A Mobile Phone HIV Medication Adherence Intervention:

Care4Today™ Mobile Health Manager

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Submitted to the Faculty of the Graduate School of Carlow University in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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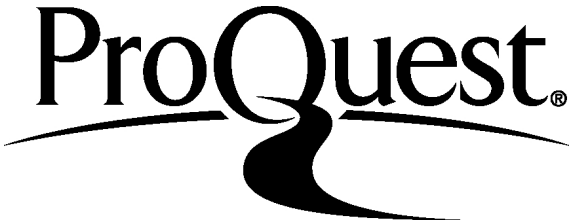

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Abstract

This paper presents the findings of a qualitative study designed to describe the experience of HIV medication adherence using a mobile phone application. For the purpose of this qualitative study, nine semi-structured focus group discussions were conducted over a three-month period at an AIDS service organization in Central Texas. The data were analyzed following the principles of thematic analysis. During analysis, four themes were identified and relations between these themes were delineated to reflect the experiences of the 23 participants. Improving adherence to antiretroviral therapy is key in reducing the morbidity and mortality of HIV disease; and daily medication adherence may prevent the occurrence of the development of drug resistant mutant strains of HIV (Mbuagbaw et al., 2011). Adherence to ART may be complex secondary to person, behavioral, and treatment factors (Halkitis, Palamar, & Mukjerjee, 2008); and noncompliance to taking daily HIV medications may be considered a community health issue secondary to risk for viral transmission. The mobile phone application, *Care4Today™ Mobile Health Manager*, was the intervention tool; and collection of focus group discussion outcomes over a three-month period with baseline versus end-of-study data determined the feasibility and acceptability of this medication adherence intervention. The greater the intention to engage in a behavior, such as daily adherence to HIV medication regimes, the greater is the likelihood of its performance. The findings suggest that when individuals are offered the necessary resources, such as a mobile phone medication reminder application, they may have greater success in performing the behavior.

Chapter 1

Introduction

Background of Problem

The behavior of nonadherence to taking daily human immunodeficiency virus (HIV) medications is a population health issue secondary to the potential for viral transmission from individuals in which the virus is not suppressed (< 200 copies/mL) (Health Resources and Services Administration [HRSA], n.d.). Medication adherence is crucial as it determines how effective the current HIV medication regime will be in decreasing viral load. The lower the HIV viral load, the healthier the individual and thus less risk of transmitting the virus to others. Medication adherence may also prevent HIV medication resistance. When doses are missed, HIV can replicate and possibly mutate to a new strain of HIV that might be resistant to the current medication regime and to other possible regimes, reducing future treatment options. Medication adherence is measured at taking medication more than 95% of the time (National AIDS Manual [NAM] aidsmap, n.d.). With once a day dosing, only two or more missed doses per month translate to less than 95% adherence. With twice a day dosing, only four or more missed does per month equals less than 95% adherence. This minimal 5% variance of adherence from scheduled dosing is considered being non-adherent to HIV medication treatment.

Purpose / Statement of Problem

The likelihood of increased HIV medication adherence with the support of the mobile phone application, *Care4Today™ Mobile Health Manager*, and with its integrated daily reminders, is the feasibility and usability research focus. The importance of this topic is related to the fact that "as HIV shifts from an acute to a chronic condition, interventions to support self-management and medication adherence are critical to enhancing the quality and length of life for

PLWH [People Living With HIV]" (Lewis et al., 2013, p. 251). The HIV Treatment Cascade, also known as the HIV Care Continuum, monitors the number of individuals living with HIV who are in medical care and are receiving antiretroviral therapy (ART). In the United States, approximately 1.2 million people are living with HIV. Of those individuals, 86% are aware of their diagnosis; 80% are linked to care; 40% are retained in care; 37% have been prescribed ART; and only 30% are virally suppressed (AIDS.gov, n.d.). The fact that only 30% of all individuals living with HIV have successfully achieved viral suppression, currently measured at < 200 copies/mL, speaks to the importance of HIV medication adherence as a population health problem.

Human behavior is an additional potential barrier to medication adherence. Explaining human behavior with all its complexities can be a difficult task. Intentions and perceptions about behavioral control can result in variances of outcome in the actual behavior. The greater the intention to engage in a behavior, such as daily adherence to HIV medication regimes, the greater the likelihood will be of its performance. When individuals have the necessary resources, such as a mobile phone medication reminder application, they may have greater success in performing the medication adherence behavior.

Research Question

The research question directing this study is: What is the likelihood of HIV-infected individuals adhering to daily HIV medication with the technological support of the mobile phone medication reminder application, *Care4Today™ Mobile Health Manager*, during a three month adherence self-report period?

Theoretical Frameworks

There is a strong behavioral component toward medication adherence; and there is also a strong behavioral component toward adopting and using new technology, such as installing and actively using a daily mobile phone application. To address these related behavioral components, two theoretical frameworks, the Technology Acceptance Model (TAM) and the Theory of Planned Behavior (TPB) are used in this research project.

The Technology Acceptance Model.

Davis' TAM (Davis et al., 1989), based on Azjen's Theory of Reasoned Action (TRA), hypothesized that the behavioral attitude of the user toward the technology is a determinant of whether the user will ultimately reject or use the technology; the three determining factors are: 1) perceived usefulness (PU), 2) perceived ease of use (PEOU), and 3) attitude toward the technology. "In order to design effective training interventions to improve user acceptance, it is necessary to better understand the antecedents and determinants of key acceptance constructs" (Venkatesh & Davis, 1996, p. 451). Although the user might have little to no knowledge about the ease of use of a newly introduced technology, the user may have a pre-formed sense of how to use the technology. Davis considered that the use of the technology is a behavioral attitude and the TRA was an appropriate model to adapt in order to predict and explain this behavior (Chutter, 2009). TAM is a theoretical framework that specifically addresses participants' technology acceptance attitudes that may affect the actual use of the *Care4Today™ Mobile Health Manager* mobile phone application.

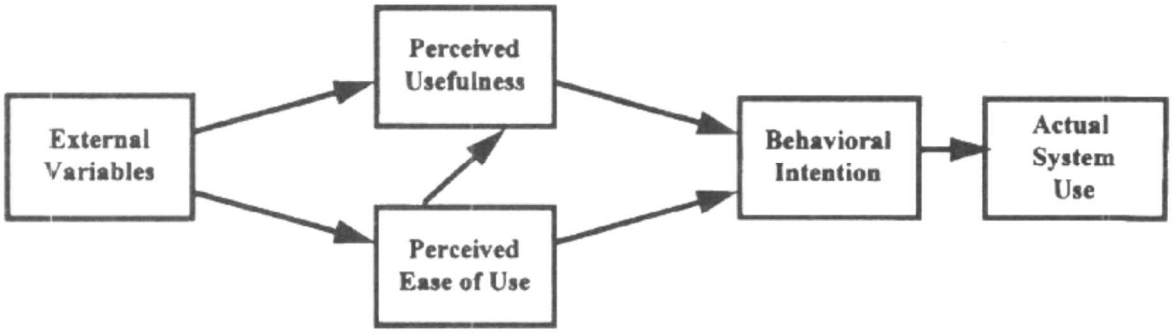

Figure 1. Final Version of TAM. Adapted from Venkatesh, V., & Davis, F. D. (1996). A model of the antecedents of perceived ease of use: Development and test. *Decision Sciences, 27*(3). p. 453.

The Theory of Planned Behavior.

Ajzen's TPB was developed in 1985, later updated in 1987, and originated from the TRA. The TRA was initially developed in the late 1960s by social psychologists Ajzen and Fishbein and explains the relationship among beliefs, attitudes, intentions, and behavior. The TRA's goal was to understand and predict behaviors that are under the control of the individual. The TPB was developed to predict an individual's intention to engage in a particular behavior at a specific time and place. *Intention* is the most important determinant of behavior and is something over which individuals may have some self-control. The key component to this model is behavioral intent; in such, the likelihood that the behavior will have an expected outcome is dependent upon the perceived risks and benefits of the outcome. The TPB can be used to predict and explain many health behaviors and intentions such as tobacco use, alcohol use, substance use, breastfeeding, and utilization of health services, to name a few. A central assumption of the TPB is that behavioral intentions are the most important determinants of behavior (Ajzen, 1991). The TPB was an appropriate theoretical framework for the research project focusing on HIV medication adherence, secondary to the strong behavioral component toward medication

adherence. Adherence to ART may be complex secondary to person, behavioral, and treatment factors (Halkitis, Palamar, & Mukjerjee, 2008).

The TPB describes three categories of beliefs–behavioral, normative, and control. Six constructs make up the TPB; and the theory addresses the individual's actual control over behavior. The six concepts/constructs are:

1. Behavioral belief refers to the individual's favorable or unfavorable evaluation of performing the behavior. It is concerned with the individual's beliefs about the consequences of performing the behavior. It explores the outcomes of performing the behavior. Attitude may be a combination of intentions, beliefs, feelings, and perceptions.
2. Attitude toward the behavior refers to motivational factors that influence the given behavior. The stronger the intention to perform the behavior, the greater the likelihood that the behavior will be performed.
3. Normative belief refers to the social pressure upon the individual to either perform or not perform the behavior. The individual may consider what peers may think of the behavior or how important it might be to comply with the wishes of peers, whether other people approve or disapprove of the behavior, and whether the individual should engage in the behavior.
4. Subjective norm refers to the customs or behaviors within a group of people, looking at a more global cultural context. Social norms may be standard within a group of people.
5. Control belief refers to the perceived power of factors that may facilitate or impede the behavior. Perceived behavioral control may vary across situations and actions, which can result in the individual having varying perceptions of behavioral control depending on the

situation. It is interesting to note that this construct of the TPB created the shift from the TRA to the TPB with the addition of perceived behavioral control.

6. Perceived power refers to the perceived presence of factors that may facilitate or impede performance of a behavior. Perceived power adds to an individual's perceived behavioral control over each of those facilitating or impeding factors (Ajzen, 1991; McEwen & Wills, 2011).

Intervening events can alter beliefs—behavioral, normative and control; and events can modify attitudes, subjective norms or perceptions of control. The result can be revised intentions. These changes may reduce the predictive validity of intentions that were assessed prior to the changes taking place (Ajzen, 2011).

The theory's model is parsimonious and is succinctly depicted in the following figure:

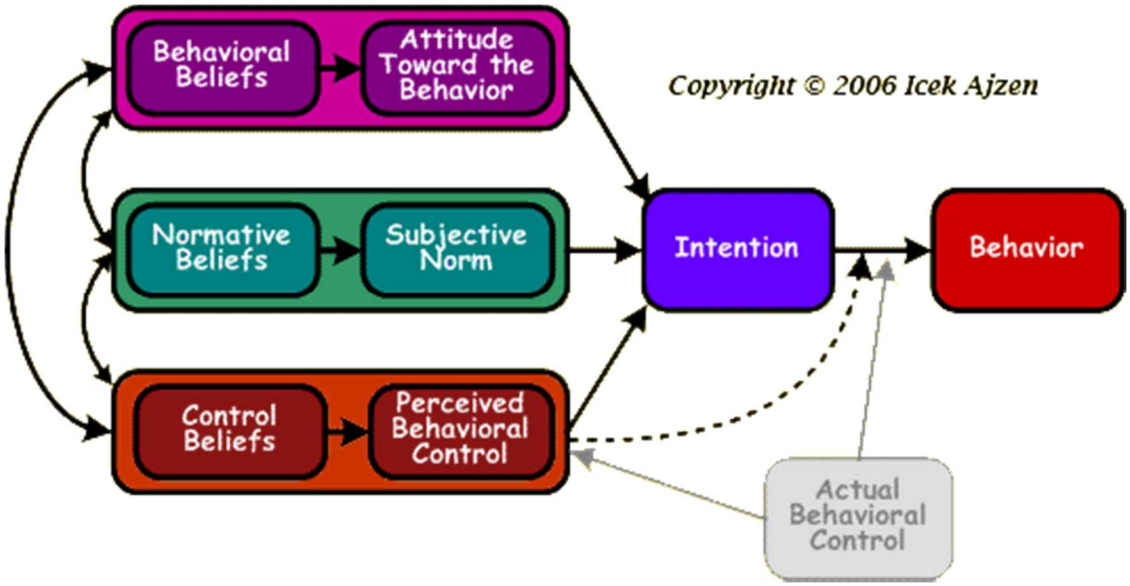

Figure 2. The Theory of Planned Behavior. Adapted from http://people.umass.edu/aizen/tpb.diag.html. Copyright © 2006 Acek Ajzen.

There are several limitations of the TPB to consider: 1) the theory assumes the individual has the opportunities and resources to perform the behavior, regardless of intention; 2) the theory

does not take into account other potential barriers such as past experience or environmental or economic factors; and 3) the theory assumes that behavior results from a linear process of making decisions and does not address the timeframe between intention and desired behavioral action.

An article published in 1991, related to Ajzen's TPB, was obtained for background significance relative to the proposed conceptual framework of the research project. The article revealed that the TPB was an appropriate theory to use when conducting focus group methodology research. Focus group methodology readily elicits accessible beliefs from participants in a free response format. When asking about the behavior of interest, such as medication adherence, the participants' responses will reflect control factors, normative referents, and likely outcomes. Ajzen also gives guidance to the construction of a TPB Questionnaire, using a 7-point Likert scale, although this questionnaire was not used in this study.

An additional supplementary article published in 1989, related to the Davis et al.'s TAM, was also obtained for the research project's conceptual framework. The TAM was originally adopted to address technology in the computer technology workplace; however, its focus on other workplaces has emerged and now includes the perceptions of workers in the health care field. The weakness of the TAM instrument is that it does not account for variables such as subjective norms. However, this was an appropriate model to use in this research study secondary to its strong association between perceived usefulness (PU) and the technology design variable of perceived ease of use (PEOU). Technology design was a consideration in the evaluation of the *Care4Today™ Mobile Health Manager* mobile phone application.

Definition of Terms

Medication adherence is not only a challenging concept, but also one that has been in terminology transition.

> The transition in terminology from compliance to adherence, and more recently to concordance, requires re-clarification of 'adherence' as a concept in nursing practice. Differences exist in the use of the term adherence and how or if it differs from compliance or concordance. (Bissonnette, 2008, p. 634)

Adherence is based on the assumption that it implies that the patient agrees with the prescribed recommendations; compliance is based on the assumption that the patient is passively obeying. Concordance implies that the provider and the client are working together in mutual agreement with the recommendation. A review of the literature revealed the use of the term adherence was used most frequently and is therefore the term used in this study.

Medication adherence / non-adherence.

Poor adherence to antiretroviral therapy may be one of the strongest predictors of the progression from HIV status to AIDS diagnosis (CD4+ T cell count <200 cells/mm^3) to AIDS-related death. Adherence is key to treatment success; non-adherence may contribute to HIV drug resistance, initiation of more expensive second line ART regimes, and possibly therapeutic failure (Shet et al., 2010). Monitoring percentage adherence is an important indicator. At least 95% HIV medication adherence maintenance is necessary to achieve virological and immunological success (NAM aidsmap, n.d.). Investigators in various studies may define medication adherence differently. Burda et al. (2012) state that defining adherence may be based upon a set period of time, such as seven days, when the medication was not taken; whereas, other investigators may use longer timeframes, such as over a 30-day period. Hardy et al. (2011) use

this formula for calculating percent adherence: (number of prescribed doses – number of missed doses) / number of prescribed doses x 100. Although medication adherence self-report is an imperfect measure of adherence, it continues to be the most common method for medication adherence assessment and has been used in greater than 70% of medication adherence studies (Burda et al., 2012). This study uses Hardy et al.'s formula over a seven-day period to calculate percent adherence.

Mobile phone.

