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Using Telehealth to Support Informal Caregivers of Elders with Urinary Incontinence: A Pilot/Feasibility Study

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ACCEPTANCE

This dissertation, USING TELEHEALTH TO SUPPORT INFORMAL CAREGIVERS OF ELDERLY WITH URINARY INCONTINENCE: A PILOT/FEASIBILITY STUDY by Nicole J. Davis was prepared under the direction of the candidate's dissertation committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis School of Nursing in the Byrdine F. Lewis School of Nursing and Health Professions, Georgia State University.

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- Davis, NJ, Johnson, TM (2009). Another study of the prevalence of incontinence...or much more? *International Journal of Clinical Practice*; 63(4):535-7.

ABSTRACT

USING TELEHEALTH TO SUPPORT INFORMAL CAREGIVERS OF ELDERERS WITH URINARY INCONTINENCE: A PILOT/FEASIBILITY STUDY

by

NICOLE J. DAVIS

Urinary Incontinence (UI) is a prevalent and burdensome condition affecting care-dependent, community-dwelling elders (CRs) and their informal caregivers (CGs). Although treatable, UI remains inadequately managed resulting in negative medical, physical, psychosocial and economic impacts. Behavioral treatments for UI, though considered ideal, are rarely prescribed and understudied in this cohort. Equally scarce are evidenced-based programs designed to support CGs delivering UI care. Health information technology has been shown to be an effective approach to support CGs and elders in the management of chronic illness; its effectiveness in UI treatment has yet to be determined.

A quasi-experimental, pre-posttest design was used to explore the feasibility and acceptability of a technology-facilitated, multi-component behavioral intervention designed to enhance the home environment of CRs with UI and strengthen informal CG self-efficacy. CGs received a 6-week evidence-based, prompted voiding and educational program delivered via tablet-personal computer. CGs also received a supportive component in the form of weekly telephone calls from a UI nurse expert. Care-recipient (% change in wetness) and CG outcomes (technology usage, perceived ease of use, UI knowledge, self-efficacy, burden) were measured at 3-weeks and 6-weeks and analyzed

descriptively. Qualitative feedback regarding CG satisfaction and perceptions of the intervention were obtained at the conclusion of the study.

The development and implementation of the intervention were feasible. The major challenge to feasibility was the recruitment of eligible participants. Three CG/CR dyads enrolled and completed the study. CGs were all female (Mean age=71.67 years, SD =15.95). CRs were mostly male (Mean age = 86.67 years, SD=8.51). CGs were adherent to technology usage, however adherence to prompted voiding was inconsistent. CGs demonstrated slight increases in UI-related self-efficacy, UI knowledge, and decreases in UI-related bother. CRs demonstrated a mean 62.53% reduction in wet checks. In qualitative interviews, CGs consistently rated the intervention extremely high and found access to a UI expert beneficial.

These preliminary findings suggest that the use of telehealth systems to deliver an evidence-based, UI intervention may be a feasible and acceptable way to improve CG confidence and knowledge in UI management and reduce CR wetness. Future studies are warranted and should consider potential recruitment barriers.

USING TELEHEALTH TO SUPPORT INFORMAL CAREGIVERS OF ELDERERS
WITH URINARY INCONTINENCE: A PILOT/FEASIBILITY STUDY

by

NICOLE J. DAVIS

A DISSERTATION

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DEDICATION

“The family is one of nature’s masterpieces.”

-George Santayana

I dedicate this dissertation to my amazing family, who endured with me and whose love and support carried me through the most challenging of times...

To my wonderful husband Dale, thank you for believing in me, for sacrificing so much to allow us to live this dream. Thank you for always being exactly what I needed, every time that I needed it. You are my rock and biggest source of strength. This would never have been possible without you.

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I love you all dearly

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LIST OF ABBREVIATIONS

ADLs	Activities of Daily Living
CG	Informal Caregiver
CR	Care-Recipient;care-dependent community-dwelling elder
Health IT	Health Information Technology
IADLs	Instrumental Activities of Daily Living
Tele-Prompt	Telehealth-Delivered Prompted Voiding and Educational Intervention to Support Caregivers of Elders with Urinary Incontinence
UI	Urinary Incontinence
IRB	Institutional Review Board
PI	Principle Investigator
NP	Nurse Practitioner
QID	Four times daily
BID	Twice daily
PHI	Protected Health Information
LAR	Legally Authorized Representative
MCG	micrograms
MG	milligrams

