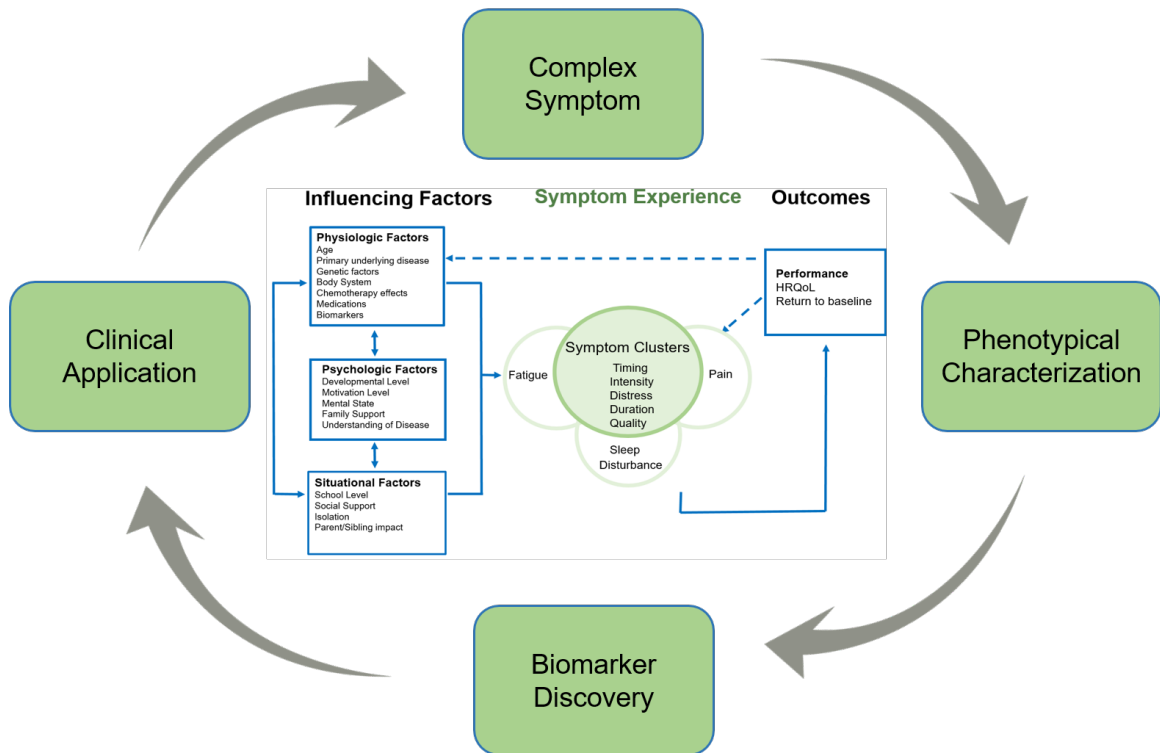


Figure 8: Theory of Unpleasant Symptoms and NIH Symptom Science Model

4.2 Design and Methods

4.2.1 Study Design:

The longitudinal mixed-methods study began in August 2018 at a major medical facility in the southeastern United States. Eligible participants were children (8-12 years) or adolescents (13-17 years) undergoing cancer treatment or a blood and marrow transplant.

4.2.2 Participants

Participants received a study loaned wearable device (Apple watch) to record physiologic data (heart rate, step count) and an iPhone with a proprietary mobile app for the child, adolescent, or parent to enter daily responses to queries about symptoms. Because some patients might forget or be too ill to wear the Apple Watch or record in the app daily, we also incorporated Patient-Reported Outcome Measurement Information System (PROMIS) surveys for pain, fatigue, and sleep disturbances to be obtained at 30, 60, and 90 days. PROMIS measures are validated self-report surveys and were administered via Research Electronic Data Capture (REDCap) hosted at (blinded) university. REDCap is a secure, Health Insurance Portability and Accountability Act (HIPAA) compliant, web-based application that supports data capture and management for research studies (Harris et al., 2009). Semi-structured interviews were also conducted with study participants and parents at study discharge. We sought to obtain feedback on participants' and their parent's perspectives on the feasibility of using two

mobile devices during the study, and experiences with the Apple Watch and study app. Additionally, we aimed to obtain input and feedback on visualizing the symptom data generated from the mobile device data. Using Tableau software (Tableau, 2018), we created visualizations; bar charts depicting symptom patterns and trajectories, pie charts depicting symptom percentages, and heat maps depicting symptom intensities over time for each participant. These data visualizations were shared with children, adolescents, and their parents during the study interviews.

Setting and Sample Size: This single-site study enrolled a convenience sample of 20 children and adolescents with life-threatening illness, ages 8-17 years, undergoing cancer treatment or blood and marrow transplantation. Children or adolescents diagnosed with cancer were hospitalized (inpatient or day hospital) for myelosuppressive chemotherapy and/or radiation and could be followed up to 120 days. Children and adolescents were recruited irrespective of cancer diagnosis and not during first round of treatment. All children and adolescents requiring blood and marrow transplantation were hospitalized for the acute phase of treatment (myelosuppressive treatment through engraftment and bone marrow regeneration) and could be followed outpatient up to 120 days in the study. As this study was exploratory in nature, we planned that participants could remain in the study for up to 120 days with the aim of determining a reasonable benchmark for future research. We chose this sample (children and adolescents undergoing cancer treatment or blood and marrow transplantation)

since they both share an aggressive treatment regimen, hospitalization for treatment, and intense symptom distress.

Our sample size (N =20) was based on human factors testing citing 5 users as sufficient to closely realize most usability benefits (Nielsen & Landauer, 1993), to examine feasibility of recruitment and retention, and to receive diverse qualitative feedback from participants. Our sample was consistent with other studies piloting mobile devices for persons with chronic disease including cancer (Baggott, Gibson, et al., 2012), blood and marrow transplant (Hacker et al., 2018; Rodgers et al., 2013) and diabetic patients (Cafazzo et al., 2012), all who found the size adequate to evaluate study feasibility. Twenty participants allowed us to test out the study procedures, assess the feasibility of using the wearable and study app, discover any unexpected design problems, estimate dropout rates, and obtain reasons for dropouts.

Participants were recruited from the pediatric oncology clinic or pediatric blood and marrow transplant (PBMT) clinic. A clinic practitioner screened for potential participants then introduced the study to the child or adolescent and their parent(s). If the child or adolescent and their parent expressed interest, a nurse researcher met with them to present the study, discuss objectives and risks, and answer questions. Informed consent was obtained from the parent and assent was obtained from the child or adolescent.

Ethics: The medical center Institutional Review Board approved the study protocol (Pro00068979). Data was secured on a server that meets Health Insurance Portability and Accountability Act (HIPAA) requirements. Patient mHealth data was transmitted without identifying information and entered into the system with a study-provided password.

4.2.3 Data Collection:

Feasibility was assessed as mobile device acceptability and engagement. Multiple data collection techniques were used to collect feasibility data:

- 1) An Apple Watch Series 1 collected daily physiologic data (heart rate, step count);
- 2) A smartphone (Apple iPhone 6 or 6S) study app collected daily symptom data;
- 3) Patient Reported Outcomes Measurement Information System (PROMIS) survey adherence rates via email; and
- 4) Interview data from children and adolescent study participants and their parent(s) designed to elicit their perspectives and mobile device use, engagement, and visualization of the data.

The Study measures are summarized in Table 8.

Table 8: Study Measures

Variable	Instrument	Description	Data Points
Demographics	Abstracted from EHR	Age in years, gender, race, ethnicity, diagnosis. For PBMT participants, transplant date, engraftment date.	Enrollment
Heart Rate (HR) & Sleep	Apple Watch	Tracks HR & hours and quality of sleep	Continuous
Physical Activity	Apple Watch	Step count	Continuous
Symptoms (all)	Self-report via TRU-PBMT/Onc app	App has numeric rating scales (intensity), time, interventions used (if any),	Daily
Fatigue, Sleep, Pain	PROMIS Ped Fatigue, Sleep Disturbance, & Interference, Pain Behavior	PROMIS Scales: Pediatric scales, Short Form (SF), well validated/reliable. Pediatric Scales: (PED Fatigue v. 2.1 SF 10a 10 item, Sleep Disturbance 6a 6 item, Sleep Related Impairment 8a 8 item, Pain Behavior SF 8a 8 item)(PROMIS, 2017)	Enrollment Monthly Study DC
Patient/Parent perspectives	Interview guide	Study developed symptom experience interview guide	Study DC

Quantitative Data Collection: Data was collected at baseline, daily, and monthly.

Demographic data from the electronic health record (EHR) was collected at baseline.

Acceptability was measured by enrollment rate, attrition rate, and overall participation in the study each week.

Wearable data collection: Apple Watch data (heart rate (HR), step count) were continuously collected when a patient wore the device, then were manually uploaded by the research nurse who visited the participants frequently to assist with technical or logistical issues (such as charging or software updates). We loaded a sleep app on the Apple Watch for participants interested in monitoring their sleep (n=15). Patients were asked to wear the Apple Watch except when bathing or charging.

Study App data collection: For the daily app data collection the investigative team developed the study app, Technology Recordings for better Understanding Pediatric Blood and Marrow Transplant (TRU-PBMT) app (Vaughn, Jonassaint, Summers-Goeckerman, Shaw, & Shah, 2018) (Figure 9). This same app was re-designed for use with the pediatric oncology patients and named the Technology Recordings for better Understanding Pediatric Oncology (TRU-Onc) app. The apps were similar except for the health provider specified daily care goals (bathing, mouth care), number of laps walked, and the addition of symptom emojis to the text list in the TRU-Onc app (Figure 9). Both apps were designed with a key feature, the “Symptom Tracker” tab that served as a symptom diary. Participants (or parents if participants were too ill) were asked to record symptoms such as pain, fatigue, and sleep quality in the app. Children and adolescents rated their symptoms’ intensity using the psychometrically valid and reliable numeric

rating scale (0 = no symptom; 10 = worst intensity of symptom) (Bailey, Daoust, Doyon-Trottier, Dauphin-Pierre, & Gravel, 2010; Castarlenas, Jensen, von Baeyer, & Miró, 2017; Miró, Castarlenas, & Huguet, 2009). They recorded the timing of symptoms and any pharmacologic or non-pharmacologic interventions used to treat the symptom(s). The study app had an audible daily prompt set for 6:00 pm to remind children and adolescents to record their data. Children and adolescents were asked to record any symptoms they experienced daily. The study app also used the psychometrically valid and reliable Bristol Stool chart (Lane, Czyzewski, Chumpitazi, & Shulman, 2011), an appetite tab, and a general health tab. The TRU-Onc app had a mood tracker tab using emoji to encourage the children and adolescents to record their mood each day (Figure 10). The study apps were developed in Apple HealthKit with patient, parent, and healthcare provider input. Both apps feature child-friendly language and graphics. Participants recording on any tab in the study app was used as a measure for study app engagement.

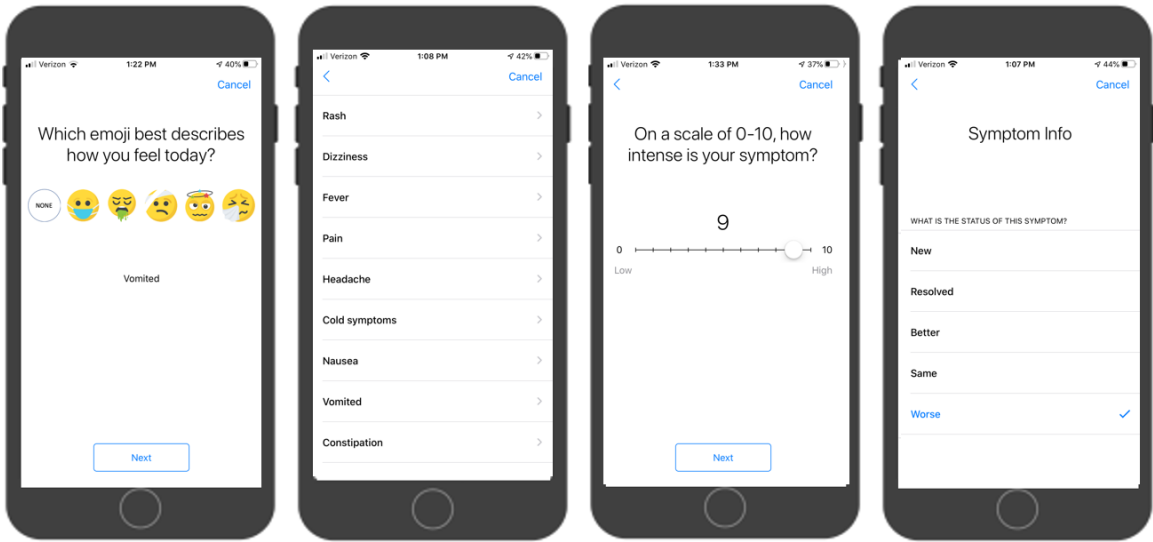


Figure 9: Study App

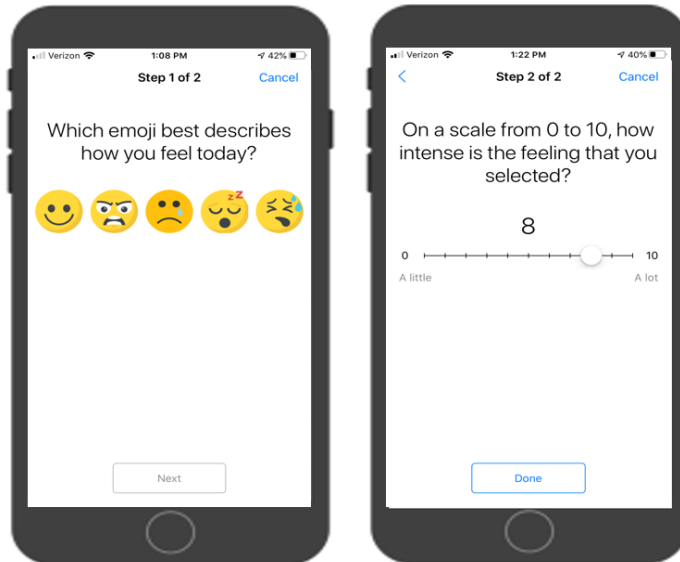


Figure 10: Study App Emoji Mood Scale

Survey data collection: At baseline and every month for four months, four Patient-Reported Outcomes Measurement Information System (PROMIS) surveys (Pain Behavior, Fatigue, Sleep Disturbance, and Sleep Related Impairment) were collected. PROMIS surveys are National Institutes of Health Tool Box measures developed to evaluate health in adults and children. These valid and reliable surveys facilitated a systematic approach and were chosen to complement the daily data collection and assessment (PROMIS, 2017; Varni et al., 2014). The surveys provided symptom data if the patient did not wear the watch or record data in the study app. PROMIS surveys are scored using a T-score which uses a range of 20-80, a mean of 50, and a standard deviation of 10 of a relevant reference population (PROMIS, 2017). T-Scores are easily interpreted using the Interpretation PROMIS Scores Graph and can range from “Within Normal Limits” to “Mild,” “Moderate,” and “Severe” (Figure 11).