Shet et al. (2010) report that there has been interest in the use of mobile phone health care in low-income settings; and secondary to studies that integrate mobile phones in chronic diseases such as asthma or diabetes, there is an interest in integrating it into HIV care. Coomes et al. (2012) report that 83% of American adults own a mobile phone. They report no significant difference in phone ownership by race or ethnicity; therefore, use of the mobile phone to support medication adherence has the potential for a far-reaching medication adherence tool. Short message service (SMS) allows for instantaneous message delivery via a mobile phone. One challenge in the use of the mobile phone as an intervention for medication adherence can be that study participants may report lost, stolen or damaged phones during the study timeframe (Smillie et al., 2014). Participants may also report interrupted access to mobile phone services secondary to inability to pay monthly installments for service.

***Care4Today™ Mobile Health Manager* mobile phone application.**

Care4Today™ Mobile Health Manager was the selected mobile phone application used in this study. The user was able to enter medications into the application from either a mobile phone or a computer; and the user could set up medication reminders and schedule prescription refill reminders. The application tracked how often the user took each medication, generating a

weekly or monthly adherence report on the mobile phone; and the user had the capability to share this information about medication usage with either a family member or health care provider. The phone application uses an easy to understand color-coded system to prompt the user when it is time to take medications. Each reminder message prompts a response that is recorded in the user's adherence report. The application is a secure, two-way messaging platform that works on almost all mobile phones including basic feature phones (Janssen Research & Development, n.d.).

The Janssen Biotech. Inc. Privacy Policy (Appendix A) describes how information is collected, used and disclosed; it can be found on their website at http://www.care4today.com/privacy-policy.html. To register for this application, the site does not request the submission of personal information. However, certain information may be passively collected using various technologies such as through the user's browser using cookies; flash cookies; pixel tags, web beacons, clear Graphics Interchange Formats (GIFs), or other similar technologies; and Internet Protocol (IP) address. The Privacy Policy states that they use reasonable organizational, technical, and administrative measures to protect personal information under their control. Users may opt out of this sharing with their affiliates and/or third party partners by contacting them directly. Any questions about the Privacy Policy may be directed to RA-rndus-care4today@its.jnj.com or via mail to: Janssen Healthcare Innovation; 3210 Merryfield Row; San Diego, CA 92121-1126.

Chapter 2

Review of the Literature

Introduction

A review of the literature indicates that the use of mobile phones may be instrumental in the delivery of HIV care and medication adherence, and that using mobile phones for this purpose has high feasibility and acceptability in this targeted population. The mobile phone application, *Care4Today™ Mobile Health Manager*, was implemented to test and evaluate for its feasibility and acceptability. Three scheduled focus group sessions, Start-of-Study, Midpoint-of-Study, and End-of-Study, were facilitated to evaluate the perceived usefulness, perceived ease of use, and the attitude toward the smart phone application technology in supporting increased HIV medication adherence. This research had similar objectives to those reported by Lester et al. (2009): following the phone message intervention study, the primary objective is improvement of adherence to HIV medications.

Critique and Synthesis of Previous Research

Embracing new technologies may improve medication adherence, offering support to those living with HIV. International organizations such as

> the World Health Organization and UNAIDS [Joint United Nations Programme on HIV] have outlined ambitious goals of universal access to those in need among the 28 million people infected with HIV globally, and include a directive to embrace new technologies to help achieve that goal. (UNAIDS, 2008, as cited in Lester et al., 2009, p. 2)

Medication adherence appears in the literature of multiple disciplines, such as nursing, medical, and psychology, and it is directly related to behavioral actions and socioeconomic

conditions. Rolnick, Pawloski, Hedblom, Asche, and Bruzek (2013) report that their assessment of medication adherence across eight diseases yielded variable adherence rates. The eight diseases studied were asthma or chronic obstructive pulmonary disease, cancer, depression, diabetes, hyperlipidemia, hypertension, multiple sclerosis, and osteoporosis. Of these eight medical conditions, the lowest reported adherence was in asthma (33%) and diabetes (51%). Their study found overall adherence rates were higher for white individuals living in higher socioeconomic status; and those in the lowest quartile of the living area variables of income, poverty, and education reported lower drug adherence. Increasing comorbidity also resulted in lower adherence, as those with fewer conditions and fewer drugs had higher adherence rates.

There is a large extent of information about medication adherence and medication non-adherence in reference to chronic disease management; however, the search becomes more limited when specifying HIV medication adherence / non-adherence. The literature search revealed even more limited studies on HIV medication adherence when *mobile phone* and *application* were also entered into the search. This dearth of literature suggests that HIV medication adherence / non-adherence studies with advanced technology are just beginning to become more available. Also, at the time, the literature does not support studies using the specific mobile phone application, *Care4Today™ Mobile Health Manager*. Most reviewed studies use either two-way SMS text messaging or voice messaging as the interventions. This research study generalized study outcomes from SMS text messaging found in the literature to the mobile phone application intervention research project.

Reviewed studies for chronic diseases appear to build upon another, bringing a new body of knowledge from study to study as research advances from voice messaging to SMS text messaging. Starting with other prevalent, chronically managed diseases such as diabetes and

cardiac disease, studies reveal that there appears to be a progression from voice messaging to basic SMS text messaging interventions to the more sophisticated phone and iPad application interventions. Mobile phone applications that are engaging to the user appears to be the challenge; applications that do not offer consumer engagement appeal undermine their effectiveness.

Tao et al. (2015) conducted a meta-analysis of randomized controlled trials through January 2014 evaluating patient adherence to medication in chronic disease care with electronic reminders. Data from 20 studies were synthesized. The electronic reminders ranged from pagers to alarm devices, and SMS reminders. Their meta-analysis revealed that the use of electronic reminders was associated with a small improvement in patient adherence to medication. They concluded that electronic reminders appear to be an effective method of improving chronic medication adherence.

In reference to the chronic disease diabetes, Goyal and Cafazzo (2013) described a diabetes self-management phone application for adolescents. Diabetes is one of the most intensive self-managing and prevalent chronic health conditions in adolescents. They found that "a comparison of behavior in the 12 weeks before adolescents began using [the phone application] and the 12 weeks after revealed evidence of clear behavioral change. The average daily frequency of blood glucose measurements increased by 49.6%" (p. 52).

Foreman et al. (2012) studied the use of text message reminders with clients taking both glycemic medications in addition to blood pressure medications. Their findings revealed that participants opting into a text message reminder program demonstrated greater oral medication adherence compared with those not choosing to receive text message reminders. The use of a text message reminder program results in higher rates of adherence over time.

Finally, in reference to HIV medication management, the literature reviews also referred mainly to SMS messaging interventions. Lester et al. (2009) identified use of new technology interventions and studied the effectiveness of mobile phone SMS text messaging medication adherence messages to a population receiving ART in Nairobi, Kenya. The suppression of HIV viral load determined by lab results and self-reported adherence to ART were the primary outcomes measured. Their study built upon the WelTel Kenya1 SMS technology. Smillie et al. (2014) later conducted a prospective pilot study to adapt the WelTel Kenya1 intervention to a Canadian clinical setting (WelTel BC1) and test for its acceptability and feasibility in this setting.

Because there is no discovered research identifying a specific mobile phone application used for HIV medication adherence, the outcomes of the use of SMS text messaging and its acceptability and feasibility might be generalized to this research study's mobile phone application. This study's focus was a first step to broaden this knowledge by evaluating acceptability and feasibility of a mobile phone application.

Rather than large sample, multi-site, randomized controlled trials, most of the research in the literature was focused on the acceptability and feasibility of using this technology as an implementation tool. There was little uniformity across most study designs; and the eight most frequently used study designs ranged from the following: qualitative and quantitative mixed method system review; cross sectional study; randomized control trial; pre-experimental proof-of-concept study; quasi experimental pilot study; single centered randomized control trial; exploratory interview; and multisite randomized controlled open label study (Burda et al., 2012; Coomes et al., 2012; Crankshaw et al., 2010; Hardy et al., 2011; Lester et al., 2009; Lewis et al., 2013; Mbuagbaw et al., 2011; Shet et al., 2010; Sidney et al., 2012; Smillie et al., 2014; Tran &

Houston, 2012; van Velthoven et al., 2013). The evidence in the literature to support valid and reliable study designs appeared to be weak.

Sample settings.

The sample settings in the reviewed HIV medication adherence articles were varied in both target populations and settings; three of the reviewed studies were conducted in the United States. The three studies in the United States were conducted on (a) men who have sex with men (MSM) recruited from a health clinic in the Midwest United States (Lewis et al., 2013); (b) ten homeless individuals in Baltimore City, MD (Burda et al., 2012); and (c) 23 participants from an outpatient clinic at Boston Medical Center (Hardy et al., 2011). Some studies were in low or middle-income countries in Africa, such as those conducted in Cameroon and Kenya, in addition to a study conducted in Durban, South Africa (Crankshaw et al., 2010; Lester et al., 2009; Mbuagbaw et al., 2011; van Velthoven et al., 2013). One study reached both urban and rural outpatient clinics in South India (Shet et al., 2010); the Canadian study had 25 clinic participants (Smillie et al., 2014); and the Vietnamese study had 1016 injection drug user (IDU) participants who were interviewed in Hanoi, Hai Phong, and Ho Chi Minh City (Tran & Houston, 2012). These studies from the literature represented study participants from both lower and higher socioeconomic levels and from various countries. Homeless individuals, IDUs, and clinic patients were some of the varied demographics of participants across studies. Although there were different settings and different target populations, a concentration on the theme of acceptability and feasibility studies appears to have generated positive acceptability outcomes in these various settings.

Interventions.

Because these reviewed articles were primarily focused on acceptability and feasibility of use studies, the interventions using SMS text messaging were very similar. However, the time frames of the SMS text messaging studies varied. Dynamically tailored text messaging was delivered via mobile phone in some studies (Lewis et al., 2013). Other studies delivered weekly text messages (Hardy et al., 2011; Lester et al., 2009; Mbuagbaw et al., 2011; Sidney et al., 2012; Smillie et al., 2014) and one study delivered weekly voice messages via mobile phone, secondary to participant preference over text messaging (Shet et al., 2010). The study of ten homeless individuals delivered daily messages (Burda et al., 2012). One study that stands alone is the Vietnamese study that was an acceptability and feasibility study with a one-time telephone interview that did not deliver the adherence reminder intervention (Tran & Houston; 2012).

This research used the *Care4Today™ Mobile Health Manager* mobile phone application as the intervention, rather than SMS text messaging. Participants were educated on the use of the application and they were encouraged to answer a daily-automated HIV medication reminder that appeared on the screen of the mobile phone. This research study required more participant interaction than most of the reviewed studies that offered a weekly SMS text message to support HIV medication adherence. The evidence in the literature to support use of SMS text messaging appeared to be strong for acceptability and feasibility; however, the evidence was weak in large scale, multiple site, and randomized controlled trials.

Data collection.

Depending upon the study, data collection methods and objectives varied. The most common methodology was the researcher driven interview. Many studies interviewed primarily for demographic information and perception of ease of use of mobile phone for medication

adherence reminders (Crankshaw et al., 2010; Shet et al., 2010; Sidney et al., 2012). Very few studies collected clinical data such as CD4+ T cell counts and HIV viral loads (Hardy et al., 2011; Lester et al., 2009). Data collection times also varied from initial interview only (Tran & Houston, 2012) to collection points conducted at one month (Burda et al., 2012), three months, six months and up to twelve months (Lester et al., 2009; Mbuagbaw et al., 2011; Smillie et al., 2014).

The evidence in the literature was very weak in collecting clinical data. Collecting baseline and study end CD4+ T cell counts and HIV viral loads would support not only medication adherence other than by self-report, but might also support clinical measurement of improved quality of life.

Results / outcomes.

Of the studies that implemented SMS text messaging to support HIV medication adherence, positive outcomes were achieved and reported (van Velthoven et al., 2013). However, two studies indicated that although there was acceptance of mobile phone use for the intervention and that it was considered helpful, the participants stated that the content of the medication reminder messages did not matter and they did not view the intervention as critical to the success of their medication adherence (Crankshaw et al., 2010; Hardy et al., 2011). One study indicated that 87% of the participants preferred voice reminders to SMS text messages; and half of those participants preferred voice with the accompanying SMS text (Sidney et al., 2012). One outlier article was the study of the ten homeless individuals who received daily reminders; 93% were reached every day for one month and 100% reported medication adherence (Burda et al., 2012). The authors noted that additional research is needed to explain the high adherence percentage reported by these participants. The Vietnamese interview-only feasibility study indicated that

78% of the respondents agreed that using mobile phone text messages could be an effective strategy to support adherence (Tran & Houston, 2012).

The evidence in the literature was strong in supporting the acceptability and feasibility of using the SMS text messaging feature on mobile phones for HIV medication adherence support; however, the evidence was non-existent in using mobile phone applications on a mobile phone for HIV medication adherence support.

Rationale for Study

HIV medication adherence with resulting HIV viral suppression is a topic of both global and local concern as health care providers look at individual and community viral suppression as one means toward achieving the President's Emergency Plan for AIDS Relief's (PEPFAR) AIDS Free Generation (The Office of the Global AIDS Coordinator, 2012). The use of the mobile phone may be an example of such emerging technology to support The World Health Organization's and UNAIDS' directives to embrace new technologies to help achieve universal access to those in need. Measuring HIV medication adherence is also challenging in that medication adherence has primarily been measured by patient self-report. The literature reveals that mobile phone messaging was perceived as an acceptable mode of communication between patient and health care provider, but the limited studies did not allow generalizable conclusions (van Velthoven et al., 2013).

There appeared to be no evidence based practice literature regarding the use of mobile phone applications to support HIV medication adherence. The existing literature investigated SMS text messaging interventions and most of the reviewed studies were of small scale and primarily addressed the acceptability and feasibility of the intervention, as opposed to actually conducting and reporting trial studies. There also appeared to be few studies in the literature that

described theoretical constructs to support the proposed interventions of mobile phones as a tool to support individuals' HIV medication adherence.

Coomes et al. (2012) assessed some of the gaps in the current knowledge base. From their literature review, some identified needs are: (a) a rigorous evaluation of SMS-based and other mobile technology-based applications specifically for HIV care; (b) studies with larger sample sizes; and (c) collecting clinical data, such as viral loads. Further studies that look at the influence of the intervention on medication adherence are needed, including the addition of a mobile phone application platform. The *Care4Today™ Mobile Health Manager* mobile phone application may be one of these identified other mobile technology-based applications specifically for HIV care.

Chapter 3

Methods

Design

The research study question investigating the perception of the feasibility and acceptability of a mobile phone application's potential for increased daily HIV medication adherence suggested using a qualitative descriptive design for this study with focus groups as the means for data collection. Digital audio recordings from focus groups and field notes with observations of nonverbal behaviors were the collected qualitative data. This is consistent with Moran, Burson, and Conrad (2014) who recognized the significance of qualitative data with this research focus. They observed "the phenomenon of interest [medication adherence] may have been described in a population or social setting, but there is a gap in practice knowledge with a new group of clients or a new setting…." (p. 334).

A qualitative descriptive design allowed for data collection of the targeted population's characteristics, attributes and / or experiences; and collected data was reported using both descriptive statistics and narrative. Qualitative descriptive design studies have been utilized in other medication adherence studies. This design was appropriate for studying medication adherence as it provided better understanding of the dynamic, ever changing, real life social environments. The qualitative descriptive design also expanded and addressed gaps in the existing knowledge, exploring both the facilitators and barriers to medication adherence (Badahdah & Pedersen, 2011; Musumari, Feldman, Techasrivichien, Wouters, Ono-Kihara, & Kihara, 2013).