CHAPTER I

INTRODUCTION

Failure to effectively treat urinary incontinence (UI) among the 38 million United States (US) adults over age 65, has been associated with decreased quality of life, increased morbidity, falls, nursing home placement, and approximately \$19 billion dollars in annual health related costs (AOA, 2011; Talley, Wyman, & Shamliyan, 2011). The prevalence of the condition increases with age and disability—disproportionately affecting frail older adults (Talley et al., 2011). For frail older adults residing in community settings, UI prevalence rates have been between 29% and 50% (Shamliyan, Wyman, Ping, Kane, 2009; Sorbye, Finne-Soveri, Ljunggren, et al., 2009). The presence of UI among frail community-dwelling older adults has been shown to adversely affect their informal caregivers (i.e., family and friends) by significantly increasing the physical, economic and psychological burdens of care (Gotoh, Matsukawa, Yoshikawa, Funahashi, Kato, et al., 2009; Langa, Fultz, Saint, Kabeto, Herzog, et al., 2002; Sorbye et al., 2008; Upton & Reed, 2005). Given the rapid aging of the US population and the continued shift of healthcare delivery from institutional settings toward the home environment; there is a critical need for innovative and effective interventions to treat UI in frail community-dwelling elders and reduce the quality-of-life burden in these persons and their informal caregivers (CGs) (DuMoulin, Hamers, Ambergen, Janssen, & Halfens, 2008; Gotoh; 2009, DuBeau, Kuchel, Johnson, & Palmer 2010). To date, however, clinical studies evaluating the effectiveness of patient-centered

behavioral interventions for UI in vulnerable elders have largely focused on nursing home residents receiving formal care (Fink, Taylor, Tacklind, Rutks, & Wilt, 2008). Further, despite the increasing prevalence of UI among community-dwelling elder populations; it has been approximately two decades since patient- and family-centered behavioral interventions for UI have been explored within this cohort (Colling et al., 2003; Engberg et al., 2002; McDowell et al., 1999). Therefore, there is a critical need for additional studies to explore the use of behavioral interventions for UI among frail community-dwelling elders—taking into account their unique needs and the needs of their CGs (Dubeau et al., 2010; Talley et al., 2011; Teunissen, de Jonge, van Weel, & Lagro-Janssen, 2004).

Health information technology (IT) (e.g., home telehealth) has been shown to be an effective approach to deliver patient- and family-centered clinical interventions (Dang, Dimmick, & Kelkar, 2009) and may be an innovative and effective way to deliver a specialized UI intervention to frail elders and their informal caregivers. Using technology to reach vulnerable elders and their caregivers may reduce the burden of travel to healthcare sites to learn specialized interventions for UI and may reduce other burdens associated with inadequate UI care (e.g., medication costs, cost of supplies, hospitalization related to complications, or nursing home admission) (Dang et al., 2009; Shamliyan, Wyman, Bliss, Kane, & Wilt, 2007).

In 2001, the Institute of Medicine published their landmark work, *Crossing the Quality Chasm*, which highlighted Health IT as having a central role in transforming the healthcare system to achieve effective and equitable, patient-centered care—which includes informal CGs (Institute of Medicine, 2001). More recently, a study of 1,000

informal CGs found that informal CGs who had the opportunity to experience these technologies in caregiving, found them to be beneficial and desired the use of technology to care for loved ones (National Alliance for Family Caregiving, 2011). Despite this, to date, no studies have explored the use of these technologies to support UI caregivers specifically in their role. Therefore, developing and testing patient- and family-centered, community-based interventions to manage UI in vulnerable elders has the potential to improve the evidence base by addressing a significant problem area with a paucity of research. Additionally, the novel use of health IT will advance the current body of knowledge on the use of these technologies in chronically ill, care-dependent populations—possibly impacting care decisions.

Background and Significance

The Burden of Informal Caregivers

CGs are crucial to the delivery of homecare to older adults—providing annual services valued at over 300 billion dollars (Arno, 2006). Historically, the CG role has focused primarily on providing custodial care (e.g., bathing, dressing, transportation, etc.). However, as healthcare continues to shift from the inpatient and long-term care environments toward the home, caregivers are frequently called upon to perform routine medical interventions and oversee the management of chronic illnesses (O’Mara, 2005). Despite this, a significant number of CGs lack the basic information needed to carry out their duties and feel ill-prepared for their role (Levine et. al., 2006). Several studies of the impact of UI on the lives of CGs found that UI caregivers specifically, lacked practical information regarding the condition (e.g., proper selection of incontinence

products) and also lacked the supportive systems needed to assist them in managing the illness (Cassells & Watt, 2003; Gallagher & Pierce, 2002; Upton & Reed, 2005).

Given these conditions, it is not surprising the many UI CGs are overwhelmed in their role. The presence of UI in care recipients has resulted in increased reports of CG burden in multiple realms—physical, financial, and psychological (Gotoh et al., 2009; Langa et al., 2002; Sorbye et al., 2008; Upton & Reed, 2005). One study found that managing UI in care recipients added \$4,000 to the annualized costs of informal care, and as much as 16 hours of physical care per week to existing CG burden (Langa et al., 2002). Another study evaluating the psychological burden of UI on family caregivers found the impact of UI to be significant—regardless of the level of care required (Gotoh, 2009).