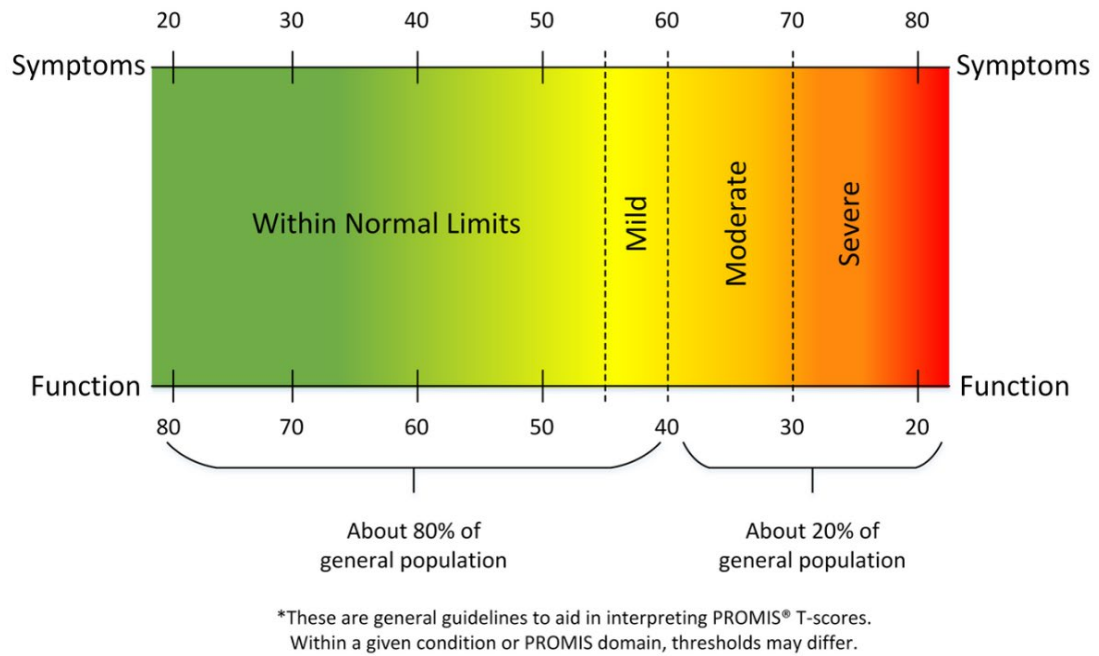


Figure 11: PROMIS Guide for Interpreting T-Scores

Qualitative Data Collection: A study team member trained in qualitative methods conducted individual, in-person semi-structured interviews with children and adolescents at study discharge. The interviews ranged from 5-15 minutes in length and consisted of open ended questions designed to explore the participant’s experiences with the mobile devices and perspectives on feasibility, usability, and acceptability of the devices. Children and adolescents were asked to describe their perspectives on the feasibility of using the devices, level of engagement with the devices, and if use of the devices influenced their symptom awareness or management during the study. Near the end of the interview, participants were shown data visualizations displaying their data

from the Apple Watch and study app that showed their symptom trajectories during their time in the study. Interview questions were designed to elicit their understanding of the data visualizations, perspectives on data visualization characteristics (i.e., color, shape, graph type, amount of information), meaning of the data visualization, and overall impression of the data visualizations. Interview data was both audio-recorded and/or obtained using field notes, then transcribed.

Interviews were also conducted with parents to obtain their perspectives on the feasibility of using the mobile devices to better manage their child's symptoms. Parents viewed their child's data visualizations and gave feedback on usefulness, meaningfulness, effectiveness, and ease of interpretation. Parents were also asked to describe how these visualizations might have influenced awareness or management of their child's symptoms or influence their communication with clinicians about their child's symptoms.

4.2.4 Data Analysis

Acceptability: Acceptability was measured as study enrollment rate and attrition rate for those who withdrew from the study within the first week. We also assessed the number of weeks that children and adolescents participated in the study to inform future study endpoints.

Engagement:

1. Apple watch engagement: the proportion of days that participants wore the watch during the study. We confirmed use of the Apple Watch each day by the heart rate being recorded. Engagement was defined as number of days the participant wore the watch over the total number of days in the study and represented as a percentage. In addition, these same data were aggregated on a weekly level to explore the engagement trend during the study period. Frequencies, means, medians, interquartile, ranges, and standard errors were assessed for Apple Watch data (HR) and provided a quantitative description of the Apple Watch engagement.
2. Study App engagement: the proportion of days that the participant recorded in the study app during the study. Engagement was defined as number of days the participant recorded in the study app over the total number of days in the study and represented as a percentage. Study app engagement was also calculated on a weekly basis to explore the trend over time. Frequencies, means, medians, interquartile, ranges, and standard errors were assessed for the study app. Any daily data recorded in the app was used as a measure of app engagement. For example, a participant might record symptoms in the symptom tracker one day, then record stool output in the Bristol stool record on another day, and thus received credit for recording on 2 days. Individual symptoms were analyzed for frequency, intensity, and duration longitudinally during the study. Frequency of

daily app recording were analyzed in relation to the timeline to determine engagement patterns (for example, when patients felt sicker, such as during engraftment or immediately after chemotherapy, they may be less likely to record in app).

3. Survey adherence: The proportion of PROMIS survey completion at each time point (baseline, 30 day, 60 day, 90 day) for the four PROMIS surveys was assessed.

Quantitative Data Analysis: Quantitative data was analyzed using SAS 9.4 (Cary, NC) statistical software and visualized using Tableau software. Data were analyzed descriptively using graphics, frequencies, percentages, means, and measures of dispersion. Statistics for participant characteristics: age, gender, ethnicity, treatment category were summarized. For children and adolescents undergoing blood and marrow transplant, date of transplant and date of engraftment were summarized and used in the data visualizations as treatment benchmarks.

Apple Watch Data: Device engagement and engagement patterns were analyzed to assess for the feasibility of using the Apple Watch. Engagement of Apple Watch use was analyzed over time using empirical summary plots. These data were plotted to visualize significant trends during treatment and complications.

Study App Data: Device engagement and engagement patterns were analyzed to assess for feasibility of using the study app. Engagement with the study app was analyzed over

time using empirical summary plots. These data were plotted to visualize significant trends during treatment and complications.

PROMIS survey data: was collected at baseline and monthly using REDCap electronic data capture tools. The analysis included rates of adherence for survey completion and descriptive statistics for symptom T-scores. Participant T-scores were plotted on the PROMIS Scores Interpretation graphs.

Qualitative Data Analysis: The semi-structured interview data was analyzed and used to enrich the quantitative data and to gain deeper understanding of participants' and parents' experiences with and perceptions of the mobile devices (Colorafi & Evans, 2016). Data analysis was conducted using content analysis (Hsieh & Shannon, 2005; Zhang & Wildemuth, 2009) and supported by NVIVO 12 software (QSR International 2018). The interviews were transcribed, reviewed in their entirety, and systematically coded (phrases, sentences, and paragraphs) by the research team, initially by the first author (JV) then reviewed and discussed with a co-author and qualitative expert (SD) and study team members. Apriori codes were based on the mHealth and symptom literature and the semi-structured interview guide. Emergent codes were generated based on participants' comments. Credibility and rigor were ensured by consistent study team meetings to review data collection and analysis, creation of a codebook, and maintenance of an audit trail which documented codes, themes, and analysis progression (Cope, 2014). We initially developed a code book, then further refined the

codes which guided subsequent application. Refined codes were grouped into categories. This process led to the establishment of the broader themes which described relationships among categories that illuminated key elements of feasibility, engagement, usability, satisfaction, suggestions for improvement, and usefulness of data visualizations (Vaismoradi, Turunen, & Bondas, 2013).

4.3 Results

Participant recruitment and enrollment into the study began in August 2018 and finished in March 2020.

4.3.1 Quantitative Results:

Descriptive statistics: A total of 20 children and adolescents were approached and enrolled for study recruitment. Table 9 presents the demographic and clinical characteristics of the sample. The mean age was 13.25 years, range (8-17 years); overall, 45% of the sample was children 8-12 years of age, and 55% was adolescents 13-17 years of age. Of the total sample, 35% was Black, 15% of the sample was Hispanic, and 50% of the sample was White, 45% identified as male and 55% identified as female. For treatment group, 60% were oncology patients while 40% underwent blood and marrow transplantation.

Table 9: Sample Characteristics

N=20	n	%	M (SD)	Range
Gender				
Male	9	45%		
Female	11	55%		
Race				
Black	7	35%		
Hispanic	3	15%		
White	10	50%		
Age			13.25 (3.04)	(8-17 years)
8-12 years	9	45%		
13-17 years	11	55%		
Treatment Group				
Pediatric Oncology	12	60%		
Pediatric BMT	8	40%		

Standard Deviation (SD)

Acceptability: A total of 20 patients were approached to join the study and all 20 enrolled in the study (enrollment rate 100%). Of the 20 patients who enrolled in the study, 15 (75%) remained in the study for at least one week. Three participants withdrew from the study within 4 days and two more withdrew within seven days (attrition rate 25%). All five children and adolescents who withdrew from the study described feeling too ill to continue participation. Figure 12 shows the changes in study participation each week of the study.

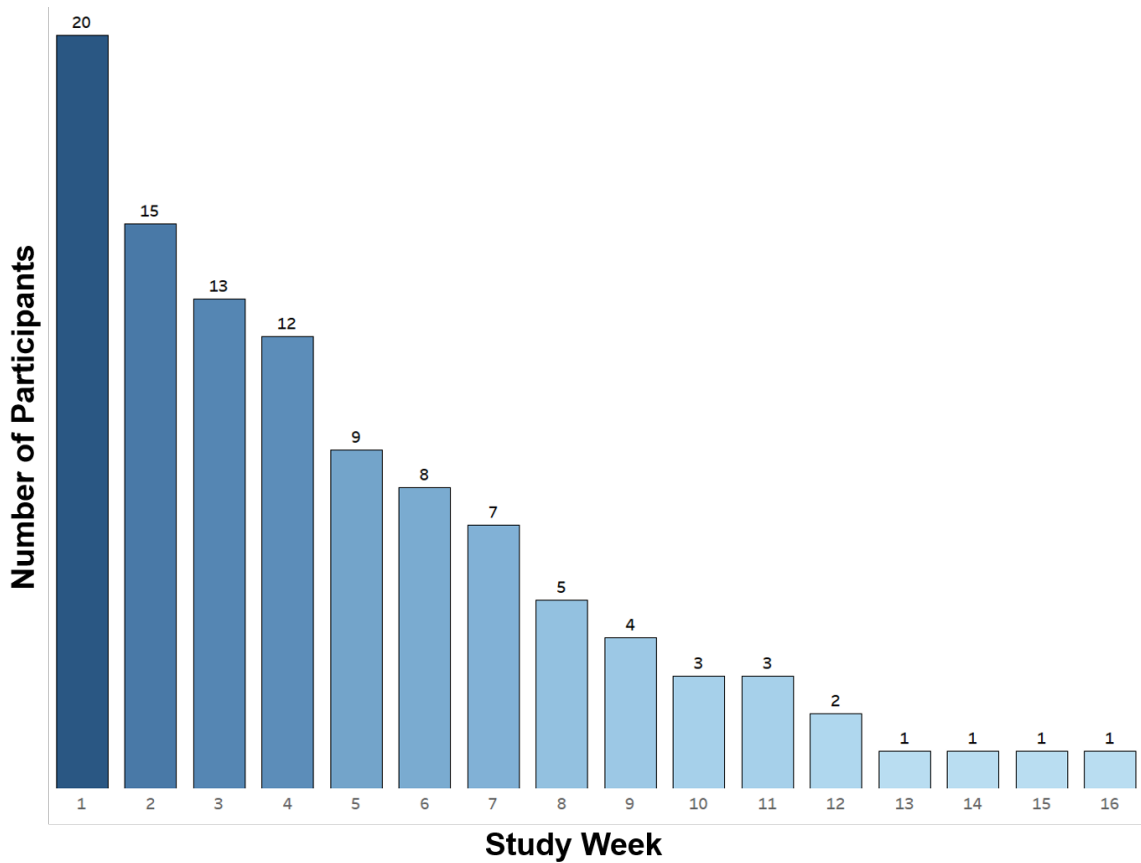


Figure 12: Study Participation by Week

The median number of weeks in the study was 3.9 weeks (27 days; IQR 44, range 4 - 107 days) for all 20 participants. Comparing children to adolescents, we found children (n = 9) had a median of 4 weeks in the study (28 days, IQR 34, range 4 – 107 days) while adolescents (n = 11) had a median of 3.7 weeks (26 days, IQR 50, range 4 – 82 days) (Table 10). Additionally, we compared the median number of weeks in the study for each treatment group (PBMT or oncology). We found children and adolescents undergoing a PBMT (n = 8) had a median of 3 weeks in the study, (21 days, IQR 36,

range 5 - 82 days) while children and adolescents undergoing oncology treatment had a median number of 4.7 weeks in the study (33 days, IQR 46, range (4 - 107) (Table 10).

Table 10: Study Participation by Age Group and Treatment Group

N=20	Median # Days	IQR	Range
All Participants (N = 20)	27	44	4 - 107
Children (n = 9)	28	34	4 - 107
Adolescent (n = 11)	26	50	4 - 82
PBMT (n = 8)	21	36	5 - 82
Oncology (n = 12)	33	46	4 - 107

Pediatric Blood and Marrow Transplant (PBMT), Interquartile Range (IQR)

Engagement: Engagement was measured as participants' use of the Apple Watch and study app throughout the study. Overall, participants (n = 20) wore the Apple Watch 56% of their days in the study and engaged with the study app 63% of their days in the study (Table 11). Device engagement was also analyzed by week to give an indication of the trend in engagement over time (Table 12). Figure 13 shows the proportion of each device's weekly engagement throughout the study by all participants. We assessed device engagement trend for both children and adolescent groups and treatment groups (PBMT and Oncology) to see if differences occurred. The overall group mean proportion of device weekly engagement for both children and adolescent groups from each device over the number of weeks in the study are described in figure 14 for the Apple Watch, and figure 15 for the study app. The overall group mean proportion of device

engagement for the PBMT and Oncology groups are described in figure 16 for the Apple Watch and figure 17 for the study app.

Evaluating differences in device use by age group (child vs adolescent) is shown in Table 11. Findings revealed the children used the Apple Watch an average of 48% of the study days and the engaged with the study app 63% of the study days. Adolescents, however, used the Apple Watch and study app an average of 63% days in the study. To show the trend of engagement throughout the study, we assessed the mean device engagement each week of the study for each age group (Table 13).

We also assessed the two treatment group's device use (Table 11). The PBMT treatment group wore the Apple watch an average of 71% of the study days and recorded in the study app an average of 75% of the study days. The oncology group wore the Apple Watch only 48% of the study days and engaged with the study app 56% of their days in the study. To show the trend of device engagement for the treatment groups throughout the study, we calculated the mean device engagement each week of the study (Table 14).