This qualitative descriptive study was conducted over five phases:

- Phase I: Marketing the Intervention / Invitation to Participate (June-July 2015)

- Phase II. Start-of-Study, Three Individual Focus Groups of 8-10 participants (August: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 1 Food Bank)
- Phase III. Midpoint-of-Study, Three Individual Focus Groups of 8-10 participants (September: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 3 Food Bank)
- Phase IV. End-of-Study, Three Individual Focus Groups of 8-10 participants (October: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 3 Food Bank
- Phase V: Data Analysis and Report (November-December 2015)

Population

An accessible, convenience sample of thirty eligible participants was recruited during Phase I from a population of approximately 250 people living with HIV (PLWH) who regularly attend an AIDS Services Organization (ASO) food bank in a city located in the Southwest region of the U.S. The use of a convenience sample addressed the constraints of the limited three-month period of this research study and allowed for the maximization of the number of voluntary participants from this accessible population.

Inclusion eligibility criteria was: registered clients of the food bank, English-speaking as primary language, HIV-infected, at least 18 years old, currently on ART for at least three months, reporting less than 95% adherence to ART over the past seven days, and consistent access to a mobile phone with data service. Exclusion criteria was non-English-speaking, under 18 years of age, currently not on ART, and >95% adherence to ART. No identifiable information was collected other than first name, last initial, and preferred contact information in order to remind participants of three scheduled focus groups throughout the study. Challenges to daily HIV medication adherence that are frequently observed are: “incarceration, poverty, food and

housing instability, substance use, and mental health disorders" (Thompson et al., 2012, p. 822); however, these variables were not under consideration for this feasibility and usability study.

During the recruitment period for the study, eligible participants were determined through an intake and eligibility process. All participants eventually enrolled in the study were predicted to be at high risk for HIV medication non-adherence. The final participants were determined when all completed surveys had been returned by the provided deadline date and reviewed for study eligibility.

A total of 16 participants out of the 30 invited participants attended all three focus group meetings. Some reported reasons for attrition over the three-month period were: 1) lack of dependable transportation; 2) being out of town; 3) unexpected hospitalization / illness; 4) lost / stolen mobile phone at time of focus group meeting; and 5) conflicting priorities. One participant who was unable to attend Focus Group #2 was allowed to attend Focus Group #3 to continue to participate in the study for the purpose of contributing to the study.

Procedures

Institution Review Board (IRB) approval from Carlow University (Appendix B, Appendix C), the academic institution of record, was obtained prior to the start of this study. In addition, written approval was obtained by the ASO (Appendix D) where the study was conducted.

Phase I: Marketing the Intervention / Invitation to Participate (June-July 2015).

The food bank located at the ASO is in operation from Tuesday-Thursday during two weeks each month. This schedule allowed for twelve days, over four weeks duration, for research study marketing opportunities during June 2015. Marketing collateral / posters were placed in the food bank lobby for participants to review to inform them of the study. *Study*

Introduction / Intent to Participate (Appendix E) flyers with an introduction to study information on the front side and eligibility criteria / intent to participate in the study on the reverse side, were placed in outgoing food bank grocery bags during Week One and Week Three (the six days of open food bank) throughout the month of June 2015. The researcher and research assistant were onsite during food bank hours to offer a laptop demonstration of the mobile phone application to generate interest during food bank hours. There was the consideration that food bank clients may not know the researcher(s), and consequently have not built trusting relationships with the researcher(s). Therefore, existing food bank staff, food bank volunteers, and ASO case managers, if applicable, encouraged potential participants to complete and return the *Study Introduction* / *Intent to Participate* form to the researcher(s). Completed *Study Introduction / Intent to Participate* forms were returned by potential participants into a collection box at the food bank by the deadline date of June 30, 2015. The potential participant's first name, last initial, and preferred return contact information was provided on the *Introduction to Study* / *Intent to Participate* form for study follow-up and for focus group meeting schedule notification / reminder follow-ups. Participants who consented to be approached for this research study, by returning the *Introduction to Study* / *Intent to Participate* form, and who met eligibility inclusion criteria as determined on the flyer, were contacted and invited to participate in the study's three scheduled focus groups. "A focus group study is a carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, nonthreatening environment" (Krueger & Casey, 2015, p. 2).

Potential participants were advised that the initial focus group meeting with the researcher(s) would take approximately ninety minutes and participants would be provided with an information packet containing an overview of the study describing highlights of the value of

study participation. Participants had the option and opportunity to decline or discontinue their involvement in the study at any time with no threat to current food bank participation. A contact email address and phone number was provided for participants to contact the researcher(s) with any questions concerning the study.

Phase II. Start-of-Study, Three Individual Focus Groups of 8-10 participants (August: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 1 Food Bank).

Participants were informed about the purpose of the study, the voluntary nature of their participation in the study, and the confidentially of all collected data before providing informed consent for study participation. Completion of a signed *Informed Consent Letter* (Appendix F) at the first focus group meeting served as the participant's consent to participate in the study. Written informed consent met confidentially and Health Insurance Portability and Accountability Act (HIPAA) standards; and ethical considerations to guarantee the participants' confidentiality were in place. Any potentially identifiable information collected during the study was placed in a confidential, separate, locked file, with access only to the researcher(s). No collected information was shared with the staff and volunteers at the food bank or the ASO. Refusal to participate in the research did not in any way interfere with the services provided to the food bank clients.

The initial focus group meeting was held in a private conference room located at the ASO. A light lunch, swag bag, and gift certificate were provided to all participants. The researcher(s) initially facilitated participants' completion of the following documents:

- Appendix F: *Informed Consent Letter*
- Appendix G: *Participant Demographics*

- Appendix H: *Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV)*

Participants received the following educational support materials:

- Appendix J: *Taking Medications for HIV: Adherence*
- Appendix K: *Care4Today™ Mobile Health Manager: Application Instructions*

Participants were also given the researcher's email address/phone number where they could maintain connections with researcher(s) to troubleshoot issues related to the application.

For those participants who had not installed the phone application prior to the initial focus group meeting, the researcher(s) offered *Care4Today™ Mobile Health Manager* mobile phone application installation support to theses participants prior to the start of the focus group discussion. Following the first focus group meeting, the researcher(s) facilitated installation of the mobile phone application on any phones to which it had not been downloaded. The intention of the initial discussion was to identify potential challenges and concerns with using the phone application and to gather collective perceptions of its usefulness in improving daily medication adherence. All focus group discussions followed the Krueger and Casey (2015) outline for facilitating focus groups: opening, introduction, transition, key questions, ending questions, and oral summary / troubleshoot. *Start-of-Study Focus Group Questions* (Appendix L) led this focus group discussion. At the completion of the initial focus group meeting, participants were given a $10 gift card for participating in the initial focus group. The three-month medication adherence self-report study period began upon the end of the first focus group meeting.

Phase III. Midpoint-of-Study, Three Individual Focus Groups of 8-10 participants (September: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 3 Food Bank).

The intention of the Midpoint-of-Study Focus Group was the sharing of positive and negative experiences and the changing perceptions of usage of the application for medication adherence. Additional mobile phone application technical support was also provided, as needed. *Midpoint-of-Study Focus Group Questions* (Appendix M) led this focus group discussion. At the completion of the Midpoint-of-Study Focus Group meeting, participants were given a $15 gift card for their ongoing participation in the study. The three-month medication adherence self-report study period was now at the halfway milestone.

Phase IV. End-of-Study, Three Individual Focus Groups of 8-10 participants (October: Tuesday, Wednesday, Thursday, 12:00-1:30pm during Week 3 Food Bank.

The intention of the End-of-Study Focus Group was the overall evaluation of the study and whether participants' perceptions of the mobile phone application usage matched adherence outcomes. *End-of-Study Focus Group Questions* (Appendix N) led this focus group discussion. At the completion of the End-of-Study Focus Group meeting, participants were given a $25 gift card for their completion of participation in the study. The three-month medication adherence self-report study period concluded with this focus group.

Phase V: Data Analysis and Report (November 2015).

This was the phase of discovery to determine if the intervention had usability and affected participants' medication adherence behavior. Participants' demographic data was transcribed onto Microsoft® Office Excel worksheets and the Statistical Package for the Social

Sciences (SPSS) was used for further analysis. Following data cleaning and evaluation of any missing data, the data analysis began with basic descriptive statistics to describe the characteristics of the sample. Complete audio-recorded transcripts from the focus groups, in addition to supplemental field notes taken by the researchers, was the basis for an abridged transcript-based analysis of data. Following each focus group session, the research assistant completed the transcript from the audio recording. The researcher then verified the transcript for accuracy by listening to the audio recording and following along with the transcript. Participants' focus group response data was transferred onto Microsoft® Word worksheets for organization and identification of themes with codes.

The analytic framework was the constant comparative method, as described by Krueger and Casey (2015). The objective of the constant comparative framework was to identify patterns in the focus group data and to then reveal associations among concepts. The researchers compared one segment of data with another to identity similarities and differences.

Instruments

Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV).

The *Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV)* was administered during the Start-of-Study focus group meeting to assess both HIV knowledge and action. The strengths of this tool are that it may better represent health literacy for HIV patients than more general tools measuring reading ability in a health context. Scores on the BEHKA-HIV are significantly associated with self-reported medication adherence. Limitations of this tool are that it is not a direct test of functional health literacy in terms of reading comprehension and that further validation is needed (HIV Guidelines, n.d.). Osborn et al. (2010) report that this psychometric tool demonstrates high internal consistency and construct validity, items are

written at a 5th grade reading level, and it is a strong predictor of HIV medication adherence. Haun, Valerio, McCormack, Sørensen, & Paasche-Orlow (2014) report validation of this health literacy measurement tool as "item-total correlations were significant: knowledge (0.63) and action (0.94). Scores predicted medication adherence with a sensitivity of 0.76, and specificity of 0.82" (p. 323). They noted that the "assessment of knowledge of HIV can be integrated into health care as strength" (p. 323) of the tool; and the tool's limitation is "limited psychometric testing" (p. 323). The *BEHKA-HIV* is an 8-item assessment of HIV knowledge and treatment action. The knowledge subscale measures the participant's ability to understand HIV health information and the action subscale measure the participant's ability to make decisions to obtain health information. Three of the eight items measure knowledge and five items measure action. The scales are: 0-3 score = low literacy; 4-5 score = marginal literacy; and 6-8 score = adequate literacy.

The *Care4Today™ Mobile Health Manager*.

Participants installed the *Care4today™ Mobile Health Manager* phone application onto their mobile phones as a personal medication adherence report instrument. The instrument allowed the participants to enter prescribed HIV medications into the application from the mobile phone or from a computer. The application has the capability for the participant to set up medication reminders and schedule prescription refill reminders. It tracks how often each medication was taken and the application has the option of sharing adherence information with a health care provider or family member. The application includes a medication database of 40,000 FDA-approved medications and 20,000 images inclusive of generic and brand name medications. The application prompts the participant when it is time to take a specific medication using an easy to understand color-coded system. The application is a secure, two-way messaging

platform that works on most mobile phones, including basic feature phones. Participants were able to track their weekly percent medication adherence via the report feature of this application. In the following figure, a green box indicates medication taken; a yellow box indicates medication taken late; and a red box indicates medication not taken. Percentage adherence is also listed (Janssen Research & Development, n.d.).

Figure 3. *Care4Today™ Mobile Health Manager*. Adapted from http://www.care4today.com/mhm/

Data Collection

During the month of June 2015, potential study participants were recruited through study

promotional flyers placed in outgoing food bank grocery bags, through lobby signage, and through research assistant lobby presence during selected food bank hours. A secure *Study Introduction / Intent to Participate* form drop box was created and placed in the food bank lobby so that interested individuals could return the completed form during food bank hours throughout the collection month. During the research assistant's lobby presence, approximately 15 out of 70 food bank recipients expressed interest and completed the eligibility form. The research assistant displayed a laptop, with a two-minute looping video that described the *Care4Today™ Mobile Health Manager* application, in addition to making *Care4Today™ Mobile Health Manager* fliers available to generate study interest and participation. Twenty-five additional *Study Introduction / Intent to Participate* forms were later received in the drop box.

The research assistant approached potential participants as they waited for their food orders to be filled, and discussed the benefits of the *Care4Today™ Mobile Health Manager* mobile phone application through study participation. During these discussions, ten individuals declined participation stating reasons such as "I don't have a phone" or "I barely know how to place calls using my phone" and "I'm not interested". Some individuals stated that their "viral loads were suppressed or undetectable" or that they "have no problems taking their medications on time". Descriptions of a provided lunch at the scheduled focus group meetings and gift card incentives were major driving forces for promoting participation in the research study. Some individuals stated that they were "looking for a way to give back" and indicated that the research study would allow this. The research assistant assessed the population for perceived literacy; individuals ranged from functioning levels of literacy to needing assistance reading the food pantry menu items; some individuals requested that the research assistant read the entire *Study Introduction / Intent to Participate* form. The research assistant also assessed the population for

technology literacy; individuals ranged from expressing a comfort level with mobile phones to those stating that "I just use my phone for making calls". A variety of smart phones, basic cell phones, and some government issued phones were noted. Health literacy was not assessed secondary to the food bank lobby setting and confidentiality issues; however, some individuals stated that they never forget to take medications as they understood the importance of medication adherence and controlling the disease.

At the close of June 2015, an additional twenty-five *Study Introduction / Intent to Participate* forms were received. The principle researcher and research assistant reviewed all forty *Study Introduction / Intent to Participate* forms to determine the 30 eligible participants to be invited for the study.

During July 2015, the research assistant was available to meet with selected study participants to support them with downloading the application to their phones and to enter the HIV medications into the application prior to study start. Eleven of the thirty individuals committed to meeting at the designated time, with nine participants following through with attending the appointments. The intent was to have the mobile phone application installed prior to attending the first focus group meeting in August 2015, so that the focus group meeting time could be spent primarily in discussion and not assistance with technology issues. However, time was allotted at the close of the August focus group meeting to assist with the installation of the application for those individuals who had not yet downloaded the app or entered their HIV medications and to trouble shoot any encountered technology issues.

From August 11, 2015 through October 22, 2015, qualitative focus group data was collected monthly from the eligible participants, who were invited to participate in this qualitative focus group methodology pilot project. There were three consecutive days, during

one scheduled week each month over three months, in which groups of up to eight individuals were invited to participate in the focus group discussions. After the researcher explained the study objectives and written informed consent was obtained at the start of the first focus group meetings, the participants were instructed in how to complete the demographic and technology use questionnaire; this was done in person, with the support of the researcher and research assistant. The researchers were available to answer any questions the participants had about the questionnaire and survey during completion. Completeness of the questionnaires was checked for missing data. All survey data was coded and stored securely.

Focus Group #1 was held during August 11-13, 2015, and 23 of the 30 (77%) invited participants attended. The thirty selected individuals were contacted via email and/or phone prior to the first focus groups, as a reminder to attend. Individuals also received a memo reminder attached to their food bank grocery bags two weeks prior to the focus group meeting. Although multiple scheduled attempts were made to remind the thirty subjects, only twenty-three participants arrived at the first set of focus group meetings.

The focus group meetings were recorded using iPhone 6 voice memo application and the conversations were analyzed using the constant comparison method by the research team, consisting of one masters prepared nurse (researcher) and one baccalaureate prepared nurse (research assistant). Krueger and Casey (2015) describe the constant comparison method, or The Classic Analyses Strategy, as:

> Objective: Identify patterns in the data, and discover relationships among ideas or concepts.