Table 11: Device Engagement by Group

N=20	Apple Watch Use Mean (SD)	Study App Engagement Mean (SD)
All Participants (N = 20)	56 (50)	63 (48)
Children (n = 9)	48 (50)	63 (48)
Adolescent (n = 11)	63 (48)	63 (48)
PBMT (n = 8)	71 (46)	75 (43)
Oncology (n = 12)	48 (50)	56 (50)

Pediatric Blood and Marrow Transplant (PBMT), Standard Deviation (SD)

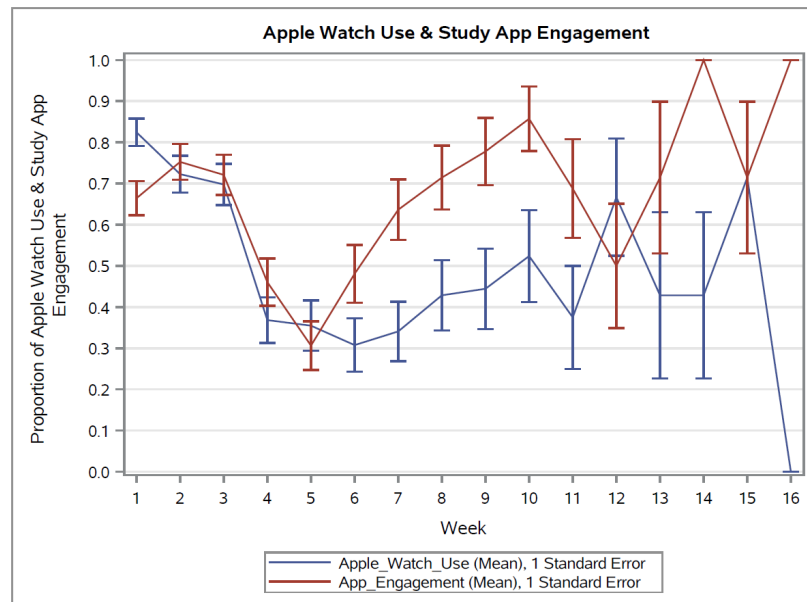


Figure 13: Proportion of Apple Watch Use & Study App Use by Week for all Participants (n = 20)

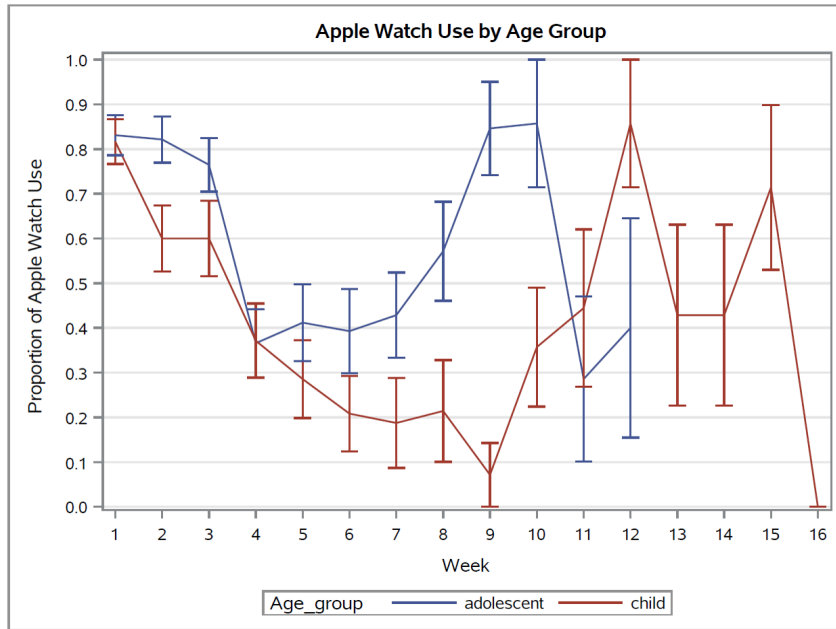


Figure 14: Apple Watch Use Empirical Summary Plot by Age Group

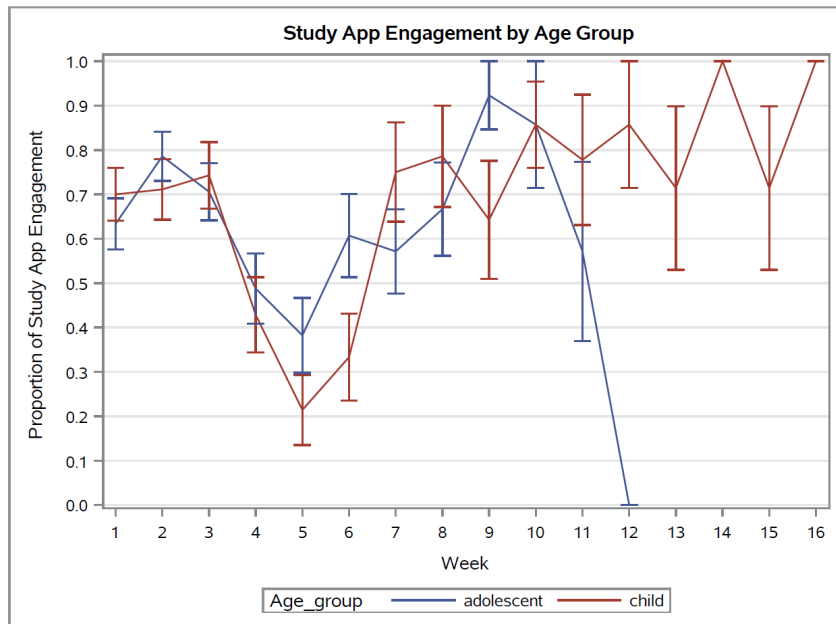


Figure 15: Study App Engagement Empirical Summary Plot by Age Group

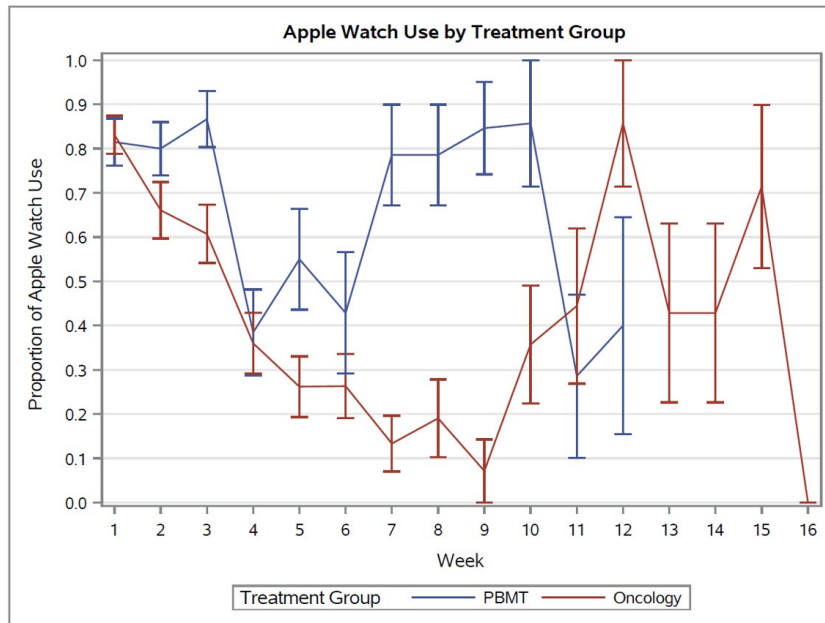


Figure 16: Apple Watch Use Empirical Summary Plot by Treatment Group

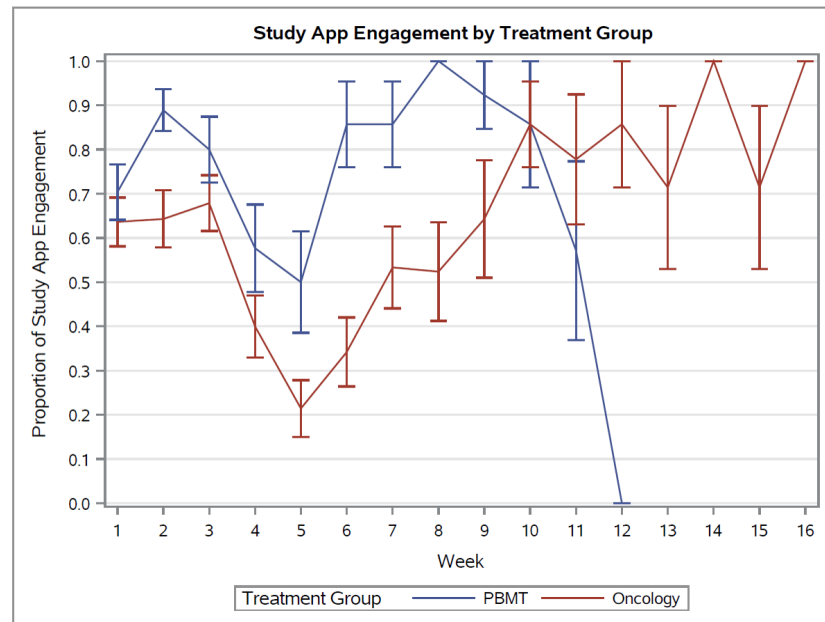


Figure 17: Study App Engagement Empirical Summary Plot by Treatment Group

Table 12: Mean Device Engagement by Study Week

Week in study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Sample Size (n)	20	15	13	12	9	8	7	5	4	3	3	2	1	1	1	1
Apple Watch Use	82%	72%	70%	37%	35%	31%	34%	43%	44%	52%	38%	67%	43%	43%	71%	0%
App Engagement	66%	75%	72%	46%	31%	48%	64%	71%	78%	86%	69%	50%	71%	100%	71%	100%

Sample Size = the number of participants (n) remaining in the study each week

Table 13: Mean Device Engagement for Age Groups by Study Week

Week in Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Sample Size (n)	20	15	13	12	9	8	7	5	4	3	3	2	1	1	1	1
Children Apple Watch Use	82%	60%	60%	37%	29%	21%	19%	21%	7%	36%	44%	86%	43%	43%	71%	0%
Adolescent Apple Watch Use	83%	82%	76%	37%	41%	39%	43%	57%	85%	86%	29%	40%	na	na	na	na
Children Study App Engagement	70%	71%	74%	43%	21%	33%	75%	79%	64%	86%	78%	86%	71%	100%	71%	100%
Adolescent Study App Engagement	63%	79%	71%	49%	38%	61%	57%	67%	92%	86%	57%	0%	na	na	na	na

Sample Size = the number of participants (n) remaining in the study each week; Not Applicable (na)

Table 14: Mean Device Engagement for Treatment Group by Study Week

Week in Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Sample Size (n)	20	15	13	12	9	8	7	5	4	3	3	2	1	1	1	1
PBMT Group Apple Watch Use	81%	80%	87%	38%	55%	43%	79%	79%	85%	86%	29%	40%	43%	43%	71%	0%
Oncology Group Apple Watch Use	83%	66%	61%	36%	26%	26%	13%	19%	7%	36%	44%	86%	na	na	na	na
PBMT Group Study App Engagement	70%	89%	80%	58%	50%	86%	86%	100%	92%	86%	57%	0%	71%	100%	71%	100%
Oncology Group Study App Engagement	64%	64%	68%	40%	21%	34%	53%	52%	64%	86%	78%	86%	na	na	na	na

Sample Size = the number of participants (n) remaining in the study each week; Not Applicable (na)

A detailed view of device engagement by day is seen in Table 15. We summarized each device’s use by day for all participants, age group, and treatment group.

Table 15: Number of Days Devices were Used for All Participants, Age Group, and Treatment Group

	Days of Apple Watch Use		Days of Study App Use	
	Mean (SD)	Median Range	Mean (SD)	Median Range
All Participants (N = 20)	19.25 (16.9)	14 (3 - 55)	21.6 (20.2)	18.6 (1 - 76)
Children (n = 9)	17.3 (16.9)	12 (4 - 55)	22.8 (22.6)	21 (4 - 76)
Adolescent (n = 11)	20 (17.6)	17 (3 - 55)	20.6 (19.2)	18 (1 - 63)
PBMT (n = 8)	22 (19.5)	14.5 (4 - 55)	23.4 (21.3)	18.5 (2 - 63)
Oncology (n = 12)	17.4 (15.5)	14 (3 - 55)	20.4 (20.3)	18.5 (1 - 76)

Standard Deviation (SD)

PROMIS Survey Adherence: We measured survey adherence rates as completion of the four PROMIS surveys (Fatigue, Pain Behavior, Sleep Disturbance, and Sleep Related Impairment) at each time point; baseline, 30, 60, and 90 days (no participants reached the 120 day time point). Table 16 shows the survey completion rates at each time point throughout the study by all participants. Eighteen of twenty participants completed the baseline surveys for 90% completion rate. By day 30, nine participants remained in the study, five of whom completed the surveys (56%), by day 60, four participants remained in the study 2 of whom completed the surveys, only one participant reached the 90 day mark and they did not complete the surveys.

Table 16: Adherence for PROMIS Surveys at Time Points

Survey Time point	Number (n) of participants who completed surveys	Number (n) of participants in Study at Time Point	Percent of Participants in Study who completed surveys at each time point
Baseline	18	20	90%
Day 30	5	9	56%
Day 60	2	4	50%
Day 90	0	1	0%

The PROMIS website and manual for scoring was used to calculate T-scores. We plotted the baseline, 30, 60, and 90 day T-scores. Figures 18-21 show the participant’s T-scores plotted on the PROMIS Scores Interpretation Graphs.