> Process: 1) Data are grouped together on a similar dimension; 2) The dimension is given a name; it becomes a category; 3) These patterns are arranged in a relationship to each other. (p. 157)

The first round of focus group lunch meetings started with the researcher reading the *Consent to Participate* form aloud. Individuals were given the opportunity to voice questions prior to signing consents. The researcher then read aloud the demographics survey and the *BEHKA-HIV* assessment. Participants completed these documents during the readings so that any questions could be answered. The documents were also read aloud to respond to any potential low reading level / health care literacy issues in the group. The researcher and research assistant then conducted the focus group meeting by engaging the participants in answering pre-determined questions using Krueger and Casey (2015) focus group methodology. The analysis was: 1) systematic in that it followed a prescribed sequential process; 2) verifiable in that there were recordings during each focus group and field notes taken during debriefings; 3) sequential in the planning, recruiting, questioning, and moderating; and 4) continuous in that focus group data collection and analysis was concurrent (Krueger & Casey, 2015).

Immediately following each focus group session, the researcher and research assistant debriefed to share highlights. The research assistant prepared an abridged transcript of each session, after which the researcher listened to the audiotape and made any noted edits to the original abridged transcript. The next step was the coding process in which both researcher and research assistant first individually read the entire transcript, and then each question's responses were examined and coded by similarity following the constant comparative method. The transcripts were line numbered by response and cut into individual quotes, and individual quotes were displayed in consecutive order on a conference table. Large Post-it® flip chart notes were

placed on the walls of a conference room, and individual study questions were written at the header of each Post-it® flip chart note. Each response was read aloud and analyzed for the following questions: 1) Did the participant answer the question that was asked?; 2) Does the comment answer a different question in the focus group?; 3) Does the comment say something of importance about the topic?; and 4) Is it like something that has been said earlier? Comments were continuously analyzed for grouping placement on the corresponding Post-it® flip chart note, saved for further review, or discarded. All relevant data responses, related to the participants' medication adherence experiences using the mobile phone application/text messaging function, were grouped on the Post-it® flip chart notes and assigned concept / category codes. The researchers assigned codes to give meaning to the text, in order to develop a list of relevant concepts / codes. The research team analyzed the data immediately following each focus group week, taking into account the frequency, specificity, and emotions related to the responses. Using constant comparison techniques, the team combined the codes into higher-level concepts / categories. Credibility and trustworthiness was supported using field notes and memos to record decisions related to coding the data.

After the coding and analysis process was completed, the researchers prepared a descriptive summary highlighting the findings for each of the questions. Quotes per category were included in each question's thematic summary, as appropriate. The researchers reviewed for emphasis to comments that shared frequency, specificity, and emotion (Krueger & Casey, 2015).

Participants received a $10 gift card and swag bag of items (including items such as medication box, beverage tumbler, pedometer, and condoms) for their participation.

Focus Group #2 was held from September 8-10, 2015, and 15 of the 23 (62%) returning participants attended. Focus Group #2 was conducted in a similar fashion to Focus Group #1 and data was analyzed with the same method. Participants received a $15 gift card for their continued participation.

Focus Group #3 was held from October 20-22, 2015, and 16 of the 15 (70%) returning participants from Group #2 and 1 from Group #1 attended.

Focus Group #3 was conducted in a similar fashion to the previous focus group meetings and the data was analyzed with the same method. Participants received a $25 gift card for participating in the third and final focus group meeting.

Data Analysis

To answer the research question, the following analyses were performed:

1. Descriptive statistics of participants' demographic information, in addition to their responses on the *Brief Estimate of Health Knowledge and Action—HIV Version (BEHKA-HIV)* tool were compiled to promote understanding of the participants (Tappen, 2011).
2. Qualitative data obtained from the Start-of-Study, Midpoint-of Study, and End-of-Study focus group discussions were analyzed using the constant comparative method framework as described by Krueger and Casey (2015): 1) data were grouped together on a similar dimension; 2) the dimension was given a name, it then became a category; and 3) these patterns were arranged in a relationship to each other (Krueger & Casey, 2015, p. 157).

Audio recordings were the primary strategy for capturing focus group data, with concurrent note taking as a secondary means of gathering data. The researcher and research

assistant conducted a 15- to 30-minute debriefing meeting following each focus group to share highlights. An abridged transcript was prepared by the research assistant following all nine focus group meetings and a coding process began, placing labels on similar comments to arrive at analytic themes to report findings. Krueger and Casey (2015) describe a constant comparative analytic framework that identifies patterns in the data to discover relationships, identifying similarities and differences of those relationships. The process for constant comparative analysis is: 1) grouping data on similar dimensions; 2) naming each dimension to create categories; and arranging categories in relationship patterns. The qualitative information was reported in both narrative and table formats.

Quantitative research's alternative terms to the reliability and validity of qualitative research are: credibility (internal validity), transferability (external validity), dependability (reliability), and confirmability (objectivity). The rigor, or trustworthiness, of this study was "what persuades others that the findings reported are worth paying attention to, that they are credible, dependable, confirmable and transferable to other situations" (Tappen, 2011, p. 153).

Credibility was established with prolonged engagement with participants over a three-month period. Member checking occurred by sharing preliminary findings with the participants and asking them for feedback, which was included in the study findings. Peer debriefing occurred by seeking feedback from the research study committee members. Also incorporated was: 1) negative case analysis, which is reporting any negative findings, and 2) triangulation, which is using multiple methods to collect data. To ensure credibility of the results, analysis was first performed independently by the primary researcher and then independently by the research assistant. Transferability was established by providing a detailed description of the sample and the context under which the study was conducted, so that the reader may determine if the study is

generalizable to other people and settings. The researcher made connections between study findings and those of other studies. Dependability was established by use of an audit trail during the study to provide transparency, so that the reader may determine trustworthiness of the study. Confirmability was established by the researcher by recording tracking progress though personal experiences, feelings, and preliminary hypotheses about the phenomenon of interest in an ongoing reflective journal.

Chapter 4

Results

Analysis of Data

Statistical Package for the Social Sciences**,** IBM Version 21, was utilized for the statistical analysis. Demographic variables were expressed as frequency, mean and standard deviation.

Table 1 summarizes the demographic characteristics of the participants. A convenience sample of 23 subjects was included. Most of the subjects were male (69.6%) and 30.4% were female, with a mean age of 52.87 years (SD 10.065, range 37-72 years). Race/ethnicity was self-identified as 47.8% Black / African American; 21.7% Hispanic / Latino; 21.7% White; and 8.7% Mixed Race. Primary language for all participants was English. Highest level of education completed was reported as 17.4% less than high school; 43.5% high school; 26.1 % some college; 4.3% Associate degree; and 8.7% Baccalaureate degree.

Table 1

Characteristics of 23 Participants Completing Patient Demographics

Characteristic	(%)	n=23
Gender		
Male	16 (69.6)	
Female	7 (30.4)	
Age		
Minimum	37	

Maximum	72
Mean	52.87
SD	10.065
Race/Ethnicity	
Black / AA	11 (47.8)
Hispanic / Latino	5 (21.7)
White	5 (21.7)
Mixed Race	2 (8.7)
Language	
English	23 (100.0)
Other	0 (0.00)
Level of Education	
< High school	4 (17.4)
Black / AA	2 (18.2)
Hispanic / Latino	0 (0.0)
White	1 (20.0)
Mixed Race	1 (50.0)
High school diploma	10 (43.5)
Black / AA	6 (54.5)
Hispanic / Latino	3 (60.0)
White	1 (20.0)
Mixed Race	0 (0.0)
Some college	6 (26.1)

Black / AA	3 (27.3)
Hispanic / Latino	1 (20.0)
White	1 (20.0)
Mixed Race	1 (50.0)
Associate degree	1 (4.3)
Black / AA	0 (0.0)
Hispanic / Latino	1 (20.0)
White	0 (0.0)
Mixed Race	0 (0.0)
Baccalaureate degree	2 (8.7)
Black / AA	0 (0.0)
Hispanic / Latino	0 (0.0)
White	2 (40.0)
Mixed Race	0 (0.0)

Note. SD = standard deviation

Demographics and Access to Mobile Phone over Past 3 Months (Table 2) lists participant demographics with start of study cell phone use. A comparison of demographic data and cell phone frequency of use was investigated. The percentage of participants who reported uninterrupted access to a working mobile phone during the past three months was 78.3%. Most participants used their phones multiple times each day and primarily for placing calls, followed by texting, taking photos, using apps, and lastly emailing. The study revealed that this group of participants was not email literate. When analyzing the likelihood of using a mobile phone

medication reminder application at study start, 82.6 % of participants indicated a perceived usefulness.

Table 2

Demographics and Access to Mobile Phone over Past 3 Months

Race/Ethnicity	No Issue with Access to Phone (%)	n=23
Black / AA	9 (72.7)	
Hispanic / Latino	4 (80.0)	
White	4 (80.0)	
Mixed Race	2 (100.0)	
Total	18 (78.3)	

Table 3

Phone Use

Reason	(%)	n=23
Multiple times/day	4 (100.0)	
Calling	23 (100.0)	
Texting	17 (73.9)	
Email	11 (47.8)	
Photos	13 (56.50)	

Applications	12 (52.2)

Table 4

Likelihood to Use Application

Educational level	Very Likely (%)	n=23
< High School	4 (100.0)	
High school diploma	8 (80.0)	
Some college	4 (66.7)	
Associates degree	1 (100.0)	
Baccalaureate degree	2 (100.0)	
Total	19 (82.6)	

Demographics and Access to HIV Medication (Table 5) and Demographics and Missed HIV Doses (Table 6) compared participant race / ethnicity demographics with HIV medication data. Slightly over half the participants, fifteen individuals (65.2%), reported taking more than one HIV medication a day; and sixteen participants (69.6%) reported no issue with access to medications over the past three months. The start of study prevalence of reported adherence to medication is summarized at slightly over half of the participants; thirteen individuals (56.5%) reported no missed doses in the past seven days. Access to medication was reported as a potential challenge; 30.4% of the participants reported interrupted access to medications over the

past thirty days, with the Black / AA cohort reporting the greatest no access to medications barrier at 54.5%.

Table 5

Demographics and Access to HIV Medications

Race/Ethnicity Gender	Access to Medications (%)	No Access to Medications (%)	n=23
Black / AA	5 (45.5)	6 (54.5%)	
Hispanic / Latino	5 (100.0)	0 (0.0%)	
White	4 (80.0)	1 (20%)	
Mixed Race	2 (100.0)	0 (0%)	
Total	16 (69.6)	7 (30.4%)	
Male	13 (81.3)	3 (18.7)	
Female	3 (42.9)	4 (57.1)	
Total	16 (69.6)	7 (30.4)	

Table 6

Demographics and Missed HIV Doses

Race/Ethnicity	0 Missed (%)	0-1 Missed (%)	2-3 Missed (%)	>3 Missed (%)	n=23
Black / AA	4 (36.4)	4 (36.4)	3 (27.3)	0 (0.0)	
Hispanic / Latino	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	
White	5 (100)	0 (0.0)	0 (0.0)	0 (0.0)	
Mixed Race	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	
Total	13 (56.5)	5 (21.7)	4 (17.4)	1 (4.3)	
Male	8 (50.0)	3 (18.8)	4 (25.0)	1(6.3)	
Female	5 (71.4)	2 (28.6)	0 (0.00)	0 (0.00)	
Total	13 (56.5)	5 (21.7)	4 (17.4)	1 (4.3)	

Table 7

Number of HIV Medications

Race / Ethnicity	Number of HIV Medications (%)	n=23
One	7 (30.40)	
Male	4 (25.0)	

Female	3 (42.9)
More than one	15 (65.2)
Male	11(68.8)
Female	4 (57.1)
Unknown	1 (4.3)
Male	1(63.3)
Total	23

A comparison of Demographic Data and CD4 Knowledge (Table 8 & Table 9) and Demographic Data and HIV Knowledge (Table 10 & Table 11) data was collected at start of study. Only 17% of the 23 participants (2 Black / African American, 0 Hispanic / Latino, 1 White, and 1 Mixed Race) were able to correctly describe a CD4+ t cell count; however, 87% could identify that the CD4+ T cell number should increase. Sixty-nine percent of the 23 participants (6 Black / African American, 3 Hispanic / Latino, 5 White, and 2 Mixed Race) were able to correctly describe a viral load; however, only 52% could identify that the viral load number should decrease.

Table 8

Demographics and CD4 Knowledge / Education Level

Education level	Describe Correctly (%)	Up Direction Correct (%)	n=23
< High School	4 (100.0)	4 (100.0)	
High school diploma	8 (80.0)	9 (90.0)	

Some college	3 (50.0)	4 (66.7)
Associates degree	1 (100.0)	1 (100.0)
Baccalaureate degree	2 (100.0)	1 (100.0)
Total	18 (78.3)	20 (87.0)

Table 9

Demographics and CD4 Knowledge / Race / Ethnicity

Race / Ethnicity	Describe Correctly (%)	Up Direction Correct (%)	n=23
Black / AA	2 (18.2)	8 (72.7)	
Hispanic / Latino	0 (0.0)	5 (100.0)	
White	1 (20.0)	5 (100.0)	
Mixed Race	1 (50.0)	2 (100.0)	
Total	4 (17.4)	20 (87.0)	

Table 10

Demographics and HIV Viral Load Knowledge / Education Level

Education Level	Describe Correctly (%)	Down Direction Correct (%)	n=23
< High School	3 (75.0)	0 (0.0)	
High school diploma	6 (60.0)	2 (20.0)	

Some College	4 (66.7)	2 (33.3)
Associates degree	1 (100.0)	1 (100.0)
Baccalaureate degree	2 (100.0)	1 (100.0)
Total	16 (69.6)	7 (30.4)

Table 11

Demographics and HIV Viral Load Knowledge / Race / Ethnicity

Race / Ethnicity	Describe Correctly (%)	Down Direction Correct (%)	n=23
Black / AA	6 (54.5)	1 (9.1)	
Hispanic / Latino	3 (60.0)	1 (20.0)	
White	5 (100)	4 (80.0)	
Mixed Race	2 (100.0)	1 (50.0)	
Total	16 (69.6)	7 (30.4)	

Reasons Why Participants May Not Take HIV Medications (Table 12) lists potential barriers in which participants may not take medications. The two most reported reasons were *when they make me feel bad* (17.4%) and *when I am too tired* (13.0%).

Table 12

Reasons Why Participants May Not Take HIV Medications

Reason	Agree (%)	n=23

When they make me feel bad	4 (17.4)
When I am too tired	3 (13.0)
When I am feeling down or low	2 (8.7)
Because it tastes bad	1 (4.3)
When I feel good	1 (4.3)

Focus Group Results

Krueger and Casey (2015) suggest analyzing the participants' responses for frequency, specificity, and emotion, identifying common themes. Questions were asked to assess changes over time in medication adherence behavior and acceptability and usability of the mobile phone application over the three-month study period. The following is a synopsis of revealed themes / concepts from the questions assessing both medication adherence behavior and technology acceptability and usability over the three monthly meetings.

Start-of-Study Focus Group Questions

Q1. What attracted you to participate in this study?

Curiosity, giving back to the community, and current poor medication adherence were frequent and specific comments. Several participants discussed that working with the community meant "doing something positive" and "giving back to your community." A few participants also noted the need for support in medication adherence, stating "I don't always take my meds when I should" and "I am really bad at taking my meds".

Q2. What is the first thought that comes to mind when you think of medication adherence or taking your medication as the doctor told you to take them?

The common themes regarding medication adherence included supporting a prolonged life and including support in medication adherence from family members, doctors, and nurses. Some responses regarding support were, "I trust the doctor that he's doing the right thing, so I do what he tells me," and "I would just stop taking it [medication] period, until I came to [the ASO] and met [my nurse]." Another participant when discussing support stated, "my sister told me if you don't take these medications you aren't going to live". She then discussed how this conversation transformed her understanding of taking HIV medication. Several individuals also discussed that medication adherence means having a "prolonged life" and "being consistent".

Q3. What have your experiences been with how you take your medications on time? (Possible probe: Please give an example of a time you forgot take your medication.)