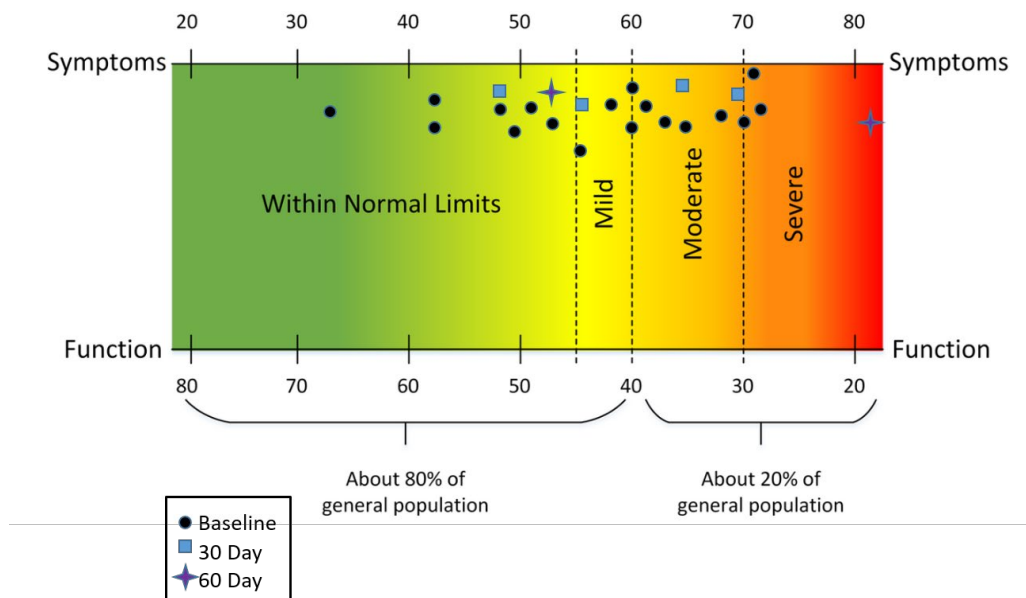


Figure 18: T Score for PROMIS Fatigue Survey

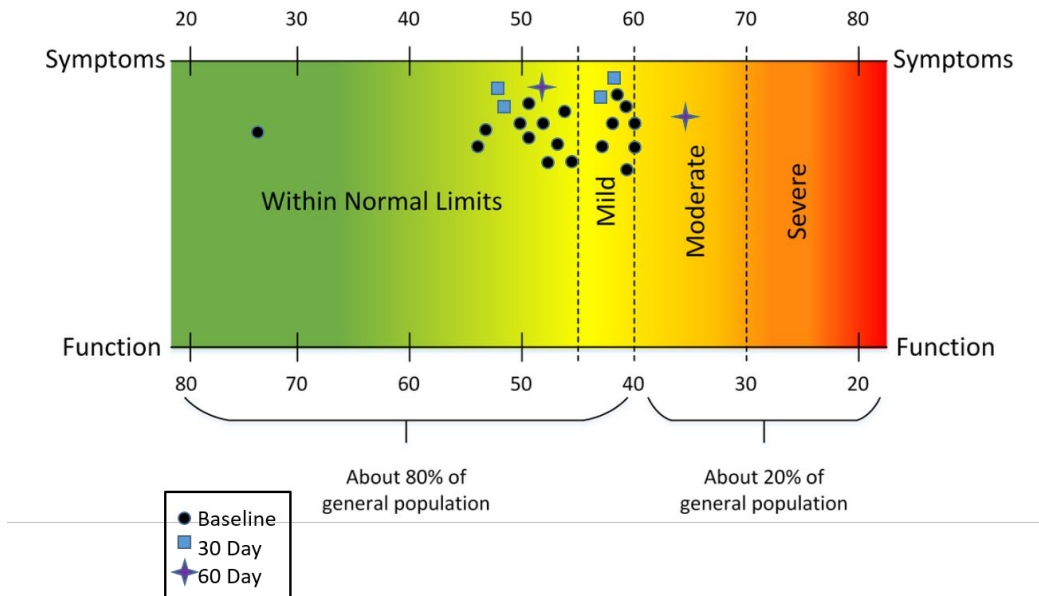


Figure 19: PROMIS Pain Behavior

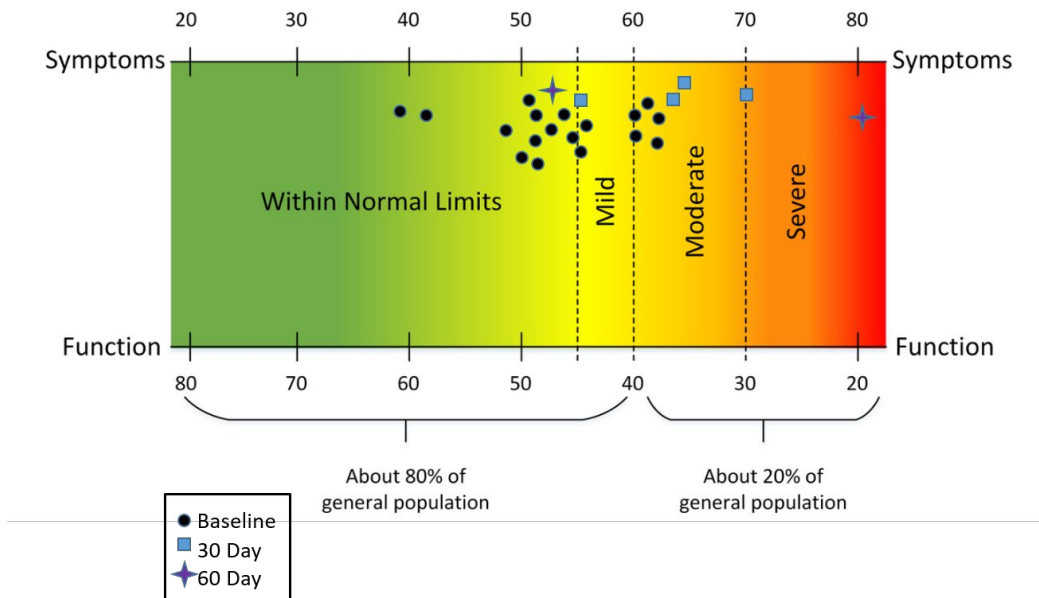


Figure 20: PROMIS Sleep Related Impairment

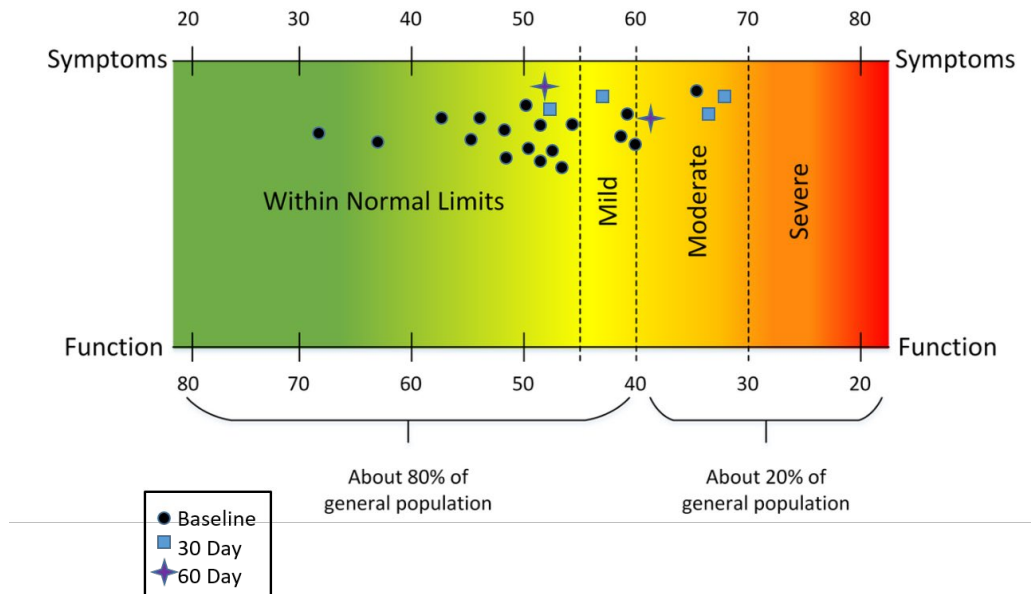


Figure 21: PROMIS Sleep Disturbance

Data visualizations: Data Visualizations were created using patient generated health data to give insight into the symptoms experienced for each participant. Personalized symptom profiles were generated by plotting each participant’s mHealth device data to visualize symptom dynamics (occurrences, clusters, and trajectories). Figures 22-26 are examples of personalized symptom profiles created for an individual participant. Figure 22, the pie chart depicts the top five symptoms the participant reported. We chose to limit the pie chart to the top five symptoms for easier viewing. Figure 23, a bubble chart reflects the frequency of reported symptoms in the size of the bubble. The stacked bar chart, figure 24, presents multiple symptoms denoted by different colors, and their intensities on a scale of 0 – 10 denoted by the height of the bar over the participant’s 107

days in the study. Figure 25, the symptom pattern bar chart, is a snippet of the overall chart that shows the patterns of symptom occurrences over time. Finally the symptom heat map depicts a chronological visualization that highlights symptom occurrences and intensities (Figure 26). The x-axis shows the study day and the y-axis shows the symptoms. The colors represent symptom intensity on a scale of 0-10 ranging from blue (low intensity) to red (high intensity).