Predominant themes were forgetfulness, routines, and the benefits of a decrease in pill number by prescriber. Several participants discussed "forgetfulness" as an issue with taking medications in the past, especially when there is more than one pill to be taken. Another participant stated, "I keep forgetting to take the second one [pill], so [the doctor] switched me so I just have to take one a day". In addressing forgetfulness, a number of participants discussed that a helpful strategy included establishing a routine, stating "taking your meds at the same time every day", and "picking the time of day". Others discussed the benefits of using pillboxes and placement of medications, such as "I leave them [medications] on my TV."

Q4. When people talk about not taking medications, what are some reasons they mention? (TPB-normative beliefs) (Probe: Where does forgetfulness fall within these examples, if at all?)

Participants noted a number of reasons for inadequate medication adherence including being "in a rush", stress and fatigue, issues with pharmacies, and the inhibiting affects of alcohol and substance use. Several participants elaborated the primary reason for missing medications as

"being in a rush", "jumped up rushing", and "getting up late and taking off". Many also discussed fatigue stating "I get stressed out a lot or got a lot on my mind" and "I just get tired of taking them [medications] in the first place". One participant brought up "partying" as an issue, and many agreed that drug and alcohol use interfered with medication adherence. Another barrier identified was issues with pharmacies, such as "copays being hard to pay" and "having to wait for refills".

Q 5. How comfortable do you feel using technology on your cell phone? (TAM 3. Attitude toward all the things that can be done with a cell phone other than making phone calls.)

The specificity and emotion of common themes regarding level of comfort in technology use included security concerns, learning gaps, and a general feeling of comfort by some. Many participants stated, "I love texting!" and "I use it [text messaging] every day!" Others stated, "I don't know enough about it [text messaging] to know" and "I'm not comfortable with sharing things on the Internet". Ideas that technology also serves to strengthen communication between individuals included statements such as "somebody cares" and "the main thing that somebody is caring about you," were frequently identified.

Q6. What challenges (Probe: Cost, ease of use, forgot to carry, battery not charged) do you have with your cell phone? With apps on your cell phone? (TAM 2. Perceived ease of use.)

The majority of participants discussed the frequency of lost phones as a major barrier to using cell phones. Some stated, "I lost it in a shopping cart" or "I lost mine on the bus". Others discussed memory space / available minutes issues, and dropped calls as obstacles. Several discussed limited minutes as being a reason for decreased technology use stating, "I only have a certain amount of minutes."

Q7. What are some problems you might find when using this phone app?

Most participants could not identify potential issues with the medication application; however a few stated “I’m not tech smart” or “I don’t have apps so I wouldn’t know”.

Q8. On a scale from 1-10, 1 being easy and 10 being difficult, rate how this app will be for you to use in your everyday life. (Have participants write a number on a card - will use this card for comparison at final focus group meeting.) (TAM 2. Perceived ease of use.)

Ten participants rated perceived use of the app at 1 (easy); 5 rated at 2; 5 rated at 3; 3 rated at 4 and 0 rated at 5, providing baseline data to access for perceived change over the three month study period.

Q9. How useful do you think using a cell phone app every day will be in helping you to take your medications? (TAM 1. Perceived usefulness; TPB - Behavioral belief.)

All participants agreed that an application offering daily reminders to take medications would be helpful. Statements such as “I think it’s a good way” and “I think it’s a good idea” were frequently expressed. Many discussed a belief that reminders, in general, were helpful. One participant stated “In our culture today it’s common to have a cell phone stuck to the hip, and it’s probably the wave of the future and people don’t realize it yet”, supporting the convenience of reminders via cell phones.

Q10. How likely are you to use this app every day? (TPB- Attitudes toward behavior)

What are some ways you have for making this app work for you considering some barriers you’ve mentioned?

Most participants agreed that using this app everyday would be highly likely. Early adopters who came to the first focus group with the app pre-downloaded made statements such as “I have been using this app everyday”. A few participants, however, stated, “so far it’s okay, but other people could be bothered by it”. One participant agreed the application is easy to use

stating, “It’s not technically difficult” but questioned, “will I actually use it?” Overall, most agreed the application would be utilized in their daily lives.

Midpoint-of-Study Focus Group Questions

Q1. Tell us about your experiences with the phone app so far.

Participants agreed that the app has been a helpful reminder, stating, “I like it because it helps me” and “I think it’s very helpful.” One participant emphasized several times throughout the focus group meeting the idea that the app “is a keeper”, asserting an emotional connection. Another participant admitted that he “does not immediately respond to the app sometimes, but will go back and respond at a later time. I don’t always answer at that time. I’ll answer it later.”

Q2. What words come to mind at this point when you think about the terms technology and medication adherence? (In other words, what part do you believe technology may play in helping with medication adherence, if any?)

One common theme was the thought, as stated, “I, myself, feel pushed in technology. You just have to do it”; and another added, “to keep up with the times.” Feeling compelled to embrace technology, as a means of necessity, seemed to be a commonality. Advancement in technology is helpful “not only for HIV, but for all your medications”. Other participants described the technology as “confusing” or “[technology] helps a lot.”

Q 3. What have your experiences been with taking medications on time when using this app? (Possible probes: Please give an example of a time you failed to take your medication when the app gave a reminder.)

Frequent experiences mentioned include overall improved medication adherence, a delayed response to app reminder due to phone location, and delayed adherence related to pharmacy refill issues. Several participants’ ideas reflected upon one participant’s following

comment discussing its benefits. “Before this reminder technology, I had missed a lot of my doses in the evening time because I forget.” Another stated “It’s a good thing in a way…it’s kind of ribbing you to say come on, you know you need to do this, come on, let’s go!” Not being in the same room when the reminder app went off” was noted. “I take it when I hear it go off…just sometimes it’s in the other room…but I don’t tell the stupid app I took it until later.” A few participants added that although the app has been helpful, obstacles with pharmacy refills have interfered with adherence stating, “I missed a couple [medications] but not because of the app, it’s because I didn’t have them [medications]…they weren’t filled.”

Q 4. Has your comfort level with using this phone app changed since the first time you began using your cell phone app? (TAM 3. Attitude toward technology)

Most participants discussed that using the application became easier with the passage of time since last month’s meeting. A few participants admitted that technology support during these focus groups improved their general phone use. “I think I’ve gotten more comfortable. It’s something different I learned that I never thought I would learn because I’m illiterate when it comes to these cell phones.” Another participant followed stating, “I pretty much just learned how to text,” and a third added, “it had to grow on me”. Some participants stated that learning to text was not a barrier, noting “I’ve been texting for a while.” A final comment made added an emotional component admitting feelings of excitement in receiving reminders. “It’s an excitement when [the app] goes off. It kind of like lifts you.”

Q5. What challenges or frustrations are you having with your cell phone or the app on your cell phone? (TAM 2. Perceived ease of use)

Overall themes related to challenges with cell phones included a learning curve, especially with new phones, and a low ringer volume challenge on the phones related to use of

the application. One participant also noted having occasional "monthly service cut off". In reference to phone volume, one participant stated, "Yeah, that is the problem with some of these phones that don't ring very loud." Another added, "If I drop it on the floor or it falls off the bed, I don't hear it." The issue with the need to learn how to navigate the phones was the most common theme. "I'm very skeptical about it [a new phone]… I don't know how long it will take to adapt." Another concisely stated, "I really need to learn," and then asked the researchers to be taught how to text message.

Q 6. Now that you have been using the app for a few weeks, what are some things that you have found that get in the way of using the app? (Revisit the barriers discussed in first focus group.)

Regarding issues that have arisen as participants use the app in their everyday lives, common themes discussed include misplaced phones and medications, having technical app difficulty, and waking up late resulting in missed meds. A few participants reported that "waking up late" poses as an issue resulting in a delayed or failed response in the app response. Several participants also expressed concerns about technical issues stating "last week I was having some problems…it wouldn't work." Another participant shared, "one day it [the app] was acting really weird. I mean it's never done that before, and I thought it [was] my phone." Upon notification of a potential phone app technology glitch, the researcher contacted *Care4Today™ Mobile Health Manager* and was informed that the app was experiencing difficulties, which were resolved within forty-eight hours. One participant discussed an issue of having a shared phone, stating "the only thing is that somebody else is using my phone and they don't want to get off [the phone]."

Q 7. On a scale from 1-10, 1 being easy and 10 being difficult, rate how this app been for you to use in your everyday life. (Have participants write a number on a card - will use this for comparison from first focus group.) (TAM 2. Perceived ease of use)

Twelve participants rated use of the application at 1; 3 rated at 2; 1 rated at 3; 0 rated at 4; and 0 rated at 5, indicating a positive direction in ease at mid-point of study period.

Q 8. What have you found most useful in using the app? (TAM 1. Perceived usefulness)

Participants discussed themes including ease of use, overall improvement of medication adherence, the benefit of app persistency, and the additional perk of a charitable contribution by *Care4Today™ Mobile Health Manager* when participants report daily medication adherence. Several focus group attendees discussed the ease of the app stating, "it's really easy." A few described the fact that the app supports overall health, stating "I think my health is better" and "much better health." One participant commented on the benefits of the persistency of the app, discussing "you don't answer, it don't cut off! It keeps going." The charitable donation was another major driving force as an identified benefit of the app. "I take my meds and help somebody."

Q 9. What are some ways have you found that help you to use the app?

The common thread was repeated as, "I keep my phone with me at all times", as a way to support app engagement.

End-of-Study Focus Group Questions

Q 1. Write one word on your card that describes your overall experience in using the phone app to help remind you to take your medications.

Most participants reported words including "helpful" and "great" when asked to discuss their overall experience in using the phone app. All reported descriptors were found to have a

positive connotation, and participants in all three groups felt comfortable in sharing their designated words with group members.

Q 2. Tell us about your experiences in using the app? (Possible probes: Best thing? Worst thing?)

When asked about experiences in using the app, participant responses varied widely. Some participants felt it was important to discuss an improvement in daily routine noting, "I'll hear the phone go off and I go, oh man, look at the clock", and "my adherence and timing was clearly based on the fact that the app was popping up and telling me to take my meds" (referring to a lapse in app use after a temporary loss of a phone). Many discussed the "helpful" aspect of the app because it "keeps you more focused". Several participants alluded to an emotional component of the app, describing it as "it was like it was speaking to me," and "it feels good that I responded." No participant reported a decrease in medication adherence or a negative experience relative to app use during the three-month time period.

Q 3. Think back to before you learned about this phone app. How might your opinion changed about using technology to remind you to take your medications?

Many participants discussed that they believed their use of technology, whether through the daily use of a smart phone app or via daily text messages, has improved, and opinions evolved toward a more supportive perspective. One participant described, "I'm technologically illiterate. I don't know the first thing. It's got me to where I try now…before I'd say no I can't do it". Others expressed similar sentiments stating, "it [technology] is pushing me", and "the app is why I'm leaning toward it [technology]." Those who displayed more technological experience and comfort expressed, "I was surprised that it was as easy." Throughout the three focus groups,

no participants discussed discomfort or unease in using the app, however one mentioned a general fear of cyber attacks and online theft.

Q 4. How did your comfort level change as you used the app over time? (Probe: What became easier/harder about using the app? TAM 3. Attitude toward technology)

All participants expressed a positive degree of comfort in using the medication app reminder. Many alluded to the app becoming a part of their routine stating, "it got easier", and "I poured over it for a while, and now I can roll over, [press the button], and go eh". Several participants utilizing the text message function described their experience as being "easier" as time passed with the app response system.

Q 5. What, if anything, would you change about the app considering the challenges we have discussed in the past with using it? (TAM 2. Perceived ease of use)

Responses varied when questioned about possible changes to the app. Several participants asserted that no changes would need to be made, but a few discussed that the additional step in needing to review the "thank you" message after responding to medication compliance step was redundant, stating "I just hate the extra step of having to go back and find my phone where I threw it". A second participant added, "it says thank you immediately after you put your *one* in…it's kind of unnecessary." Others requested that the app offer more messages, stating "I think it should go off for at least three times." A few others agreed with this suggestion.

Q 6. On a scale from 1-10, 1 being easy and 10 being difficult, rate how it was to use this app overall? (Have participants write a number on a card - will use this for comparison at final study) (TAM 2. Perceived ease of use)

Fourteen participants rated the ease at 1; 1 rated at 2; 0 rated at 3; 0 rated at 4; and 0 rated at 5, indicating a positive direction in ease over the three-month study period.

Q 7. How has your overall medication adherence in your life been affected by using this app? (Probe: In what ways have you noticed an improvement, if any?)

For the most part, the frequency of participants discussing that medication adherence has gotten "much better" was revealed to be high, with four participants sharing "better" as an immediate response. A few reported knowledge of the importance of consistent medication adherence stating, "it was important and I want to stay undetectable [HIV viral load]" and "it's a healthy habit [to be consistent]". The past tendency of forgetfulness was again discussed during this focus group session, with participants stating "before I used to forget, and I didn't have nothing to remind me," and "[I used to] wonder if I'd forgotten to take them." One participant further discussed that he felt "a great sense of accomplishment" with his medication adherence.

Q 8. How useful was this cell phone app in your daily routine in reminding you to take meds? (TAM 1. Perceived usefulness; TPB - behavioral belief)

Common themes included the cell phone app serving to encourage a routine, proving to be both reliable and consistent, and supportive in stress reduction. One participant described the app as having "helped my stress level…because I don't have to remember on my own" while another one discussed, "I'm quite used to it…I think if I went one whole day without it signaling me, I'd be like something's going on…something's wrong with this day." Other participants used words such as "faithful", "consistent", and "useful", and one simply stated, "[it] adds a little order to my chaos."

Q 9. What are some ways you made this app work for you, considering problems since beginning the study?

In discussing ways in which participants adapted to using the app as a means to support medication adherence, most all participants discussed the need for setting the medication reminder to a time that would be fitting for one's lifestyle. Many discussed the intention of purposefully ensuring that one would be near the phone at a certain time since the start of the groups. "When I set it up with you, I was like I know I'm going to be in the same room [as my meds] at nine o'clock in the morning." One discussed "at first it was annoying. I'd get busy with my hands in the dishwater….and I'd hear that thing going off and I'm like can you wait? Then I got used to it and I know what time it was going to go off."

Q 10. How likely are you to use this app in your daily life after today? How likely are you to recommend the app to someone else? (TPB- attitudes toward behavior)

The frequency of participants who discussed a high likelihood in continued use of the phone app after focus group meetings was great. Most all participants expressed to some degree that they would like to continue to use the app in their daily lives stating "I'm keeping it forever" and "I wouldn't think of giving it up." One mentioned, "as long as it's free", alluding to financial barriers some participants face. Another strong theme addressed in answering this question supported the idea that participants value the idea that someone, or something (in this case technology) is concerned with their personal medication adherence. "For me, it's more sentimental…it's nice to know there are people out there that still do care," and "I love that people are still caring, that's my biggest thing." One summed up his view regarding the decision to keep it as a part of his routine stating, "I don't like that I can't call the doctor's office and get someone to speak right then and there. However, in lieu of that, this technology is sort of like getting a response." Most participants stated they would recommend the application to others

asserting, “I want to get someone else involved…like my roommate,” and “I have an elderly person that maybe I would introduce it.”

Q 11. What difference, other than taking medications as scheduled, did this app make in your life, if any?

When posed with this question, participants discussed themes such as increasing responsibility and order, reduced stress, and learning the text feature on phones. One stated “[it] made things easier for me in the long run”, after discussing that he was originally not technologically literate. A few participants discussed, “I find myself being a little more ordered,” and “it keeps me alert and looking forward to it.” A few participants discussed benefits in learning text messaging stating, “I never did text before so…I didn’t know how to do it. I showed him [my friend] how to text [too].”