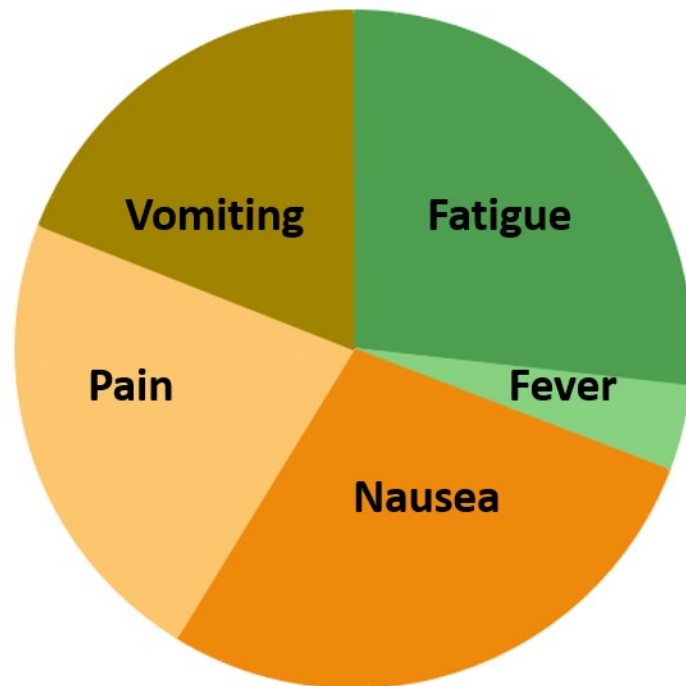


Figure 22: Symptom Pie Chart

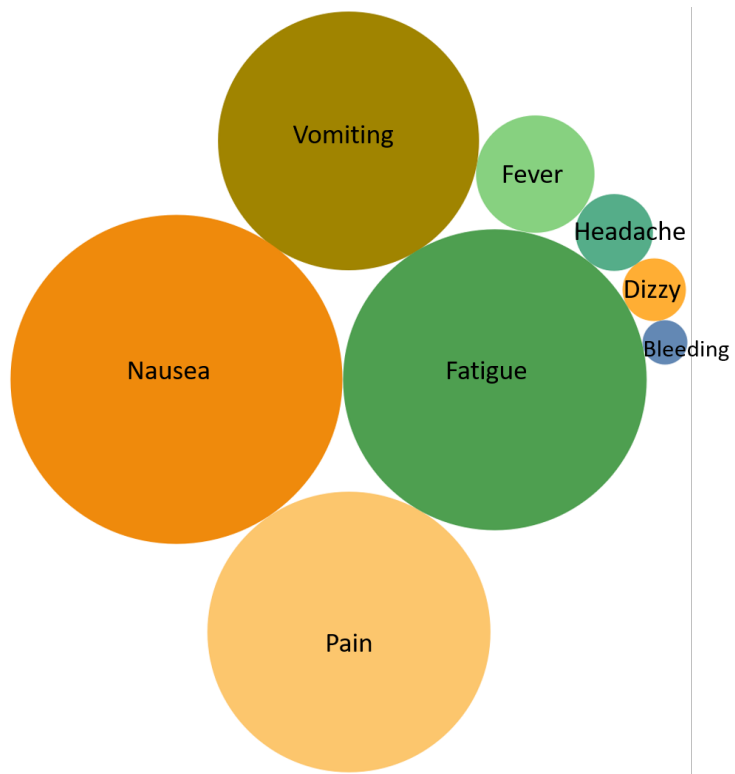


Figure 23: Symptom Bubble Chart

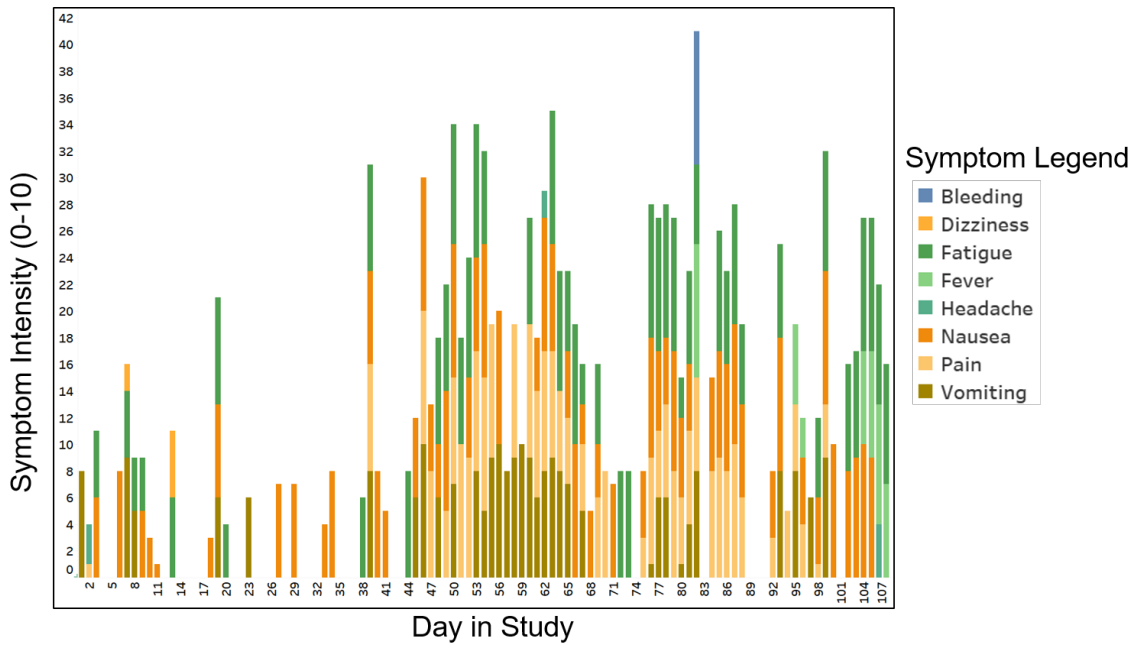


Figure 24: Symptom Stacked Bar Chart

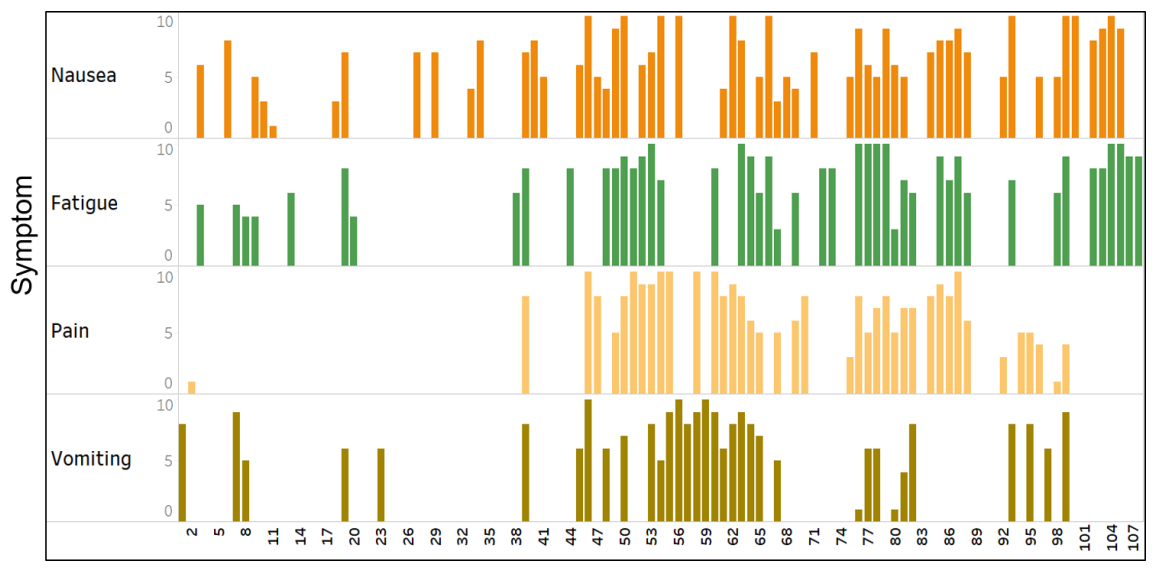


Figure 25: Symptom Pattern Bar Chart

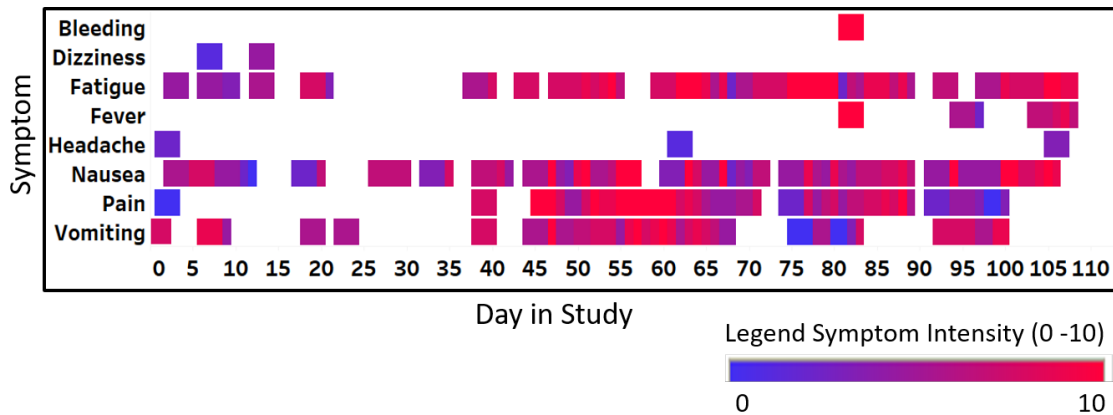


Figure 26: Symptom Heat Map

4.3.2 Qualitative Results

Children, adolescents, and parents discussed their perspectives’ on the use of mobile devices for symptom monitoring and described their thoughts on the data visualizations generated from the mobile health data. The results are organized into six themes: feasibility, usability, engagement, satisfaction, suggestions for improvement, and perspectives on data visualizations (Figure 27). In order to protect anonymity of individuals within this sample, we altered potentially identifying information attributed to data samples without affecting the context or meaning of what was communicated.

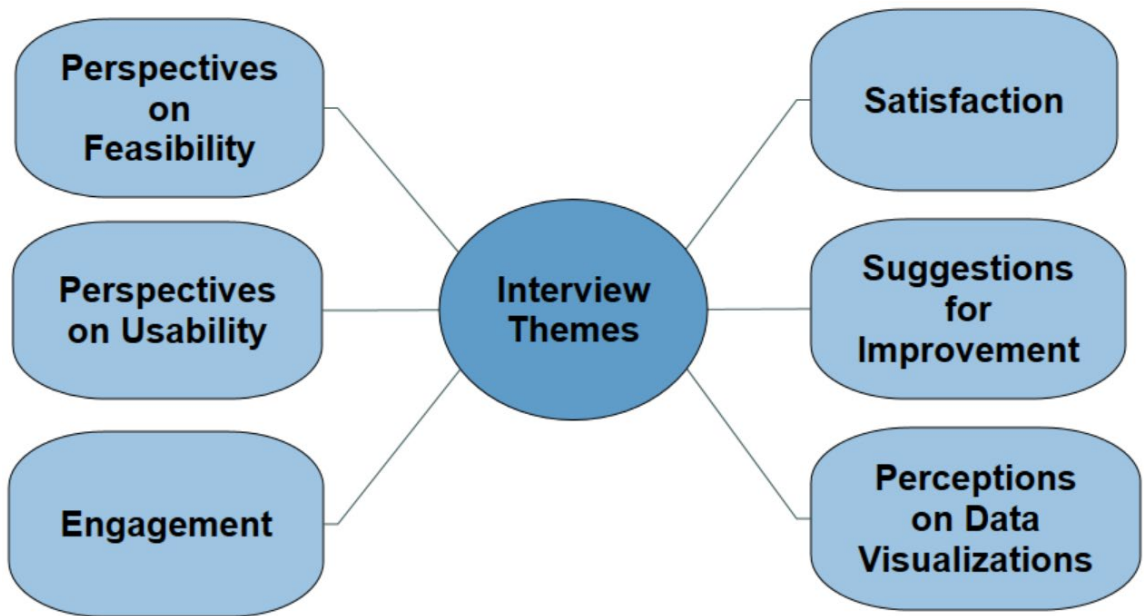


Figure 27: Qualitative Themes from Child, Adolescent, and Parent Interviews

Theme 1: Perspectives on the Feasibility of using the Mobile Technologies

We defined feasibility as the participant’s ease or difficulty using or managing both the Apple Watch and the study app. When asked to describe how easy or difficult the Apple Watch was to use, most children and adolescents responded it was “do-able” to wear the watch and they rarely had any technical difficulties. They discussed the Apple Watch as easy to wear and operate. For example, when asked if they experienced difficulty learning to use or operate the Apple Watch one child replied “No, not really, it was easy.” Adolescents reported the Apple Watch was easy to use as well, “It’s very do-able, um it’s not something you need to think about...It’s not like a continuously conscious effort, you just put it on and it does the stuff it needs to do.” Parents also expressed their views on

feasibility related to the Apple Watch, *“I just thought this should be pretty simple and it was going to help somebody along the way, basically pretty cut and dry. I didn’t think anything else of it I just thought it was a great idea and would be pretty cut and dry.”*

We also asked for participants’ perceptions on the feasibility of using the study app, as recording in the study app required more effort than simply wearing a device. The children and adolescents reported it was easy to learn how to use the app, and they had no difficulty navigating and recording in the study app. When asked about any difficulty related to the study app one child described, *“Not really, I had to get used to it but that’s pretty much it. Like how to, like I had to remember like how to use the app, but now I’m used to it,”* while an adolescent reported, *“Yeah, no, I thought it was easy, I liked the reminder at night”* [referring to an audible prompt to remind participants to record symptoms].

Parents also weighed in on the feasibility of younger children using the study app, *“For sure, uh it is. Like I said, every once in a while we’ll have to give her that reminder, but I mean for the most part she has that electronic device pretty close, she’ll pick it up and maybe play a game and then uh then put her information in. I would say, maybe 50, 60 % of the time she will, but it’s getting better the further we go along in it. She knows daily she needs to keep up with it.”*

Participants discussed a number of challenges, barriers, and concerns related to managing the mobile technologies. One of the most common feasibility challenges

expressed by the children and adolescents was the limited battery life of the Apple Watch (18-20 hours) resulting in difficulty keeping the device charged. As one child noted, *“Um sometimes I would charge it, charge the watch, and the phone then the next day um I would forget to charge it because I would think I already charged it.”* Adolescents too, commented on the limited battery life *“I feel the only thing is like charging it...it doesn’t stay charged long, and sometimes I would charge it while I was sleeping, so you know it would destroy the purpose of the sleep stuff.”*

Feasibility challenges were not limited to the devices themselves. Children and adolescents described how they would forget to wear the Apple Watch or record in the app. One child noted, *“At first it was do-able but towards the end I kind of forgot to charge it, um, I forgot to record, I don’t know actually, I would just be on my phone and then I would get up and see that [the Apple Watch or study phone] and then I’d realize I was doing the study.”*

Adolescents reported they would forget to put the Apple Watch on after charging or showering, *“I didn’t have problems, but I forgot to put it back on after it was charged. Even after you moved it closer to my bed, I just didn’t think about it. I don’t know, I’d just forget or not think about it, then I’d see it when I was in bed and I was too tired to get up and get it.”*

Parents discussed their role in reminding their child or adolescent, *“He does record [in the study app], I mean there are some days that I’m like where I’m like, if I wasn’t here, don’t forget to record your symptoms, and like he’s like “OK”. I think he’s been pretty good about it...right at first he would forget because forgot he had that extra phone for symptoms.”*

Parents also mentioned their child's level of symptom distress as a feasibility barrier for using the mobile devices, *"Uh not so much for her. It was for me but I'm not the one going through it so I wanted her to try to do it. Um I guess in the beginning when she was not doing chemo because when she got the chemo, the very next day she was like "mom I can't function enough to do this." It wasn't feasible at that time as she was going through those side effects of chemo."*

Theme 2: Perceived Usability

Our interest in usability centered on participants' use of the Apple Watch and study app throughout the study, specifically what tasks or activities they used the devices for. Interview questions were designed to elicit information on the participants' use of the study devices and their perceived usefulness of the study devices. Parents, too were asked their thoughts on these areas. Most participants described using the Apple Watch to monitor the time and their step count, and of those who wore the Apple Watch while sleeping, all reported using the sleep app to monitor their sleep patterns. One child noted about the sleep app on the Apple Watch, *"I can see how long I slept and my deep sleep, however long you have deep sleep and what time I went to bed,"* while an adolescent spoke about the Apple Watch features they used, *"Like um, the steps, I liked knowing how much I was walking. I changed the face a lot. I liked the kaleidoscope ones."* Overall, children and adolescents reported the most frequently used feature on the study app was the "Symptom Tracker tab."

Parents discussed the usefulness of study app features, *“There’s a lot of options, yeah a lot of different things you can put down on there [pointing to the symptom tracker tab]. Yes, and also just like a lot of different things like your activities, you know the laps, brushing your teeth, like a lot of different daily activities, I guess.”* For the Apple Watch usability, one parent stated, *“I think it helps her to want to do things like putting her watch on to know that it’s tracking her exercise and such.”* Another parent described the usefulness of the device prompts, *“But it was like, “You need to walk”, so she’d be like, “mom let’s go outside for a walk.” Yes, I can see where it would be helpful for people just sitting at a desk, to get up. Yes she told me she likes it for that reason and also the relaxation prompt to like take a deep breath.”* One parent described how she and her husband used the study app as a communication tool to monitor their child’s care, *“But I can look back as a caregiver, we can use it as a way to cover ourselves as to what’s going on. Absolutely and it’s on our level, where we can just take care of it, read through it, and see where we are, and I’d ask for his input and we could go back and modify things that need to be modified.”* One parent commented on the usefulness of emoji mood scale for their child to honestly record their symptoms, *“It’s a really good idea. It tracks...a lot of times they don’t want to tell us how they feel, he can be that way too sometimes I think, especially when it comes to his mom. He worries about her emotional, so that which he can do himself, he may be a lot more willing to express truly how he feels.”*

Some of the children and adolescents described how their symptom distress interfered with their ability to use the devices. For example, one child expressed *“Just*

cause you know I don't feel so good, my tummy hurts so like I just didn't want to," while one of the adolescents described how they could not wear the Apple Watch due to a skin rash, *"Yeah my skin was burning up, I felt really bad. Yeah, I didn't want anything touching me... it was bad, it didn't itch, my skin was burning and felt hot, I couldn't stand to have it on."* Still another adolescent reported *"Yeah, once I got my chemo and got sick it was harder. When I was so nauseous and throwing up I didn't care at all about the watch or the phone, I just wanted to sleep. Yeah, that's it pretty much."*

Theme 3: Perspectives on Engagement with the Mobile health devices

We defined engagement with the Apple Watch and study app as "how and when" participants interacted with the devices. Children and adolescents expressed their views on how and when they engaged with the devices and addressed why engagement changed over time. For example, one of the younger children explained, *"It's harder because I'm always feeling kind of sleepy and nauseous, and so when I'm feeling sleepy and nauseous, I don't want to get up and grab the phone, and start recording my symptoms even though I know I have to, but sometimes I'm just not feeling like I can. I feel like I can't do it."* When asked why they stopped recording symptoms one adolescent stated, *"I didn't want to I guess."*

Parents also described their thoughts on why their child's engagement with the study devices changed over time. *"But once the chemo kicks in and the radiation kicks in, and the side effects start kicking in, nobody wants to be bothered. So how can I get you to wear*

something, to record symptoms if you're not in the best position to do so yourself. It's the last thing you think of." Another parent addressed her adolescent's fatigue and emotional state as the reasons for why her daughter engaged less with the study devices, *"She was just tired, just tired. At that point in time, she was frustrated, it was just something else she had to do that she didn't want to do because she wasn't feeling at her best. It was just at that point, it was part of the process, it was just more of a nuisance than a help for her."*

Theme 4: Satisfaction with study devices

An additional theme that emerged from the interviews was satisfaction with the mobile technologies, where participants expressed their pleasure or displeasure. The Apple Watch had features that children and adolescents enjoyed and encouraged them to use the device. For example, one child described, *"I like how the Mickey Mouse thing (laughs)! Like if I need to know the time, stuff I could look on it or I can have it tell me the time. Yeah it's really fun. And I love, it's really cool how I can see how I slept. It's really cool."*

The majority of children and adolescents expressed satisfaction with the study app. Most noted liking the symptom emoji and stated they were easy to use and made recording symptoms and mood more fun. One adolescent said, *"the emojis, yeah, the emojis. It was easy and I liked them."* When asked overall to describe their satisfaction or dissatisfaction with the study app one child said, *"It was fun! I got like something to do every day. That it was the same thing, I mean I'm tracking on the same thing and how I feel."* Another child expressed their thoughts about the study app: *"It was good, because you can*

watch your sleep and how you feel, your pain, health, stuff like that.” Other study app features the children and adolescents expressed satisfaction with were the colorful radio button prompts reminding them to have “fun and do something relaxing” twice each day, “Um, I like the little like bubbles. I like “have you done anything fun today?” and there’s like 2 bubbles, I can press the bubbles. And that’s it, it’s kind of fun.”

Study participants who used the sleep app function to monitor and track their sleep expressed that they liked the feature, *“I liked the sleeping thing... because at first I thought wearing [the watch] to bed, I wasn’t going to do it, then I saw the thing recording my sleep and I thought that was kind of interesting. [I liked seeing] just how much I sleep, how much I don’t sleep.”* Finally, we asked participants if they were satisfied about participating in the study, the majority of whom expressed they enjoyed participating in the study.