Summary of Findings

The majority of studies found in the literature reviewed HIV medication adherence with a text messaging platform; whereas this *Care4Today* ^{TM} *Mobile Health Manager* study focused on a mobile phone application intervention to add to the body of knowledge. Also, most of the prior research studies collected data through researcher driven interviews; whereas, this study’s approach utilized focus groups to obtain data. Similarities between prior research and this study include the collection of self-reported data, sampling a small population size, and collecting no quantitative HIV viral load lab value data. This study’s results validated the generalization of the feasibility and acceptability of perceived ease of use from text messaging to mobile phone application platforms, with participants reporting the dominant themes of the application’s ease of use and facilitating a reliable and consistent routine to combat forgetfulness. An additional theme expressed was the caring component that the application was perceived to provide.

Chapter 5

Discussion and Conclusions

Discussion of Findings

This study's focus was a first step to broaden the knowledge by evaluating the acceptability and feasibility of a mobile phone application's effect on medication adherence. Data from focus group methodology evaluated the perceived usefulness, perceived ease of use, and the attitude toward the smart phone application technology in supporting increased HIV medication adherence. The study findings indicate that there is positive feasibility and usability of downloading a smart phone application to support medication adherence reminders with the added value of a self-reported increase in medication adherence behavior within this particular study population. Overall, participants favored incorporating a reminder application into their everyday lives with minimal barriers, and spoke to multiple benefits, noting positive outcomes.

Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV)

The BEHKA-HIV is a tool that measures health literacy in clients with HIV and was incorporated to predict medication adherence in the sample population. Its eight items were incorporated into the questionnaire that was implemented at the start of the first focus group meeting.

Of the 23 participants completing the questionnaire, 17% were able to correctly define CD4+ T cell count; and of those correctly defining, 87% were able to correctly state that the goal of this value is to increase. Sixty-nine percent of participants were able to correctly define viral load; and of those, only 52% were able to correctly state that the goal of this value is to decrease. When assessing for potential barriers for not taking HIV medication, less than 20% of the participants indicated challenges (feeling bad at 17.4%, tired at 13.0%, down or low at 8.7%, or

experiencing a bad taste of medication at 4.3%). These BEHKA-HIV survey findings suggested that there was a knowledge deficit in defining CD4+ T cell and viral load and the lab value goals. However, there were limited indications that the participants would not adhere to medication adherence based upon the BEHKA-HIV survey questions that identified potential barriers to adherence. Scores ranged from 0 to 8 and were classified as low, marginal, or adequate. Of the 23 participants, three scored low (0-3); eight scored marginal (4-5); and 12 scored adequate (6-8). "Lower scores on the BEHKA-HIV were independently associated with poorer rates of HIV medication adherence" (Osborn et al., 2010, p. 181).

Focus Group Themes

The literature review, conducted prior to implementation of this study, indicated that mobile phone technology interventions, mainly in the form of text messaging, were helpful in improving HIV medication adherence; and the *Care4Today*™ *Mobile Health Manager* study revealed a similar finding, validating the generalization of text messaging to the mobile phone application platform. This study revealed that the implementation of the app was useful, easy to use, incorporated a caring aspect, and improved the issue of forgetfulness within the target population. Examining the findings from prior literature, to determine how this data might compare, was crucial in recognizing similar or undiscovered themes. Although Tao et al.'s (2015) meta-analysis revealed that the use of electronic reminders was associated with a small improvement in adherence to medications, this study, with a mobile phone application, revealed the opposite and is more in line with Foreman et al.'s (2012) study that indicated a text message reminder program results in higher rates of adherence over time.

Theme 1: Easy to Use

In this study, the mobile phone application was perceived to be easy to use, barring potential barriers such as lost / stolen phones or expired minutes. Prior research (Crankshaw et al., 2010; Hardy et al., 2011), regarding usability of reminder applications, concluded that participants did not perceive messages as key to success in medication adherence, and discussed that participants actually preferred voice messages over text messages (Sidney et al., 2012). Neither of these findings was expressed in this mobile phone application study. In fact, participants reported the opposite, stating that they found it "very helpful" and useful in establishing routine, as revealed in Theme 2.

Theme 2: Reliable and Consistent Routine

Reminders, such as a mobile phone app, in general are useful for encouraging a reliable and consistent routine. The reviewed literature did not focus on *reliable and consistent routine* as a focus group dominant theme; however, the literature looked at the time frames of text messaging, oftentimes weekly (Hardy et al., 2011; Lester et al., 2009; Mbuagbaw et al., 2011; Sidney et al., 2012; Smillie et al., 2014). Secondary to the fact that the *Care4Today™ Mobile Health Manager* delivered daily, and oftentimes more than once each day, reminders may speak to the increase in the reliability and consistency, resulting in the expression of the routine theme.

Theme 3: Forgetfulness

Medication nonadherence behavior is oftentimes related to forgetfulness. However, medication adherence behavior improved with the addition of the mobile phone app tool that "added a little order to the chaos". The reviewed literature did not focus on *forgetfulness* as a focus group dominant theme. This study elicited the response of forgetfulness during the first focus group meeting with the fourth asked question, *When people talk about not taking*

medications, what are some reasons they mention? The universality and frequency of this term, forgetfulness, speaks to the need for a daily medication reminder intervention, and echoes Theme 2's reliable and constant routine.

Theme 4: Someone Cared

Acceptability of, and improvement in, the use of technology increased with the participants over time, in conjunction with a feeling that someone cared about the participants' health. This mobile phone application study contributes to current knowledge by introducing the theme, a caring component, not previously discussed in the literature. Although validating that the mobile app was generally useful as well as easy to use, as was the text-messaging platform, participants repeatedly discussed the idea that they felt there was a component of "caring" in using the mobile phone application. They discussed that having someone / something monitoring their medication adherence, as well as being reminded on daily basis, made them feel as though someone was invested in their health. This emotional element in feeling cared for was not revealed in prior research, and is worth being further investigated. It appears that mobile phone applications that are engaging to the user are key; if there is no consumer engagement, it undermines their effectiveness.

These four above listed themes supported the Technology Acceptance Model of: 1) perceived usefulness of the app; 2) perceived ease of use of the app; and 3) a positive attitude toward using the app technology. Themes also supported the Theory of Planned Behavior with the participants' intention to use the app with an overall behavioral normative belief that the app had positive consequences for overall health, especially with the support of a caring person / thing. The focus group responses supported the idea that participants felt that the medication app had an overall positive influence on medication adherence and acceptability views on this

technology were overwhelming. All participants stated that this experience made them more amenable to using technology. Descriptors that related to improving one's routine served to discuss the impact participants felt the app had on their daily activity, with most participants stating that it had become *a part* of their lives, and not a burden, or additional task, suggesting the supportive role the app played in participants' lives that felt distracted, chaotic, and faced with multiple barriers.

Limitations

Participants

Information provided by the participants was retrospective. However, the issue of medication adherence was very important to the participants and they provided robust and detailed descriptions about their medication adherence experiences at each of the three monthly focus group meetings. This self-selected group introduced possible participant bias, attracting responders who had an interest in either phone technology to support medication adherence or the study participation incentives (provided lunches and gift cards) of being a part of a research study. The completion rate of the thirty originally selected participants attending all three focus group sessions was disappointing, although predictable, secondary to the socioeconomic demographics of the participants, potentially affecting the validity of the results. The participating individuals' demographics may not represent the overall demographics of the approximately 5,000 HIV-positive individuals living in the study's geographical region; and the study participants may have represented a lower socioeconomic demographic presenting with technology illiteracy. The evidence in the reviewed literature to support use of text messaging appeared to be strong for acceptability and feasibility; however, the evidence was weak in large scale, multiple sites, and randomized controlled trials. This study was also weak in scale, sites,

and controlled trials; however, it was a pilot study to investigate the feasibility and usability for a mobile phone application.

Instruments

Study participants were assessed for medication adherence readiness. The instrument, The *Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV),* was administered during the Start-of-Study focus group meeting to assess both HIV knowledge and action. Limitations of this tool are that it is not a direct test of functional health literacy in terms of reading comprehension and that further validation is needed (HIV Guidelines, n.d.). This 8-item tool assesses both the knowledge and action subscales and supports the Theory of Planned Behavior in predicting medication adherence behavior.

The instrument, *Care4Today™ Mobile Health Manager*, was a self-report instrument, a method susceptible to bias. True adherence to HIV medication is measured by decreasing viral load lab values with a goal of reaching viral suppression at <200 copies/mL. The Hawthorne Effect, a term referring to the tendency of some research participants to perform better when they are enrolled in a research study, may have contributed to increased medication adherence self-reporting on this instrument over the study period.

Technology and Access to Technology

The study included participants who owned both smart phones and basic cell phones. The owners of smart phones had the capability of enhanced *Care4Today™ Mobile Health Manager* medication graphics and additional features; whereas the basic cell phone owners had medication reminder text messaging capability only. A current email address was needed to enroll for the *Care4Today™ Mobile Health Manager* application and it was discovered at study start that not all participants had an email address, validating the low technology literacy of the participants.

The research assistant facilitated opening an email address for those participants. Many individuals in the study with basic phones also did not have access to a home computer or use email. Three basic phone participants had never used the text message feature on their phones. The research assistant offered assistance in addressing technology knowledge deficits by educating participants on basic text messaging functions in order to be able to participate in the study.

Viral Load at Study Start

One study requirement was for participants to have a baseline HIV viral load of >1000 copies/mL, allowing for a potential measurable outcome of increased medication adherence. Current HIV viral load was self-report and some participants may have arrived into the study with a viral load <1000 copies/mL or a suppressed viral load of <200 copies/mL. Because the researchers, secondary to not obtaining required consents to request lab value information from various primary care providers, did not verify start of study viral load, all selected individuals were allowed to participate in the study based upon their self-report of current viral load. However, viral loads may have increased and/or decreased within each individual at study start and over the study's time, responding to whether or not the participant was actively taking HIV medications as prescribed during the three-month study period and just prior to start of study.

***Care4Today™ Mobile Health Manager* Issues**

Two participants and the researcher reported a 2-day interruption in *Care4Today™ Mobile Health Manager* service over the three-month study period, during which time the application was either not accurately logging in daily adherence reports or not responding to participants' text responses. *Care4Today™ Mobile Health Manager* was contacted by the researcher and they reported that there was a 2-day glitch that had been corrected. The two

affected participants were updated with the reason for interruption of services and given assurance that the app was capturing medication adherence data during this timeframe.

Participant Attrition

Focus group participation attrition over the three-month period may have been secondary to: 1) lack of dependable transportation; 2) being out of town at scheduled focus group meetings; 3) unexpected medical care / illness; 4) lost / stolen mobile phone at time of focus group meeting; and 5) conflicting priorities.

Implications

Data collected from the three monthly focus group meetings indicated that there is high feasibility and acceptability for mobile phone application / text messaging technology as a viable medication reminder tool within the study population; this is especially validated when supportive factors are in place including access to medication, access to a working phone, and a commitment to reducing HIV viral load and improving CD4+ T cell counts. However, depending upon the participants' baseline technology literacy, there may be initial barriers to utilizing this tool without the support and education from a caring individual / health care professional.

A common theme revealed throughout each focus group meeting was the accountability aspect, where participants felt more inclined to improve medication adherence when someone / something offered active concern regarding their behavior, whether it be family, friends, or a health care provider. Although this study indicated that using a mobile phone application, as a tool to increase medication adherence, was both feasible and acceptable, it may be the combined efforts of the mobile phone application tool in conjunction with the caring support of a health care professional that contributed to its overall success.

Recommendations for Practice and for Further Study

From this study's data, it may be determined that health care provider support, in addition to the installation of a mobile phone medication reminder application, increases the likelihood of medication adherence. Recommendations for further study are (a) a rigorous evaluation of mobile technology-based applications specifically for HIV care; (b) studies with larger sample sizes; and (c) collecting clinical data, such as viral loads, to quantify medication adherence (Coomes et al., 2012). Utilizing this study's results, this author plans further investigation by incorporating the *Care4Today™ Mobile Health Manager*'s dashboard feature into a larger scale study at the participating ASO, during which participants will give consent for the researcher to monitor the participants' daily self-report of medication adherence entered into the mobile phone application via *Care4Today™ Mobile Health Manager*'s web-based Patient Dashboard; and the researcher will consequently contact those participants who have missed two doses over a seven-day timeframe to discuss obstacles to medication adherence and discuss interventions for adherence success. With this next-step study, the recommendation will be to also have participants' HIV viral loads collected at baseline and documented over a one-year monitoring study period to quantify viral load suppression, supporting participants' medication adherence self-reports. Decreasing and / or suppressed HIV lab values are a more accurate marker of HIV medication adherence compared to participant self-report.

Conclusions

This study provided a beginning theoretical framework that depicted the process by which the participants engaged in increased HIV medication adherence with the support of a mobile phone application. There is a strong behavioral component toward medication

adherence; and there is also a strong behavioral component toward adopting and using new technology, such as installing and actively using a daily mobile phone application. To address these related behavioral components, two theoretical frameworks, the Technology Acceptance Model (TAM) and the Theory of Planned Behavior (TPB) were used in this research project.

This researcher believes that it may be the combination of a medication adherence tool, such as the *Care4Today™ Mobile Health Manager* mobile phone application, in conjunction with the participants' perceived caring effect of the researchers over a three month period that contributed to increased medication adherence in the majority of the study participants. Participants may be more apt to want to please the researcher, who has taken an interest in their medication adherence behaviors; this phenomenon is known as the Hawthorne Effect. Participants also displayed ongoing challenges with technology use, which the researchers were able to address, potentially affecting perceived usefulness, perceived ease of use, and attitude toward the technology on a one-on-one basis; this targeted IT support feature enhanced participants' technology use though a caring relationship. Ongoing research may reveal whether there is a potential social outcome of increasing medication adherence through increased provider / client social interactions in conjunction with technology, such as the *Care4Today™* mobile phone application.

While this study had a number of strengths and indications for next steps, it also had some limitations. For example, the study may have benefitted from participation by PLWH from more diverse ethnic and socioeconomic backgrounds. While the inclusion of such perspectives was not possible with the participants of this study, it should be considered for future research.

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Appendix A

Janssen Biotech, Inc. *Care4Today*^{TM} Privacy Policy

(http://www.care4today.com/privacy-policy.html)

Privacy Policy

Last Update: September 9, 2013

Janssen Research & Development, LLC is concerned about privacy issues and wants you to be familiar with how we collect, use, and disclose information. This Privacy Policy describes our practices in connection with information that we or our service providers collect through the Web site or Web property (including, for example, a mobile Web site) operated and controlled by us from which you are accessing this Privacy Policy (each, the **"Site"**). By using the Site, you agree to the terms and conditions of this Privacy Policy.

INFORMATION COLLECTION

Information You Provide

This Site does not request the submission of personal information

Passive Information Collection and Use

As you navigate around the Site, certain information can be passively collected (that is, gathered without your actively providing the information), using various technologies. We and our third party service providers passively collect and use information in a variety of ways, including:

Through your browser: Certain information is collected by most browsers, such as your Media Access Control (MAC) address, computer type (Windows or Macintosh), screen resolution, operating system version, and Internet browser type and version. We may collect similar

information, such as your device type and identifier, if you access the Site through a mobile device.

Using cookies: Cookies are pieces of information stored directly on the computer you are using. Cookies allow us to collect information such as browser type, time spent on the Site, pages visited, and language preferences. We and our service providers use the information for security purposes, to facilitate navigation, display information more effectively, and to personalize your experience while using the Site. We also use cookies to recognize your computer or device, which makes your use of the Site easier, such as to remember what is in your shopping cart. In addition, we use cookies to gather statistical information about Site usage in order to continually improve its design and functionality, understand how individuals use it, and to assist us with resolving questions regarding it. Cookies further allow us to select which of our advertisements or offers are most likely to appeal to you and display them while you are on the Site. We may also use cookies in online advertising to track consumer responses to our advertisements.