Theme 5: Suggestions for Improvement

We solicited perceptions on ways to enhance the mobile device features or study procedures for future research. Children and adolescents were eager to offer their ideas and suggestions to improve the study app to increase participant use and satisfaction. Most suggested adding engaging and interactive features such as games, puzzles, or music. When asked if they would use the app more frequently if we added games, one child responded, *“A game would be fun, really cool. I like to play racing games and also I think if like a little racing game, like stuff would be really cool, you know.”* They also suggested a

racing game might encourage them to take more steps and get up and move around more. Adolescents had the most suggestions for improving the study app which included, *“Yeah add music too. Well I mean, like let me download some songs I like,”* while another requested, *“Make it more fun! Like adding games or streaks, I like music too. Maybe we could win points or money.”*

Adolescents who owned their own smartphone suggested having the study app downloaded on their personal smartphone as opposed to the study smartphone and discussed the reasons why, *“Yeah that would be much better [having the study app on my smartphone]. Because I had 2 phones, and I use my phone all the time, your phone was always on the table,”* and another reported, *“I would have liked it more if the app was on my phone, yeah better letting me download the app on my phone, I think that would be easier.”*

Another suggestion for the study app was to have fewer tabs and make it easier to record all the symptom data. Currently participants need to navigate through five tabs to record all the symptom information: the symptom name, intensity, status, any interventions used, and timing. One adolescent noted *“I would say like there’s too many questions, like I’m not sure how to describe it but there’s like a lot of stuff to record. So like that kind of thing. And getting to the symptoms wasn’t that easy at the beginning. Yeah, to get to the other sections, like to keep answering the questions you got to go to the next page and the next page. And too many symptoms, I think.”* Still a second adolescent added *“The app...it is tedious in some terms... when you have to log in, sometimes you have to meticulously rate one*

then close out the section and you have to do it over and over again. Whereas you could set up um the symptom tracker as one scroll, one page that branches off into the rating and whenever you click on the symptom so you complete it in one go and could do this for all the symptoms."

Theme 6: Perceptions on Data Visualizations

Interview questions were designed to elicit perceptions on the data visualizations we created. We wanted to broadly explore perceptions on the types of charts, colors, preferences for visual interfaces, and data presentation that children, adolescents, and parents found meaningful and interesting. The study app had a "Charts" feature that could generate and display 3 line charts (pain, fatigue, and hours of sleep) over a 2 week time period (Figure 28). Most children and adolescents did not consistently use this feature, but the few that did found the charts were informative and useful. One child described the how they found the study app charts useful, *"Because I could see how I was at the beginning and how it was kind of towards the end,"* while another reported, *"But um I think it was good to look at the graphs and see like the past 8 days I was feeling this or this... yeah, they were good."*



Figure 28: Study App Line Charts

In addition to the study app charts, data visualizations using Tableau software were generated for each participant using their mobile technology data. These data visualizations were shared with children, adolescents, and parents during the interviews. Study participants and parents noted the data visualizations enhanced their awareness of symptoms and offered insight into the changing symptom patterns over time. After seeing the Tableau data visualizations, they also requested charts and graphs like these be available in the study app.

Several children and adolescents discussed how seeing the graphs and charts increased their awareness of their symptom occurrences and patterns, and expressed

that the data visualizations allowed their “symptom story” to be seen. One child stated, *“I like how I can see about how much I can, it’s kind of like the pie chart how I can see how much I’ve been nauseated. It is helpful because then I can see like how much I’ve stepped and a lot of other things, yeah it helps keeping track of how many steps each day.”* Another child expressed how the data visualizations helped them see their symptom trends over time, *“It is, I can understand it more, I can see how much pain I’ve been in and how much dizziness I’ve been in... yeah I’d like that and I could understand like how much pain I’ve been in and oh when I’m not sick.”*

As for the types of graphs and charts, most children and adolescents found the pie chart the easiest to understand, and most noted the symptom heat map was confusing and difficult to understand. Children reported liking the colors of the data visualizations and adolescents requested the ability to have interactive data visualizations that could combine both the Apple Watch data (heart rate, step count) with study app data (occurrences and trends of symptoms).

Most of the parents noted the data visualizations were informative, meaningful, and that they were able to interpret the data as it was presented. One father of an adolescent stated, *“Like I said you’d be able, in my opinion be able to monitor specifics, when she felt more nauseous on this day maybe we can relate that back to maybe her chemo treatment, or you know if she was maybe she had more headaches this day, kind of relate it back to specifics [of her treatment].”* One mother stated that if she had access to the data visualizations

during her child's treatment they might have clarified some of the treatment related changes her son experienced. *"Right because I know during this round of chemo when he came into the clinic for his chemo, um there was a couple medicines they had to change because they were not working, they were dropping his levels and they had to change doses. So [seeing the data visualization] would have helped me then know, OK this is what this one is doing to him, because I didn't understand what they were trying to tell me what this medicine was really doing to him. And I think if I had seen it in a chart like that, it would have been a lot easier to understand, I would have understood a lot better."*

When asked how data visualizations might enhance communicating with health care team children, adolescents, and parents noted this would be very helpful and discussed why. One adolescent stated, *"Because then they could see like how the side effects are,"* and another expressed how a visualization would help clinicians see the occurrences *"I see a lot of coughing, it would be helpful if the doctors saw that."* Parents, too, described their thoughts on how and why sharing these data visualizations with clinicians would be helpful, *"I feel these would be more helpful for doctors, because they don't know. They aren't on this side of the bed. Yes because they [clinicians] aren't going to remember. Yes they're not going to remember 3 month later she got this, then month 3 when she throws up every single day, it's right there [in the data visualization]."*

An unexpected finding was that a small number of parents (n=3) requested we not share the data visualizations with their child or adolescent. Upon being asked why,

parents responded that for their child to see the totality of the symptoms might be disappointing or upsetting, and they were concerned it may negatively affect their child's mood. The mother of one child stated, *"He already lived through the experience, he's in a good place now. I do not want him to think about that again,"* while another stated *"It's just too hard to think about."*

Mixed Method Integration:

Using a mixed methods approach we integrated qualitative data and quantitative data to illustrate, assess validity, and confirm findings (Fetters, Curry, & Creswell, 2013; Fielding, 2012). This approach allowed the multiple sources of evidence from the study to show relationships and illuminations that might not have been otherwise seen and thus enriched the breadth of the study findings (Bazeley, 2018). This approach increased our confidence in the findings as it allowed the full picture of the multiple factors related to feasibility to emerge from the data. For example, the high rate device engagement at the beginning of the study, when participants were less symptomatic was reflected in the interviews as participants expressed wearing the Apple Watch and recording in the study app were easier at this time point. This approach corroborated and helped illustrate the quantitative findings.

Integrating the quantitative and qualitative findings provided detailed and more in-depth explanation to our device engagement findings. For example, our quantitative findings showed participants engaged with the Apple Watch 56% of their study days.

Through interviews we found “it was easy to use,” “you just put it on and don’t need to think about it” which helped us understand why the engagement rate was as high as 56%. However, interview findings also revealed “I’d forget to put it back on after my shower,” and “it was too big on my wrist,” which showed us why the Apple Watch engagement level was only 56%. This information will inform future research as we will look to incorporate wearable devices that remain easy to use, but minimize disruption to data collection such as devices that are waterproof and have longer battery life.

We also derived insights by integrating qualitative and quantitative data related to changes in device engagement over time. We quantified the changes in device engagement over time by, and the interview data confirmed the quantitative findings and provided an understanding of the reasons for the changes over time. Integrating the data also deepened and extended our understanding to the challenges the children and adolescents experienced while participating in the study. For example, the decrease in study participation throughout the weeks of the study was quantitatively captured (Figure 12) but through interviews with the children and adolescents, we found their level of symptom distress to be too burdensome and thus affected their desire to continue with the study. These qualitative findings complemented and extended our understanding and importantly provided a richer detailed explanation for the quantitative findings. Using the mixed methods approach gave us insight into our study findings that neither a qualitative or quantitative method alone could provide and

helped us cultivate ideas for future research (Fetters et al., 2013; Guetterman, Fetters, & Creswell, 2015; McKim, 2017). The qualitative interviews helped construct a narrative based on the quantitative findings which added depth and meaning to our findings and enhanced our understanding of the complexities and challenges acutely ill children and adolescents encounter when using mHealth technologies.

4.4 Discussion

The mobile health phenomenon aided by the prolific adoption and use of wearables and smartphones creates new opportunities to assess and monitor patients' symptoms. Conceptually guided by the Theory of Unpleasant Symptoms and the Symptom Science Model, we focused on the use of mobile technology data to further understand the symptom experience (timing, intensity, duration, distress, and quality) of children and adolescents with life-threatening illness. Using a mixed methods approach gave us an in-depth way to explore the feasibility issues related to the use of mHealth technologies and identify ways to optimize visualization of this data. At present, there exists little in-depth qualitative research focused on children and adolescents to describe their mHealth technology experiences, perspectives, and usage patterns (Dennison, Morrison, Conway, & Yardley, 2013). The qualitative interview findings integrated with the quantitative results allowed us to further understand many complexities related to feasibility, usability, including the challenges of using mobile

technologies over time, the reasons that led to decreased engagement, and factors that led to study attrition.

Acceptability: The high rate of participant enrollment (100%) and low rate of attrition (25%) demonstrate that children and adolescents found the study acceptable. Children and adolescents discussed their satisfaction with the study during the interviews, with the majority expressing they were satisfied with their participation. The interview findings gave context and helped us understand the reasons for attrition as those who withdrew within the first week noted their decision influenced by their level of symptom distress rather than finding the study unacceptable.

Engagement: Our findings indicate it was feasible for children and adolescents to record and track relevant symptom-related data using two mHealth devices. Despite undergoing intense treatment for their disease, children and adolescents participated in the study a median of 27 days ranging from 4-107 days with no notable differences between the two age groups. Participants wore the Apple Watch an average 56% of the study days and recorded in the study app 63% of the study days. Through their engagement with mHealth technology, we obtained consistent, extensive, and first hand evaluation of the participants' symptom experience. Capturing symptom data in this manner may provide more insight than traditional methods such as surveys which typically rely on patients' ability to recall their symptoms after the fact. Most of the

participants in our study noted they liked using the Apple Watch and study app and were willing to engage with mHealth devices.

Our study app engagement results were similar with other studies that evaluated the use of mHealth apps in adult women with breast cancer (Min et al., 2014) and e-diaries in adolescents with depression (Metsaranta, Kurki, Valimaki, & Anttila, 2019). However, our Apple Watch use results differed slightly than those found in other feasibility studies using wearables in adults with chronic illness (Shaw et al., 2019) and adults undergoing blood and marrow transplant (Hacker et al., 2018). These studies both used Fitbit wearables which have a battery life of approximately five days, and is longer than the Apple Watch battery life of 18-20 hours. Moreover, the participants in our study were children and adolescents with acute illness as opposed to adults. Additionally, unanticipated reasons affected the device engagement rates in our study; three participants had unexpected inpatient hospitalizations (lasting 4-7 days) due to complications and did not have their mobile devices with them at the time of admission.

Our findings showed differences in device engagement for the two treatment groups. The children and adolescents in the PBMT treatment group used the Apple Watch 71% of their days in the study and recorded in the a study app 75% of their days in the study. The children and adolescents in the oncology treatment group wore the Apple Watch 48% of their days in the study and recorded in the study app 56% of their days in the study. While no conclusions can be drawn from this finding, future mHealth

research should investigate possible reasons for treatment group differences and explore ways to optimize support for differing patient populations.

One unexpected finding was that Apple Watch engagement was lower than the study app engagement. We had hypothesized that a passive data collection tool (the Apple Watch) which only requires a user to wear it, would demonstrate higher rates of engagement than a tool requiring active involvement such as a smartphone app where one must navigate multiple tabs to record symptoms. One reason for the higher rate of app engagement may be that children and adolescents were comfortable and familiar with smartphone technology and use of apps, thus used them readily (Baggott, Gibson, et al., 2012).

We assessed Apple Watch engagement for both children and adolescent groups and found it was similar, but adolescents wore the Apple Watch more than the children. Three of the adolescents reported owning an Apple Watch or similar wearable prior to the study, thus they were already familiar with the technology that may have enhanced engagement. Of note, one child who stayed in the study 72 days only wore the Apple Watch 7% of the study days yet recorded in the study app 49% of the study days. When asked why they recorded in the app but did not wear the watch they reported it felt too big on their wrist.

Engagement for both devices dropped sharply between weeks 3 - 5 (Figure 12). One possible explanation could be related to the health status of the participants during

this time period. For patients undergoing blood and marrow transplantation, this time reflects the period of engraftment, a time of increased symptom distress (Anderson et al., 2007; Boonstra et al., 2011). For children and adolescents receiving oncology treatment, this time period may reflect the intense effects from the chemotherapy (Buckner et al., 2014; Johnston et al., 2018). We explored this further through interviews to better understand this finding. Children and adolescents expressed how severe symptoms such as nausea, vomiting, and fatigue interfered with their ability to engage with the devices daily thus complementing this finding.

Another possible explanation for the drop in engagement at this time could be related to device fatigue, a concept where users tire of using devices and lose interest. One study using multiple mobile devices for diabetes management showed the same trend and the authors proposed device fatigue as a possible cause (Shaw et al., 2016). Through interviews, we found that participants did lose interest or forgot to engage with the devices as time progressed. Based on participant feedback we plan to incorporate additional features into the study app to increase engagement for future research. Evidence-based features such as user-centered designs and stakeholder preferences are needed in order to make an app useful and more “sticky”, a concept that describes a device’s continued and repeated use over time (Juarascio, Goldstein, Manasse, Forman, & Butryn, 2015). Features that captivate users of all ages include gamification, feedback mechanisms, educational offerings, and reward systems

(Hilliard, Hahn, Ridge, Eakin, & Riekert, 2014; A. S. Miller et al., 2016; Sage et al., 2017).

We plan to add gamification features to increase user's enjoyment and also add badges, icons, and a leaderboard to motivate them to interact more consistently with the study app.

The interview questions guided by the Theory of Unpleasant Symptoms, were designed to help us better understand the feasibility of capturing essential symptom data (timing, intensity, duration, distress, and quality) through the mHealth technology. The interview data helped us gain a deeper understanding for the reasons device engagement changed throughout the study, gave context to the reasons why it changed, and supported the quantitative results. When asked why they stopped using the devices, children and adolescents reported many different reasons that included; feeling too ill to continue, change in health status, increased symptom distress, device fatigue, and they just didn't want to do it anymore. This information will inform future study designs and implementation to minimize controllable barriers such as device fatigue.

Satisfaction: Children and adolescents expressed overall satisfaction with the Apple Watch and the study app. In addition to noting the devices were easy to use, they expressed liking features such as the symptom emojis, the colorful radio buttons, and the reminders to do something fun and relaxing each day. We found study participants and parents were eager to suggest ways to improve the app to make it more engaging.

Children and adolescent suggested adding games, music, and motivators such as badges, leaderboards, and icons. They also suggesting adding more symptom emojis. Literature supports that making an app more engaging and user-centered will increase consistent use study app to increase compliance and engagement which will optimize symptom data collection for acutely ill children and adolescents. Thus, we plan to incorporate their suggestions into our next study app to increase compliance and engagement which will optimize symptom data collection for acutely ill children and adolescents.

PROMIS Surveys Adherence: PROMIS surveys are efficient, reliable, and valid measures of health used extensively in nursing research (Badger, Heitkemper, Lee, & Bruner, 2014; Cunningham et al., 2017). We chose to use REDCap for the PROMIS survey data collection believing this approach would minimize participant burden over paper surveys and for its HIPAA compliant security features. PROMIS surveys were emailed to the study smartphone each month and RedCap would send a reminder email after one week if the surveys were not completed. We chose these surveys to capture symptom data monthly if participants felt too ill to use the study app each day. Ninety percent of the participants completed the baseline surveys. However, survey completion rate was 56%, 50%, and 0% for days 30, 60, and 90 respectively. When asked why they did not fill out the surveys, children and adolescents noted they forgot, did not want to

fill them out, or preferred using the study app to record their symptoms. Perhaps the monthly surveys resulted in too much burden in addition to the daily symptom data collection via the app.

Data Visualizations: The development of data visualizations to represent mHealth data in an efficient, understandable, and meaningful format is a critical and necessary step for usability of mobile health devices (Choe, Lee, Lee, & Pratt, 2014; Gotz & Borland, 2016; Lor, Koleck, & Bakken, 2019). Visualizations can lead to improved presentation, analysis, and understanding of large complex data streams that mHealth devices generate (Arcia, Woollen, & Bakken, 2018; Gotz & Borland, 2016; Lor et al., 2019; V. L. West, Borland, & Hammond, 2015). Effective data visualizations can provide rapid review and synthesis of patterns, changes, and trends over time. We developed individualized symptom charts, graphs, and diagrams using Tableau data visualization software for each participant using their mHealth data. We shared these with study participants and parents during the interviews. We found our visualizations illustrated symptom occurrences, patterns, and provided insight into trends over time in a succinct and easily understood manner for study participants and their parents. Participants and parents noted these visualizations were effective tools that could be used to improve understanding of the symptom experience and enhance communication with clinicians about the symptom status and management for the children and adolescents. We gained

a deeper understanding for the ways children, adolescents, and parents wanted to see the data displayed. For example, younger children preferred simple charts such as the pie chart and bubble chart, whereas parents preferred the bar charts that portrayed the symptom trends over time. Adolescents wanted interactive visuals that they could design and choose what was displayed. Parents preferred visualizing important care events displayed in the visualizations, for example transplant and engraftment dates, or dates when complications developed. Our hope is that visualizing complex health data this way will lead to enhanced understanding of symptom dynamics leading to tailored personalized symptom management strategies. We plan to incorporate these types of visualizations into the study app for future research.

Implications for Nursing Practice and Research: Our ability to collect patient-generated symptom data over time using mobile technologies demonstrates a useful approach to capture important symptom characteristics; timing, intensity, duration, distress, quality and allows the children's voice to be heard and amplified. Our findings have a number of important clinical and research implications. With the growth of precision health, mHealth technologies and the patient generated health data they obtain can be leveraged as powerful tools across the health and illness continuum. mHealth devices are familiar tools frequently and easily used by patients of all ages. Nurses play a critical role in symptom identification, assessment, and management, thus they should consider

using mHealth data to improve understanding of patient's day to day symptom experience. This enhanced symptom knowledge will guide clinical practice and inform precision health symptom management interventions and strategies to decrease symptom distress. Additionally, this approach using mHealth technology, can facilitate a longitudinal approach to collecting data that will provide a patient centered view of their symptom distress over time. Importantly, these mobile technology data need to be integrated into the electronic health record (EHR) and serve as a readily available repository for symptom data for clinician use. Beyond advancing symptom understanding, nurses can opportunistically use these mHealth data to gain more insight into patients' overall health and illness status and use mHealth data for early detection of changes in status or prediction of health care outcomes. Finally, nurses can leverage mHealth data to educate and empower children and adolescents to better understand their symptom dynamics and be actively involved in their care.

Nevertheless, as with any novel area of inquiry, further rigorous research is needed to refine which mobile technologies and approaches best allow for comprehensive symptom data collection with the lowest participant burden. Research is warranted to examine ways we can use mHealth data to monitor, track, detect, classify, and predict symptoms to lessen symptom distress thus improving patient outcomes. Finally, additional research is needed to examine effective ways to present symptom data to enhance patients' knowledge of their personal health data and thus improve

symptom management communication with clinicians and target symptom management strategies. Nursing knowledge and expertise will play a key role in translating this research into practice.

Limitations: There were several limitations to our study. First, we provided an Apple Watch and iPhone to participants, some of whom, owned neither of these devices. These may have been novel devices for this age group, thus there was potential to influence engagement in the study. Another limitation that must be addressed for future studies concerns the attrition of the 5 participants who withdrew from the study within the first week citing they felt too ill to continue. This may indicate that children and adolescents with the most distressing symptoms were not represented in the study findings.

Additionally, although this study included a diverse sampling of children with significant symptom distress, it was conducted at a single institution with a limited sample size, which may limit generalizability of the findings. Finally, we measured feasibility based on device use, such as the number of days the watch was worn, however, the limited battery life of the wearable combined with the patient's level of health may not have fully represented the patient's engagement.

4.5 Conclusion

In the digital age, there is increasing evidence demonstrating mobile health technologies are impacting the management of wellness and illness for many populations. Our mixed method approach provides important insights into the

feasibility of using these devices to monitor symptoms in children and adolescents with life-threatening illness and also explored how we might optimize visualizing mHealth data to enhance symptom awareness, understanding, and improve communication with clinicians. The interview data helped us gain deeper understanding of the quantitative feasibility results.

Our findings suggest this approach, using mHealth technology, is feasible and useful and provides insight into the symptoms of acutely ill children and adolescents. The data obtained through the Apple Watch and study app provided an extensive illustration of symptom occurrence and intensity and illuminated changes over time. Equally important as collecting this symptom data is visualizing these data. The data visualizations we developed illustrated the child or adolescent's symptom experience and enriched our understanding of the symptom dynamics. Although symptoms and symptom clusters may not be completely prevented or eliminated, data from mobile technologies can be leveraged to help children and adolescents with life-threatening illness, their parents, and clinicians monitor symptoms and develop personalized health strategies. These strategies, in turn, may improve outcomes and reduce the symptom distress in children and adolescents with life-threatening illness.

This study focused on a high-risk population that stands to benefit substantially from the use of patient generated symptom data that mHealth technologies provide. Knowledge gained from this study enhances our understanding of the use of mHealth

technologies in children and adolescents with life-threatening illness. Additionally, this study improves our understanding of how these symptoms present, interact, and cluster throughout the treatment period for these children and adolescents. This advanced understanding of complex symptoms lays the foundation for precision health symptom management.

5. Conclusion

Mobile Health (mHealth) technology is increasingly used to manage health and has the potential to revolutionize our understanding of illness as well as the associated symptom dynamics (Heintzman, 2015; Nowell, 2019; Shah et al., 2014; Shaw et al., 2019; van der Veer et al., 2017). Devices such as wearables and smartphone apps provide dense streams of real-time patient generated health data that can illuminate a comprehensive longitudinal picture of a patient's health and symptom trajectory (Shaw et al., 2019). Recently, much research effort has gone into investigating the use of mHealth technologies in self-management of chronic illness, as evidenced by studies using wearable devices and smartphone apps for self-management for diabetes (Muralidharan, Ranjani, Anjana, Allender, & Mohan, 2017; Shaw et al., 2019), asthma (Cook et al., 2016; Hui et al., 2017), and blood pressure management (Lewinski et al., 2019; Rehman et al., 2017), among others. However, there has been limited research investigating mHealth technology use in symptom management for acutely ill persons, and more specifically acutely ill children and adolescents.

Children and adolescents with life-threatening illnesses such as cancer or those undergoing blood and marrow transplantation experience significant symptom distress from both the disease and the treatment that persists for a prolonged period (Baggott et al., 2010; Brock et al., 2018; Johnston et al., 2018; Snaman et al., 2018; Zhukovsky et al., 2015). Mobile health technology has recently proven to be an effective way to assess and

monitor symptoms longitudinally (Shaw et al., 2019; Vaughn et al., 2020). Given the strong developmental fit for children and adolescents, mHealth may offer a unique opportunity to capture and collect symptom data in ways not previously used to advance understanding of symptom distress and lead to better symptom management strategies.

This chapter summarizes and synthesizes the findings of this dissertation body of work. A discussion of the implications of the findings followed by directions for future research is included. The overarching purpose of this dissertation work was to advance understanding of symptom dynamics (occurrence, clusters, and trajectories) in children and adolescents with life-threatening illness through the use of mHealth technology data and its visualization. We began by exploring the feasibility of using mHealth devices to track and monitor symptoms in this patient population, we then sought to visualize these data to better understand symptom dynamics. Through interviews we explored child, adolescent, and parent perspectives on the experience of using the devices as well as exposed facilitators and barriers to using these devices. Additionally we explored their perspectives on how to visualize mHealth data to enhance understanding, communication, and better manage symptoms. Each chapter was associated by specific aims, as noted:

Chapter 1. Specific Aims: 1) Introduced the problem, background, and significance of symptom distress in children and adolescents with life-

threatening illness; 2) Incorporated a theoretical framework, the Theory of Unpleasant Symptoms, to guide the study approach, design, and procedures; 3) Explored the current literature how the use of patient generated health data from mobile technologies' is used for health/wellness management.

Chapter 2. Specific Aim: Described the development of one of the study's data collection tools, a mobile application (app), called the Technology Recording to better Understand Pediatric Blood and Marrow Transplant (TRU-PBMT).

Chapter 3. Specific Aims: 1) Explored the feasibility of integrating a wearable device and a mobile app to collect and transmit patient-generated symptom data in children and adolescents undergoing blood and marrow transplantation; 2) Tested the study design and procedures; and 3) Explored children's perspectives on improving the study app to improve the design.

Chapter 4. Specific Aims: 1) Examined the feasibility of children and adolescents with life-threatening illness to record and transmit symptom-related data daily up to 4 months and to identify symptom dynamics (occurrences, clusters, and trajectories); 2) Described and visualized the symptom(s) occurrences, patterns, and trajectories using mobile technology data; and 3) Explored participant and parent's experiences and perceptions of using mobile health devices and visualizing the data through participant and parent interviews.

5.1. Summary of the Findings:

5.1.1 Chapter 1: Introduction to Symptom Distress and Mobile Technology

This chapter began with a review of the current literature to investigate the background, prevalence, and significance of symptom distress experienced by children and adolescents with life-threatening illness. Significant symptom distress is concerning as it has been associated with poorer health outcomes (Larsen et al., 2003; Lopes-Junior et al., 2015; Miaskowski, Barsevick, et al., 2017). Children with significant symptom distress are less likely to comply with treatment (Coughtrey et al., 2018; Ilowite et al., 2018), and more likely to delay treatment (E. Miller et al., 2011). This problem is further complicated by symptoms being under-recognized, under-reported, and thus under-treated in children and adolescents with life-threatening illness. We identified significant gaps in our knowledge of symptom dynamics for this high-risk population. We introduced a novel approach to obtain patient-generated symptom data using mobile technologies to better understand symptom dynamics which lays the foundation for advanced understanding leading to better symptom management strategies. Guided by the Theory of Unpleasant Symptoms, we designed our study to explore the feasibility of using these technologies as symptom data collection tools to investigate symptom(s) timing, intensity, duration distress, and quality.

5.1.2 Chapter 2: Customization of the TRU-PBMT App (Technology Resources to better Understand Pediatric Blood and Marrow Transplant)

Mobile technology use by children and adolescents presents new opportunities to monitor and collect health data. For our study we planned to have children and adolescents undergoing blood and marrow transplantation record and track their symptoms each day using a smartphone app. However, no app was available that suited our objectives. The purpose of this chapter and was to describe the development of the “symptom data collection tool” for the study. Our objective was to design a pediatric friendly, symptom specific app that could be used by the study participants for daily symptom reporting.

Incorporating a user-centered design framework, we conducted a survey study to obtain the stakeholders’ input (pediatric blood and marrow transplant patients, parents, and clinicians). We then incorporated this feedback into the app development. The app, Technology Recordings for better Understanding Pediatric Blood and Marrow Transplant (TRU-PBMT) was designed for users to record symptoms, dietary, stool, and daily care goals (Vaughn et al., 2018). User-Centered Design is an evidence-based approach guided by the end-users’ needs (Cafazzo et al., 2012; McCurdie et al., 2012). Including end-users in the development process improves adoption of and increases engagement and satisfaction with technologies (Cafazzo et al., 2012; Hilliard et al., 2014; Riley et al., 2019; Sage et al., 2017).

This chapter emphasizes the need for effective mHealth data collection tools. These tools must take into consideration user preferences and medical professional input when designed to enhance engagement over time and minimize patient effort needed to record data. This will lead to optimal data collection during periods of high symptom distress for children and adolescents with life-threatening illness while they are under-going treatment.

5.1.3 Chapter 3: Mobile Health Technology for Pediatric Symptom Monitoring: A Feasibility Study

While studies have been conducted to evaluate the use of mobile technologies to collect health, symptom, and dietary data for children with chronic disease, to our knowledge no studies researched the use of more than one device during the acute phase of treatment for children and adolescents with life-threatening illness. Before initiating our study, we decided to conduct a preliminary pilot study to test our study design, procedures, mobile device use, data capture and transmission, and explore participant's perspectives on the feasibility of using the mobile devices before initiating the larger scale dissertation study. The preliminary pilot study was conducted on a sample (n = 10) of children and adolescents. The preliminary study findings suggested it was feasible and acceptable for children and adolescents undergoing blood and marrow transplantation to use two mobile health devices (an Apple Watch and a smartphone app) to self-report their symptoms and monitor their physiological data. We successfully recruited 83% of participants we approached and 70% stayed in the study for more than

40 days (Vaughn et al., 2020). Overall, patients undergoing PBMT wore the watch 51% of their days in the study and recorded in the app 56% of their days in the study (Vaughn et al., 2020). We compared our device engagement to other mHealth studies and found children with juvenile arthritis averaged 72% for logged wearable activity over a 28-day period (Heale et al., 2018) and adult women average 45% app reporting rate on sleep disturbances over a 90 day time-period (Min et al., 2014). Our findings were encouraging considering the participants in our study were acutely ill and used more than one mHealth device. We used these results as benchmarks for determining success for the dissertation study and may additionally use them for future intervention studies.

Our findings also informed changes needed to conduct the larger dissertation study. Our initial wearable device, the Microsoft Band II was not acceptable to the first study participants, so we switched to the Apple Watch as a data collection device. The participants found the Apple Watch was a more acceptable device, however, the Apple Watch had a lower battery life. Changes in treatment protocols and slow admission rates at our institution encouraged us to seek additional populations of children and adolescents that experience significant symptom distress in order to proceed with the dissertation study. We expanded the study sample to include children and adolescents undergoing cancer treatment in addition to those undergoing blood and marrow transplantation.

Conducting the preliminary study was an important step and laid the foundation for the larger dissertation study. This chapter highlights the important role a preliminary pilot study provides to inform research studies.