You can refuse to accept these cookies by following your browser's instructions; however, if you do not accept them, you may experience some inconvenience in your use of the Site. You may also not receive advertising or other offers from us that are relevant to your interests and needs.

To learn more about cookies, please visit http://www.allaboutcookies.org.

Using Flash cookies: Our use of Adobe Flash technology (including Flash Local Stored Objects ("Flash LSOs")) allows us to, among other things, serve you with more tailored information, facilitate your ongoing access to and use of the Site, and collect and store information about your use of the Site. If you do not want Flash LSOs stored on your computer, you can adjust the settings of your Flash player to block Flash LSO storage using the tools contained in the Website Storage Settings Panel. You can also control Flash LSOs by going to the Global Storage Settings

Panel and following the instructions (which may include instructions that explain, for example, how to delete existing Flash LSOs (referred to as "information" on the Macromedia site), how to prevent Flash LSOs from being placed on your computer without your being asked, and (for Flash Player 8 and later) how to block Flash LSOs that are not being delivered by the operator of the page you are on at the time). Please note that setting the Flash Player to restrict or limit acceptance of Flash LSOs may reduce or impede the functionality of some Flash applications, including, potentially, Flash applications used in connection with the Site or our online content.

Using pixel tags, web beacons, clear GIFs, or other similar technologies: These may be used in connection with some Site pages and HTML-formatted e-mail messages to, among other things, track the actions of Site users and e-mail recipients, measure the success of our marketing campaigns, and compile statistics about Site usage and response rates.

IP Address: Your IP Address is a number that is automatically assigned to the computer that you are using by your Internet Service Provider. An IP Address is identified and logged automatically in our server log files whenever a user visits the Site, along with the time of the visit and the page(s) that were visited. Collecting IP Addresses is standard practice on the Internet and is done automatically by many web sites. We use IP Addresses for purposes such as calculating Site usage levels, helping diagnose server problems, and administering the Site.

How We Use and Disclose Information

We disclose information collected through the Site:

- to our affiliates for the purposes described in this Privacy Policy. A list of our affiliates is available here (click on the link for Form 10K, Exhibit 21, under "SEC Filings"). Janssen Research & Development, LLC is the party responsible for the management of the jointly-used Personal Information;

- to our third party service providers who provide services such as website hosting and moderating, data analysis, infrastructure provision, IT services, customer service, auditing services, and other services, in order to enable them to provide services; and
- to a third party in the event of any reorganization, merger, sale, joint venture, assignment, transfer, or other disposition of all or any portion of our business, assets, or stock (including in connection with any bankruptcy or similar proceedings).

In addition, we use and disclose information collected through the Site as we believe to be necessary or appropriate: (a) as permitted by applicable law, including laws outside your country of residence; (b) to comply with legal process; (c) to respond to requests from public and government authorities, including public and government authorities outside your country of residence; (d) to enforce our terms and conditions; (e) to protect our operations or those of any of our affiliates; (f) to protect our rights, privacy, safety, or property, and/or that of our affiliates, you, or others; and (g) to allow us to pursue available remedies or limit the damages that we may sustain. We may also use and disclose information collected through the Site in other ways, with your consent.

We also use and disclose information we collect passively as described above, under "Passive Information Collection and Use," and for any other purpose, except where we are required to do otherwise under applicable law (for example, if we are required to treat such information as personal information). In addition, we may use and disclose information that is not in personally identifiable form for any purpose. If we combine information that is not in personally identifiable form with information that is (such as combining your name with your geographical location), we will treat the combined information as personal information as long as it is combined.

THIRD PARTY SITES AND SERVICES

This Privacy Policy does not address, and we are not responsible for, the privacy, information, or other practices of any third parties, including any third party operating any site or web property (including, without limitation, any application) that is available through this Site or to which this Site contains a link. The availability of, or inclusion of a link to, any such site or property on the Site does not imply endorsement of it by us or by our affiliates.

SECURITY

We use reasonable organizational, technical, and administrative measures to protect personal information under our control. Unfortunately, no data transmission over the Internet or data storage system can be guaranteed to be 100% secure. If you have reason to believe that your interaction with us is no longer secure (for example, if you feel that the security of any account you have with us has been compromised), please immediately notify us of the problem by contacting us in accordance with the *"Contacting Us"* section below.

Our sharing of your passive information with affiliates and third-party partners: If you would prefer that we not share your passive information on a going-forward basis with our affiliates and/or third-party partners, you may opt out of this sharing by contacting us. In your response to us, please state that we should no longer share your passive information with our affiliates and/or third-party partners.

RETENTION PERIOD

We retain the passive information for the period necessary to fulfill the purposes outlined in this Privacy Policy, unless a longer retention period is required or allowed by law or to otherwise fulfill a legal obligation.

USE OF SITE BY MINORS

The Site is not directed to individuals under the age of 18, and we request that these individuals not provide Personal Information through the Site.

CROSS-BORDER TRANSFER

The passive information may be stored and processed in any country where we have facilities or service providers, and by using our Site or by providing consent to us (where required by law), you agree to the transfer of information to countries outside of your country of residence, including to the United States, which may provide for different data protection rules than in your country.

SENSITIVE INFORMATION

Unless we specifically request or invite it, we ask that you not send us, and you not disclose, any sensitive personal information (*e.g.*, information related to racial or ethnic origin, political opinions, religion or other beliefs, health, criminal background or trade union membership) on or through the Site or otherwise to us. In those cases where we may request or invite you to provide sensitive information, we will do so with your express consent.

UPDATES TO THIS PRIVACY POLICY

We may change this Privacy Policy. Please take a look at the *"LAST UPDATED"* legend at the top of this page to see when this Privacy Policy was last revised. Any changes to this Privacy Policy will become effective when we post the revised Privacy Policy on the Site. Your use of the Site following these changes means that you accept the revised Privacy Policy.

CONTACTING US

If you have any questions about this Privacy Policy, please contact us at RA-rndus-care4today@its.jnj.com or please write to the following address:

Janssen Healthcare Innovation

3210 Merryfield Row

San Diego, CA 92121-1126

Appendix B

Carlow University Institutional Review Board Approval

CARLOW UNIVERSITY
INSTITUTIONAL REVIEW BOARD

To: Andrew Martin, MSN
Michele Upvall, Ph.D.

CC: IRB Committee

From: Robert A. Reed, Psy.D.
Co-Chair, Carlow IRB

Date: May 1, 2015

Re: IRB # 15-283: A mobile phone HIV medication adherence intervention: Care4Today Mobile Health Manager

The above project was reviewed and approved by the Co-Chair of Carlow's Institutional Review Board. The project is approved for a period of up to one year.

Approval Date: May 1, 2015
Expiration Date: April 30, 2016

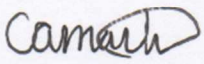
If any untoward incidents or unanticipated adverse reactions should develop in the course of your research with human subjects, you must notify the Institutional Review Board Office at 578-6349 immediately.

Appendix C

Addendum to Summary of Proposed Research for Institutional Review

April 30, 2015
Addendum to Summary of Proposed Research for Institutional Review

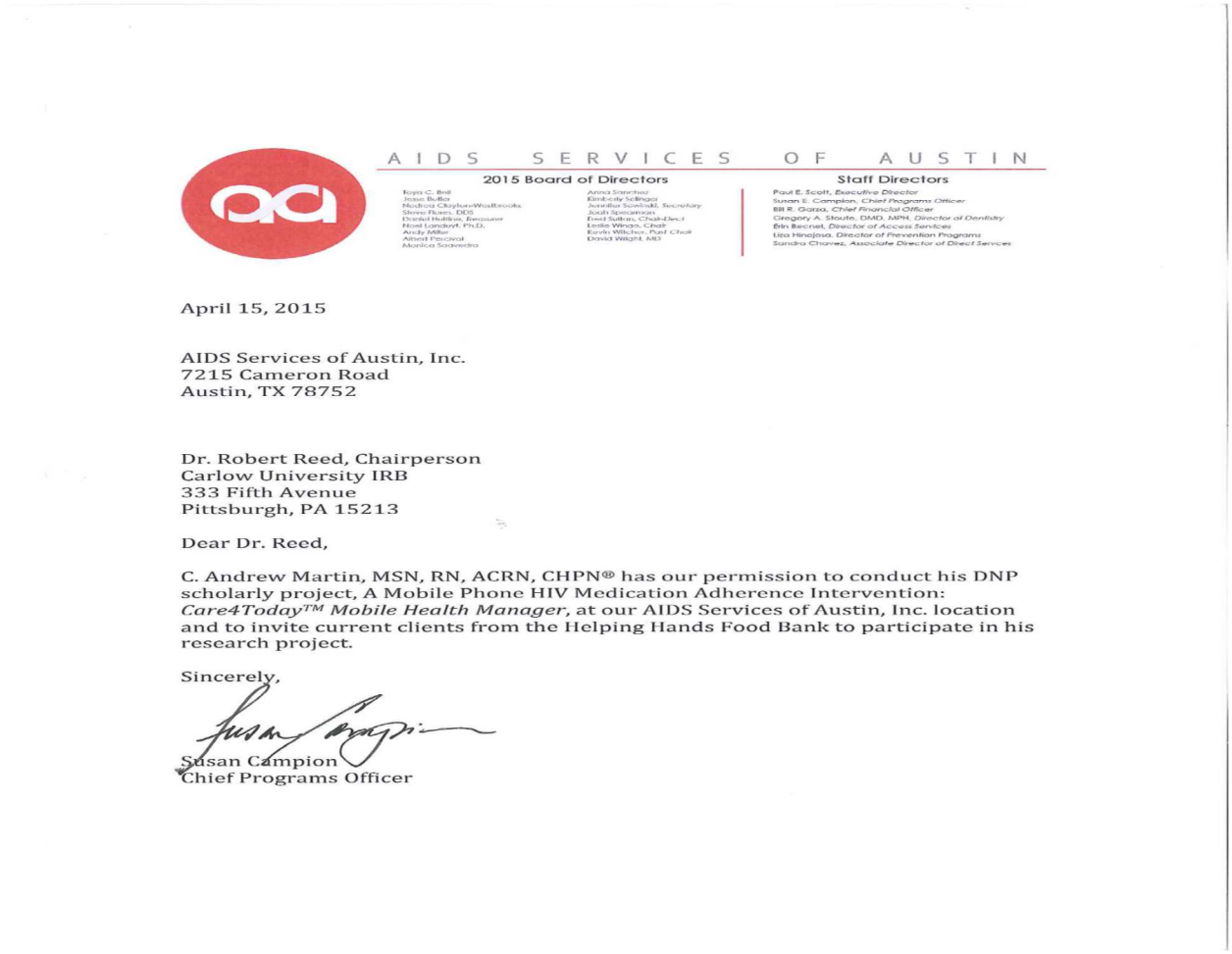
The list of collected cell phone numbers from the study participants will be destroyed at the end of the study.



C. Andrew Martin, MSN, RN, ACRN, CHPN®
Carlow University DNP Student

Appendix D

AIDS Services of Austin, Inc. Site Consent



AIDS SERVICES OF AUSTIN

2015 Board of Directors

Staff Directors

April 15, 2015

AIDS Services of Austin, Inc.
7215 Cameron Road
Austin, TX 78752

Dr. Robert Reed, Chairperson
Carlow University IRB
333 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Reed,

C. Andrew Martin, MSN, RN, ACRN, CHPN® has our permission to conduct his DNP scholarly project, A Mobile Phone HIV Medication Adherence Intervention: *Care4Today™ Mobile Health Manager*, at our AIDS Services of Austin, Inc. location and to invite current clients from the Helping Hands Food Bank to participate in his research project.

Sincerely,

Susan Campion
Chief Programs Officer

Appendix E

Study Introduction/Intent to Participate

If interested in participating in this study, please complete this form and return before June 30, 2015.

First Name: _____

Last Initial: _____

Contact Phone Number:

_____

Contact Email (if available):

_____

What is the best time to contact you by phone (circle one)?

Morning Lunch Afternoon Evening Any time of day

Do you speak English as your primary language (circle one)?

Yes No

Appendix F

Informed Consent Letter

Dear Participant,

My name is Andrew Martin, and I am a Doctor of Nursing Practice student researcher at Carlow University interested in improving medication adherence rates amongst the HIV+ population in Austin, TX. I am researching the use of a mobile phone application, *Care4Today™ Mobile Health Manager* and am currently seeking individuals who are interested in trying the application and reporting its acceptability and usability to participate in my study.

Because it is important that all HIV medications be taken on a daily basis as prescribed by your doctor, I am interested in determining whether using a secured, mobile phone medication reminder application will improve your adherence to taking HIV medications. By offering your reflections and input at three monthly focus groups, I will have a better idea as to the role that cell phone applications serve as medication reminders.

You are not required to participate in this study. If you decide not to participate, your decision will not affect your current or future relations with the AIDS Services of Austin Helping Hands Food Bank. Your daily use of the *Care4Today™ Mobile Health Manager* phone application will not be tracked nor accessed by the researchers. Your first name, last name initial, as well as a preferred contact method, will be the only identifying information collected and available solely

to the primary and assistant researcher; and this identifying information will not be revealed in any publications based upon this inquiry.

Participants are required to complete an initial survey to determine eligibility and sign consents to participate in this research study. Participants will install the mobile phone application on their personal phones and add all HIV medications into the medication reminder application, with the assistance of a researcher if needed. Participants will log whether or not medications are taken on a daily basis for a three-month period, and then report experiences and barriers at the Midpoint-of-Study and End-of-Study focus group meetings. At the close of each of the three focus group meeting, for your ongoing engagement in the research, you will be awarded the following: a $10 gift card at the close of Focus Group 1; a $15 gift card at the close of Focus Group 2; and a $25 gift card at the close of Focus Group 3.

The Carlow University Institutional Review Board has approved this activity. This Committee administers both the General Assurance of Compliance with the United States Department of Health and Human Services Policy for the protection of Human Subjects and the University policy covering the protection of human subjects. The Committee may be contacted through the Chairperson, Dr. Robert Reed, by calling 412-578-6349.

Please note that your signature indicates that you have read all of the information within this consent form and that all of your questions have been adequately answered. Your signature indicates your willingness to participate in this study. Thank you for your valuable contribution to this research.

Sincerely,

C. Andrew Martin, MSN, RN, ACRN, CHPN®

Signature of participant _____Date _____

Witness _____

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

Appendix G

Participant Demographics

1. What is your age? _____ years

2. How do you describe yourself? (circle one)

A. Male

B. Female

C. Transgender

D. Do not identify as female, male, or transgender

3. Which best describes your race/ethnicity? (Please check only one)

_____Asian

____ Black or African American

____ Hispanic or Latino

____ Native Hawaiian or Other Pacific Islander

_____White

____ _American Indian or Alaska Native

_____ Mixed Race

4. What is the highest grade or year of school you completed (check one)?

____ Less than high school degree

____ High school degree or equivalent (e.g., GED)

____ Some college but no degree

____ Associate degree

____ Baccalaureate degree

____ Graduate degree

5. What is your primary language?

____ English

____ Spanish

____ Other (please describe) _____

6. How often do you use your cell phone?

___ Multiple times a day for various reasons

___ Usually about once a day

___ Only when I receive calls/texts

7. Place a check next to the following reasons you use your cell phone (you may check more than one):

___ phone calls

___ texting

___ email

___ photos

___ phone apps (social media, games)

8. How likely are you to use a medication reminder phone application knowing that it involves one press of a button indicating you took a medication?