5.1.4 Chapter 4: Enhancing Symptom Monitoring Using Mobile Technology for Children and Adolescents with Life-Threatening Illness

The purpose of our mixed methods longitudinal study was to further advance symptom understanding through the use of mobile technology for children and adolescents with life-threatening illness. We had three main objectives, first, to explore the feasibility of using two mobile health devices to collect and monitor symptom data, second, to develop data visualizations to display the symptom patterns and trajectories for the study participants, and third, to obtain perspectives of participants and parents using mHealth technology and visualizing the data. In this dissertation study, we expanded the patient population to include both children and adolescents undergoing blood and marrow transplantation and oncology treatment. Stein et al., conducted a landmark study suggesting it is better to classify participants based on common shared elements (i.e., symptom distress, hospitalization) rather than diagnosis (Stein & Jessop, 1982). Therefore, our population was not based on disease classification, but rather children and adolescents with life-threatening illnesses that required hospitalization for treatment that results in significant symptom distress. Encouraged by our preliminary study findings of blood and marrow transplant participants wearing the Apple Watch

51% of their study days and recording in the study app 56% of their study days, we sought to increase study app engagement and thus symptom recording frequency.

A mixed methods approach using multiple data sources allowed the study team to conduct an in-depth detailed exploration and analysis of the feasibility and acceptability of the study devices. The qualitative interviews gave crucial insight into feasibility challenges, factors that influenced device engagement, and perspectives on visualizing mHealth data to better understand symptoms dynamics and facilitate communication with clinicians. Rather than simply reporting device frequency of use rates (Apple Watch, 56%; Study App 63%), the perspectives from the children, adolescents, and parents gave context and deeper meaning to these numbers. Integrating the qualitative and quantitative data illustrated and provided deeper analysis for our study. Findings from the dissertation study indicate that it is feasible for children and adolescents with life-threatening illness to monitor and record their symptoms using two mobile devices for up to 120 days, and helped us understand challenges and barriers that need to be addressed in future studies.

We explored differences between the two age groups (child and adolescent) for study participation and device engagement. Our future larger scale research will target these individual groups to better address developmental differences. We foresee a study app targeting child user's interests and another to accommodate adolescent user's preferences to promote increased engagement with the device.

This dissertation work expanded research for populations of children and adolescents who experience significant symptom distress. We are encouraged that our findings support that mHealth technology use is a feasible and acceptable approach and facilitates a precision health approach to symptom management. This precision health approach enables a patient to get the right treatment at the right time based on the symptoms they experience. We foresee further expansion to other patient populations, such as children and adolescents with sickle cell disease, to leverage these technologies to better understand and manage their symptom distress.

We developed preliminary data visualizations to illustrate symptom dynamics (occurrences, clusters, and trajectories) and found patients and parents to be captivated by the symptom patterns and asking to learn more. Through interviews with children, adolescents, and parents, we developed a better understanding of how individuals perceive, interpret, and make meaning of these data visualizations. These findings will inform improvements of data visualizations that will help users make meaning of and optimize the use of mHealth data.

This chapter highlighted the role mHealth technology can play in gathering symptom data. It also highlighted the need for optimal visualization of this data so it can be used meaningfully. This research lays the foundation for using this knowledge to enhance symptom understanding and target better symptom management for children and adolescents with life-threatening illness.

5.2 Limitations

There are several limitations to our study. Although this study included a diverse sampling of children with significant symptom distress, it was conducted at a single institution with a limited sample size, which may limit generalizability of the findings. A second limitation was that our sample age group ranged from 8-17 years of age. Developmental differences between children and adolescents may have influenced our findings. Yet another limitation that must be addressed for future studies concerns the attrition of the participants who withdrew from the study within the first week citing they felt too ill to continue. This may indicate that children and adolescents with the most distressing symptoms are not represented in the study findings.

5.3 Future Research

5.3.1 Implications for Nursing Practice

Our findings have a number of important implications for nursing practice. Symptom management is one hallmark of nursing practice (Cashion et al., 2016; Corwin et al., 2014). Nurses play a vital role in symptom identification, assessment, and treatment and thus are in a unique position to incorporate innovative technologic approaches, such as mHealth, to improve understanding of patient's day to day symptom experience for patients, families, and clinicians. This enhanced symptom knowledge will guide clinical practice and inform symptom management interventions to decrease symptom distress and improve quality of life. Nurses can leverage mHealth

data to educate and empower children and adolescents to better understand their symptom dynamics and be actively involved in their care. For example, nurses can work with patients to monitor the step count daily during treatment to evaluate physical activity. Together, they can plan and implement physical activity interventions to support or progress toward health care goals. Moreover, the step count can be used to detect early changes in status, for example if a patient's step count begins to decrease, the nurse can assess for changes in health status or worsening symptom distress.

Importantly, nurses are key to integrating mHealth data into the electronic health record (EHR) and facilitate use of this symptom data for clinical decision making. If symptom profiles such as the ones we created were available in the EHR, nurses could use them to enhance symptom assessment, monitoring, and tracking. This information could be incorporated into hand-off communication and interdisciplinary communication with the goal of providing the patient with personalized symptom management based on their profile. Beyond advancing symptom understanding, nurses can opportunistically use these mHealth data to gain more insight into patients' overall health and illness status and use mHealth data for early detection of changes in status or prediction of health care outcomes.

5.3.2 Implications for Research

Mobile health technology presents new opportunities to advance symptom science research. High-risk populations, like children and adolescents with life-

threatening illness, stand to benefit substantially from the use of patient generated symptom data that mHealth technologies provide. Not only does this approach lead to more comprehensive and consistent symptom data collection, children and adolescents prefer using these technologies. Our device engagement findings showed engagement dropped off around week four, and through interviews we found distressing symptoms factored into this result. As mHealth technology continues to evolve and improve in capability, further research is needed to refine which mobile technologies and approaches can optimize symptom data collection with the lowest participant burden during periods when symptom distress is high.

Future research is warranted to examine ways we can use mHealth technologies to monitor, track, detect, classify, and predict symptoms to lessen symptom distress. Currently there exists insufficient data on the design of evidence based interventions using mHealth data to improve outcomes in children and adolescents with life-threatening illness.

Given the results of our study, further research should focus on the development of targeted precision health interventions based on mHealth data to alleviate symptom distress in children and adolescents with life-threatening illness. An additional area of research is to further explore ways to optimize visualizing mHealth data in an efficient, understandable, and meaningful format to improve understanding of the symptom experience, enhance communication with clinicians about the symptom status, and

improve symptom management strategies for children and adolescents with life-threatening illness.

5.4 Conclusion

This body of work was among the first to explore the use of mobile technologies to obtain patient-generated symptom data for children and adolescents with life-threatening illness. This dissertation work established the feasibility and acceptability of using two mobile technologies for this group and further explored opportunities to visualize these data in an effective and useful manner. Knowledge generated from this work advances symptom science research and offers a framework to guide other study designs in the incorporation of mobile technologies to facilitate patient care, improve symptom management, and improve patient outcomes. With substantial advancements in mobile health technologies there are emerging new possibilities to leverage these technologies to develop precision health interventions for both acute and chronic conditions leading to improved health outcomes and quality of life.

Appendix A: Semi-Structured Interview Guide

Interview Guide

Thanks so much for taking the time to talk with me today about the study app. The purpose of this interview is to get your thoughts and opinions about the study app. It's important to us that you share your experience, good, bad and indifferent. There are no right or wrong answers to these questions. Your feedback will help us make the system better and to help more patients who are receiving bone marrow transplants.

As you know, the app has two parts. One part is the tracking things like symptoms on the iPad/iPhone and the other part is the activity monitor you wore. I'm going to start by asking you about your overall experience, then I'm going to ask you specific question about each part of the system.

I'd like to start by asking you about the first day you got the study app? Can you tell me about it? What were your first thoughts? What did you do first? What did you do next?

Can you tell me about that first week using the study app? What was that like for you?

How about after that? PROBE FOR SPECIFIC THINGS THAT STAND OUT.

Overall, what did you like about the study app? PROBE FOR COMPLETENESS

Overall, what didn't you like study app? PROBE FOR COMPLETENESS

Next, I'd like to ask you some more detailed questions about specific features in the study app. We've already talked about this a bit, but I'd like to get a bit more feedback. On the iPad/iPhone, you could track your appetite, your general health, your stools, and your symptoms.

Please tell me about your experience tracking your appetite? Did you use this feature?

Why or why not? PROBE FOR COMPLETENESS

How could we make this feature more useful?

Please tell me about your experience tracking your general health? Did you use this feature? Why or why not? PROBE FOR COMPLETENESS

How could we make this feature more useful?

Please tell me about your experience tracking your stools? Did you use this feature?

Why or why not? PROBE FOR COMPLETENESS

How could we make this feature more useful?

Please tell me about your experience tracking your symptoms? Did you use this feature? Why or why not? PROBE FOR COMPLETENESS

What symptoms did you track and why?

How could we make this feature more useful?

Our goal is to design tool patients can use every day to help them recover after a bone marrow transplant. What specific changes could we make that would encourage patients like you to use the study app every day?

In the future, we hope to make the study app interactive, meaning a doctor or a nurse would look at the information you enter into the study app and could send messages to the patient. Would you be interested in interacting with a doctor or a nurse via the study app? Why or why not?

The other part of the study is the **Fitness Tracker**. Please tell me about your experience using the fitness tracker? Did you use it? Why or why not? PROBE FOR COMPLETENESS

How could we make this feature more useful?

Some patients have said that they would prefer to have the study app on their own iPad/iPhone or tablet rather than one of the clinic iPads. I'm interested in your thoughts about that?

This is my last question. Overall, how much do you think the study has helped you in your recovery? Can you tell me more about that?

Is there anything else you'd like to add that we haven't already discussed?

Thank you so much for taking the time to talk with me about the study app. Your input is very valuable to this project and will help us take better care of patients in the future.

Appendix B: Study Surveys

PROMIS® Pediatric Item Bank v. 1.0 – Pain Behavior – Short Form 8a

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Pain Behavior- Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days, when I was in pain...

Had No Pain

	Never	Almost Never	Sometimes	Often	Almost Always	
PBNEW2_Ped	It showed on my face	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PAINBE9_Ped	I moved slower	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PAINBE46_Ped	I protected the part of my body that hurt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PBNEW_Ped15	I had to stop what I was doing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PBNEW24_Ped	I asked for someone to help me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PBNEW32_Ped	I lay down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PAINBE4_Ped	I asked for medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6
PAINBE5_Ped	I talked about my pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4	5	6

Pediatric Fatigue – Short Form 10a

Please respond to each question or statement by marking one box per row.

In the past 7 days...		Never	Almost Never	Sometimes	Often	Almost Always
4239aR2r	Being tired made it hard for me to keep up with my schoolwork	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4212R1r	Being tired made it hard for me to play or go out with my friends as much as I'd like	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4213R1r	I felt weak	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2876R1r	I got tired easily	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4221R1r	I had trouble finishing things because I was too tired.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4220R1r	I had trouble starting things because I was too tired.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4210R2r	I was so tired it was hard for me to pay attention	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4241R2r	I was too tired to do sports or exercise	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4208bR2r	I was too tired to do things outside.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4196R1r	I was too tired to enjoy the things I like to do	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Sleep Related Impairment – Short Form 8a

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep10	I had a hard time getting things done because I was sleepy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep119	I felt alert when I woke up	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep18	I felt tired.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep25	I had problems during the day because of poor sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep27	I had a hard time concentrating because of poor sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep30	I felt irritable because of poor sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep6	I was sleepy during the daytime.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep7	I had trouble staying awake during the day.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Sleep Disturbance – Short Form 6a

Please respond to each question or statement by marking one box per row.

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
	In the past 7 days...					
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep20	I had a problem with my sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep44	I had difficulty falling asleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep108	My sleep was restless	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep72	I tried hard to get to sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Feasibility & Acceptability Interview: Self-Report Form

Participant: _____

Date: _____

Respondent: _____

Technical feasibility:

1. How often did you have problems with the device (iPod, iPad, wearable)?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

a. Please describe problems: _____

2. How often did you have problems accessing the application?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

a. Please describe problems: _____

3. Did the application work every time you tried it?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

a. Please describe problems: _____

Ease of use:

Please rate how easy or difficult was it for you to use the application in the following areas:

1. Turning on/logging in to the application:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

2. Starting the application:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

3. Using the application to track pain and/or interventions:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

4. Using the wearable device:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

5. Uploading pain ratings and interventions to the application to send to your provider:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

6. Getting messages/feedback from my provider:

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

Satisfaction/Acceptability:

1. How easy or difficult was it for you to use the application?

0	1	2	3	4
Very easy	Somewhat easy	Neither easy/hard	Somewhat hard	Very hard

2. How practical was it for you to use the application to track your daily pain while in the hospital?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

3. How often did you remember to use the application to track your pain?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

4. How often did someone/something help you remember to use the application?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

Who/What helped? _____

5. How often did you experience physical pain or discomfort while using the application and/or wearable device?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

6. How often did you experience frustration while using the application?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

7. How often did you feel bored while using the application?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

8. How often did you enjoy using the application and wearable device?

0	1	2	3	4
Never	Rarely	Sometimes	Often	Always

Please rate the extent to which you agree or disagree with the following statements:

1. The application helped me track my pain every day.

0	1	2	3	4
Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

2. Using the application to track my pain and intervention use gets in the way of my day.

0	1	2	3	4
Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

3. Using the wearable device gets in the way of my day (e.g., is uncomfortable, etc.).

0	1	2	3	4
Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

4. It was hard to find time to incorporate using the application into my daily life while in the hospital.

0	1	2	3	4
Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

5. The application and device were helpful while I was in the hospital.

0	1	2	3	4
Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

6. Additional comments, suggestions, or concerns:

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Biography

Jacqueline Vaughn graduated with her Bachelors of Science in Nursing from the University of Michigan, Ann Arbor, MI. She practiced as a pediatric nurse in the neonatal and pediatric intensive care units before becoming a clinical instructor at the Duke University School of Nursing. As a clinical instructor she incorporated innovative technologies into simulation based learning for the nursing students. She was awarded the BAYADA “Innovation with Technology in Nursing Education” award in 2015. Her experiences using technologies in nursing education encouraged her to explore the use of innovative technologies, specifically, mobile health technologies, to better understand and manage symptoms in acutely ill children. She pursued her doctorate in Philosophy of Nursing at the Duke University School of Nursing, Durham NC. Jacqueline was the recipient of a pre-doctoral Individual National Research Service Award from the National Institutes of Health, National Institute of Nursing Research.

Jacqueline has co-authored 16 manuscripts accepted for publication in peer-reviewed journals. She is the first author on 6 of these, “User-Centered App Design in Acutely Ill Children and Adolescents is currently in press in the *Journal of Pediatric Oncology Nursing*, “Mobile Health Technology for Pediatric Symptom Monitoring: A Feasibility Study” was published in the *Nursing Research Journal*, “Customization of the TRU-PBMT App (Technology Recordings to better Understand Pediatric Blood and Marrow Transplant)” was published in the *Journal of Pediatric Nursing*, “A Protocol to

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