___ Very likely

___ Somewhat likely

___ Not at all likely

9. How many pills do you have to take each day for your HIV regimen?

___ One pill

____More than one pill

10. Have you had uninterrupted access to medications for the at least last three months?

___Yes

___No

11. In the past seven days, how many doses of ART medications have you missed?

____ I haven't missed any doses the past seven days

___ 0-1 doses in the past seven days

___ 2-3 doses in the past seven days

___ more than 3 doses in the past seven days

12. Have you had uninterrupted access to a working mobile phone for the past three months?

___Yes

___No

Appendix H

Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV)

1. Do you know what a "CD4 count" is? (place a checkmark in the boxes below)

[ ] Yes, I am aware.

Please write a definition in your best words below. If not, you may skip this question.

_____

_____

_____

Is the goal of treatment to make the CD4 count go up or down?

[ ] up

[ ] down

[ ] No, I am not familiar with this term. **Go to Question #2.**

2. Do you know what is a viral load? (place checkmark in the boxes below)

[ ] Yes, I am aware

Please write definition in your best words below. If not, you may skip this question.

_____

_____

_____

Is the goal of treatment to make the viral load go up or down?

[ ] up

[ ] down

[ ] No, I am not familiar with this term

3. What medications are you currently taking to treat HIV?

Please list them below (spelling is not important). If you are not sure, you may write "I don't know".

_____

_____

_____

<u>Please circle one of the following for each question.</u>

4 . I don't take my medicines when they make me feel bad.

a. agree

b. not sure

c. disagree

5. I don't take my medicines when I am too tired.

a. agree

b. not sure

c. disagree

6. I don't take my medicines when I am feeling down or low.

a. agree

b. not sure

c. disagree

7. I don't take my medicine because it tastes bad.

a. agree

b. not sure

c. disagree

8. I don't take my medicines when I feel good.

a. agree

b. not sure

c. disagree

Appendix I

Icek Ajzen Permission Letter

Andrew Martin

From: Icek Aizen [aizen@psych.umass.edu]
Sent: Wednesday, February 25, 2015 10:26 AM
To: Andrew Martin
Subject: RE: Request for permission to use the TPB Diagram

Dear Mr. Martin,

The theory of planned behavior is in the public domain. No permission is needed to use the theory in research, to construct a TPB questionnaire, or to include an ORIGINAL drawing of the model in a thesis, dissertation, presentation, poster, article, or book. If you would like to reproduce a published drawing of the model, you need to get permission from the publisher who holds the copyright. You may use the drawing on my website (http://people.umass.edu/aizen/tpb.diag.html) for non-commercial purposes, including publication in a journal article, so long as you retain the copyright notice.

Best regards,

Icek Ajzen
Professor Emeritus
University of Massachusetts – Amherst
http://www.people.umass.edu/aizen

Appendix J

Taking Medications for HIV: Adherence

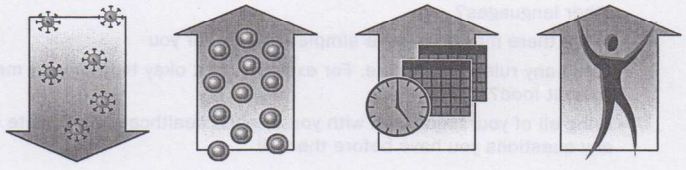
Taking Medicines for HIV: Adherence

WHAT IS ADHERENCE?

Adherence means correctly following medical advice. For HIV, adherence usually refers to taking medicines the *right* way *every* day. Another word for adherence is compliance.

WHY IS ADHERENCE IMPORTANT?

- Good adherence is needed to manage HIV. When taken correctly, the appropriate combination of HIV medicines can help to:

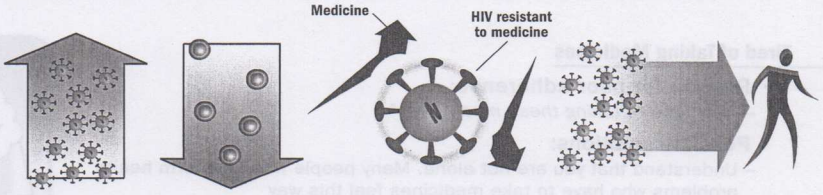


Decrease the amount of HIV in your body | Increase your CD4 cell count | Extend your life | Improve your quality of life

When you miss a dose, the amount of medicine in your body can decrease. This gives HIV a chance to outsmart the medicine and increase its population size

WHAT HAPPENS WHEN HIV FIGHTS BACK?

- When HIV fights back....



Amount of HIV in your body increases | Your CD4 cell count decreases | HIV is more likely to become resistant to the medicines | You may be more likely to pass HIV to others

WHAT STANDS IN YOUR WAY?

There are lots of reasons why people may not adhere to their HIV medicines. These reasons are often called adherence "barriers." Let's take a look at several barriers and think about some possible solutions.

Filling the Prescription

- **Reason for poor adherence:**
  - *"It's too hard to fill the prescription."*
- **Possible solutions:**
  - Talk to your healthcare team, including your case manager
  - They can give you information about programs that may help get your prescription filled, pay for your medicine, or provide transportation to the pharmacy, if needed

WHAT STANDS IN YOUR WAY? (CONTINUED):

Understanding the Directions

- **Reason for poor adherence:**
  - *"I don't know how to take my medicines the right way."*
- **Possible solutions:**
  - Ask your healthcare team to explain the directions more clearly
  - Ask for written information about each medicine. Is it available in other languages?
  - Ask if there may be a more simple regimen for you
  - Ask if any rules are flexible. For example, is it okay to take your medicine without food?
  - Bring all of your medicines with you to each healthcare visit. Write down any questions you have before the visit

Side Effects

- **Reason for poor adherence:**
  - *"I'm worried about side effects and what to do if I have them."*
- **Possible solutions:**
  - Talk to your healthcare team about the side effects you have. Some side effects may go away over time
  - If the side effects bother you or do not go away, talk to your healthcare team

Do not stop taking your medicine without first talking to your healthcare team

Tired of Taking Medicines

- **Reason for poor adherence:**
  - *"I'm tired of taking these medicines."*
- **Possible solutions:**
  - Understand that you are not alone. Many people with long-term health problems who have to take medicines feel this way
    - Experts call this feeling "treatment fatigue" or "pill fatigue"
  - Talk to your healthcare team about how you are feeling
  - Use your support system, including family and friends
  - Consider attending a support group for people with HIV
  - Make a list of all the reasons why you need to stick with your medicines

Forgetfulness

- **Reason for poor adherence:**
  - *"I'm busy. Sometimes I just forget to take my medicines."*
- **Possible solutions:**
  - Create a routine. Take your medicines at the same time every day
  - Take your medicines with other daily habits, like brushing your teeth in the morning or eating dinner at night
  - Talk to your healthcare team about reminders. You can:
    - Wear a watch or set an alarm
    - Have e-mails or text reminders sent to you
    - Fill out a medicine log or calendar
    - Use a pillbox marked with the days of the week

Talk with your healthcare team about the challenges you face with adherence

For more information about HIV, visit APositiveLife.com

APOSITIVE LIFE

ViiV Healthcare

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Appendix K

Care4Today™ Mobile Health Manager Application Instructions

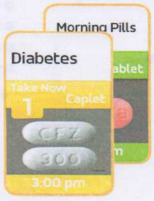
MOBILE HEALTH MANAGER
APPLICATION INSTRUCTIONS

care4today Mobile Health Manager

BASIC NAVIGATION:

Single tap

any green or yellow tile to indicate taken.

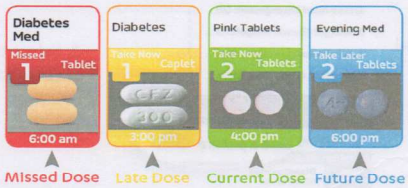


Dose indicator

The number of pills to take is displayed by the dose indicator in the tile and not by the number of pill(s) in the image.

What is the color-coded system?

The color-coded system indicates the priority of when it is time for a medication to be taken. If you take a medication on time (green tile) but miss a dose (red tile), your reports will then show a yellow square unless edited within that same day.



Medication tile colors

- Take now (30 minutes before scheduled time)
- Late (1 hour after scheduled time)
- Missed (3 hours after scheduled time)
- Future dose

Tap to indicate taken

Tap a yellow or green medication tile to indicate that you've taken that medication. The tile will appear at the bottom of the screen with a green check mark. Tapping a red tile (3 hours after scheduled time) will open a dialogue box where you can indicate whether you took or skipped the dose.

If there are reminders from the previous day that you did not respond to, swipe left to right to access the "Yesterday" screen. Swipe right to left to return to the "To Do" screen.

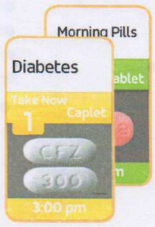
MOBILE HEALTH MANAGER
APPLICATION INSTRUCTIONS

care4today Mobile Health Manager

BASIC NAVIGATION:

Single tap

any green or yellow tile to indicate taken.



Dose indicator

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Medication tile colors

- Take now (30 minutes before scheduled time)
- Late (1 hour after scheduled time)
- Missed (3 hours after scheduled time)
- Future dose

Tap to indicate taken

Tap a yellow or green medication tile to indicate that you've taken that medication. The tile will appear at the bottom of the screen with a green check mark. Tapping a red tile (3 hours after scheduled time) will open a dialogue box where you can indicate whether you took or skipped the dose.

If there are reminders from the previous day that you did not respond to, swipe left to right to access the "Yesterday" screen. Swipe right to left to return to the "To Do" screen.

Appendix L

Start-of-Study Focus Group Questions

Ground Rules

Everyone's perspective and point of view is valued. Please feel free to speak, as your input is valuable and very important. There are no wrong answers. You can share as little or as much as you would like about your personal situations. Please be respectful of others and the opportunity for everyone to speak. Please respect the confidentiality of others. In an effort to respect everyone's time, we may politely move to the next question if too much time is spent on one question. This conversation is recorded, but only for research purposes. Your names will not be revealed in any reports. The researchers have no financial conflict of interest with the *Care4Today™ Mobile Health Manager* application or with Janssen Research and Development. Have fun!

Opening

What attracted you to participate in this study?

Introduction

What is the first thought that comes to mind when you think of medication adherence or taking your medication as the doctor told you to take them?

Transition

What have your experiences been with how you take your medications on time? (Possible probe: Please give an example of a time you forgot take your medication.)

Key Questions

When people talk about not taking medications, what are some reasons they mention? (TPB- normative beliefs) (Probe: Where does forgetfulness fall within these examples, if at all?)

How comfortable do you feel using technology on your cell phone? (TAM 3. attitude toward all the things that can be done with a cell phone other than making phone calls)

What challenges (Probe: cost, ease of use, forgot to carry, battery not charged) do you have with your cell phone? With apps on your cell phone? (TAM 2. Perceived ease of use)

What are some problems you might find when using this phone app?

On a scale from 1-10, 1 being easy and 10 being difficult, rate how this app will be for you to use in your everyday life. (Have participants write a number on a card - will use this card for comparison at final focus group meeting) (TAM 2. Perceived ease of use)

Ending Questions

How useful do you think using a cell phone app every day will be in helping you to take your medications? (TAM 1. Perceived usefulness; TPB - behavioral belief)

How likely are you to use this app every day? (TPB- attitudes toward behavior)

What are some ways you have for making this app work for you considering some barriers you've mentioned?

Oral Summary

Appendix M

Midpoint-of-Study Focus Group Questions

Opening

Tell us about your experiences with the phone app so far. (Allow participants to take two minutes to sketch a picture describing their experiences using symbolism.)

Introduction

What words come to mind at this point when you think about the terms technology and medication adherence? (In other words, what part do you believe technology may play in helping with medication adherence, if any?)

Transition

What have your experiences been with taking medications on time when using this app? (Possible probes: Please give an example of a time you failed to take your medication when the app gave a reminder.)

Key Questions

Has your comfort level with using this phone app changed since the first time you began using your cell phone app? (TAM 3. Attitude toward technology)

What challenges or frustrations are you having with your cell phone or the app on your cell phone? (TAM 2. Perceived ease of use)

Now that you have been using the app for a few weeks, what are some things that you have found that get in the way of using the app? (Revisit the barriers discussed in first focus group.)

On a scale from 1-10, 1 being easy and 10 being difficult, rate how this app been for you to use in your everyday life. (Have participants write a number on a card - will use this for comparison from first focus group.) (TAM 2. Perceived ease of use)

Ending Questions

What have you found most useful in using the app? (TAM 1. Perceived usefulness)

What are some ways have you found that help you to use the app?

Oral Summary/Troubleshoot

Appendix N

End-of-Study Focus Group Questions

Opening

Write one word or draw one picture on your card that describes your overall experience in using the phone app to help remind you to take your medications.

Introduction

Tell us about your experiences in using the app? (Possible probes: Best thing? Worst thing?)

Transition

Think back to before you learned about this phone app. How might your opinion changed about using technology to remind you to take your medications?

Key Questions

How did your comfort level change as you used the app over time? (Probe: What became easier/harder about using the app? TAM 3. Attitude toward technology)

What, if anything, would you change about the app considering the challenges we have discussed in the past with using it? (TAM 2. Perceived ease of use)

On a scale from 1-10, 1 being easy and 10 being difficult, rate how it was to use this app overall? (Have participants write a number on a card - will use this for comparison at final study) (TAM 2. Perceived ease of use)

How has your overall medication adherence in your life been affected by using this app? (Probe: In what ways have you noticed an improvement, if any?)

How useful was this cell phone app in your daily routine in reminding you to take meds? (TAM 1. Perceived usefulness; TPB - behavioral belief)

What are some ways you made this app work for you, considering problems since beginning the study?

Ending Questions

How likely are you to use this app in your daily life after today? How likely are you to recommend the app to someone else? (TPB- attitudes toward behavior)

What difference**,** other than taking medications as scheduled**,** did this app make in your life, if any?

Oral Summary

Appendix O

End-of-Study Participant Evaluation

RESEARCH STUDY EVALUATION FORM

Care4Today™ Mobile Health Manager

On behalf of the researchers, we appreciate your active participation in this research study over the past three months. Please take a few moments to answer the following questions:

After participating in this research study, I believe that my daily medication adherence behavior changed by using the *Care4Today™ Mobile Health Manager*:

- o Yes, medication adherence improved
- o No, medication adherence declined
- o No change in medication adherence

After participating in this study, I believe that a mobile phone application is a useful and easy thing to have as a reminder for taking my daily medications:

- o Yes, it is useful and easy
- o No, it is not useful or easy
- o No comment either way

Rate the researcher, C. Andrew Martin, on the following:

Please Circle The Appropriate Number, 1 = Poor, and 5 = Excellent

1) Knowledge of the Subject Matter: 1 2 3 4 5

2) Preparation for Each Focus Group Meeting: 1 2 3 4 5

3) Communicated Material Effectively: 1 2 3 4 5

4) Responded Well to Questions: 1 2 3 4 5

5) Established Positive Rapport With Participants: 1 2 3 4 5

Rate the research assistant, Mary Pomeroy, on the following:

Please Circle The Appropriate Number, 1 = Poor, and 5 = Excellent

1) Knowledge of the Subject Matter: 1 2 3 4 5

2) Preparation for Each Focus Group Meeting: 1 2 3 4 5

3) Communicated Material Effectively: 1 2 3 4 5

4) Responded Well to Questions: 1 2 3 4 5

5) Established Positive Rapport With Participants: 1 2 3 4 5

Additional comments about the focus group facilitators?

_____

_____

_____

What did you find was the most valuable part of participating in this medication adherence program?

_____

_____

_____

_____

_____

Do you have any suggestions on how we could improve this program?

Other comments?

Appendix P

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Table 1. The Brief Estimate of Health Knowledge and Action—HIV version (BEHKA-HIV)

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