With the rapid aging of the US population and the increasing prevalence of UI among elders, CGs will be increasingly called upon to provide this type of care (Du Moulin, 2008). Study findings indicate that supportive interventions aimed at adequately preparing CGs for the role of managing UI, have the potential to not only be well received, but to offer benefit to both CGs and care recipients (Colling et al., 2003; Engberg et al., 2002; McDowell et al., 1999). Despite this, little evidence exists which evaluates treatment within this cohort (Gotoh et al., 2009; Langa et al., 2002; Sorbye et al., 2008; Upton & Reed, 2005). Studies evaluating the effectiveness of UI treatments among care-dependent elders have often been limited to those residing in nursing homes, receiving formal care (Fink, Taylor, Tacklind, Rutks, & Wilt, 2008). Further, behavioral treatments of UI, although proven to be optimal in managing elders with the condition,

have been less studied in the community setting and even fewer have focused on CG support (DuBeau, Kuchel, Johnson, Palmer et al., 2010).

Interventions Targeting CG Support

Several studies have suggested that supportive services aimed at reducing CG burden improve the emotional and physical well-being of both CGs and care recipients (CRs) (Brodaty et al., 2003; Schulz, Martire, & Klinger, 2005). Educational and didactic interventions for the CG have been shown to improve knowledge—especially if focused on the CR’s specific illness (e.g., UI); however, interventions which also offer targeted skills training and social support or counseling are more effective than those which offer information alone (Bowles & Baugh, 2007; Mittelman, 2005; Schulz et al., 2005).

Many CGs need basic knowledge about their CR’s illness; skills training to appropriately provide the care required, and social support to enhance their emotional and psychological well-being (Gitlin et al., 2006). This study offered an innovative approach to support the CGs of those with UI by offering UI knowledge development, skill enhancement, and social support—through the use of emerging technology.

Telemedicine and Telehealth

Telemedicine and telehealth are interchangeable terms, which represent one facet of the vast world of Health Information Technology (American Telemedicine Association, 2011). As seen in any environment with rapidly changing technology, definitions of terms change to adjust to the concepts as they develop—the terms *telemedicine* and *telehealth* are of no exception (Maheu et al., 2001).

Telemedicine. Telemedicine is defined as the use of telecommunication technology to deliver healthcare services, provide education and clinical information over

a distance (American Telemedicine Association, 2011; Maheu, et al., 2001).

Telemedicine existed long before the internet, and involves using modern IT (e.g., computers, telemetry, 2-way interactive video) to deliver healthcare services remotely to patients and facilitate the exchange of information between primary care providers and specialists (Darkins & Cary, 2000; Maheu et al., 2001). The use of this technology allows for the deliverance of healthcare beyond cultural, social, and geographic barriers (Darkins & Cary, 2000).

Telehealth. Telehealth is seen by many as being a broader, more encompassing term, relating to public and community health, health education, the development of health systems as well as epidemiology (Darkins & Cary, 2000; Health Resources and Services Administration, 2011).

Benefits of Telemedicine/Telehealth

Engaging patients and families. In 2001, the Institute of Medicine (IOM) released the landmark publication, *Crossing the Quality Chasm*, identifying patient-centeredness as one of six key quality aims for the US healthcare system. Patient-centeredness relates to the provision of care that respects and responds to individual/family needs, values, and preferences of a patient—ensuring that their values guide clinical decisions (Institute of Medicine, 2001).

One means to achieve patient-centeredness is to allow patients and families to engage in their healthcare (Scholle, Torda, Peikes, et al., 2010). Health IT can be viewed as a tool to help improve patient and family engagement through the use of internet and computer-based tools to provide information, support communication between families

and healthcare providers, facilitate interactions between social services and support skills training (Epstein & Street, 2008; Scholle, Torda, Peikes, et al., 2010).

Access to care. To date, improvements in access to healthcare for large segments of the population have been a cornerstone of the development of telemedicine.

Telemedicine has the capability of overcoming not only distance, but also time barriers related to care—allowing patients access to primary and specialty care services regardless of their location (Bashshur, 2001). For example, the burden of travel to healthcare sites would therefore be reduced in specialty populations (e.g., frail elderly) who are often disenfranchised and underserved (Alverson, Holz, & D'Iorio, 2008).

Cost. Technology in general, is a major contributor to the rise in healthcare costs. Although technology has allowed for significant improvements in the management of illness, their use is often costly. Telemedicine technology however, has the potential to decrease and/or contain costs by allowing patients to remotely receive treatment within their home communities—and in some instances their homes environments (Bashshur, 2001; Wang, 2009). As a result, the need for transporting the frailest patients (e.g., elderly) to tertiary health care sites and/or specialist travel to remote locations can be reduced without compromising quality of care (Bashshur, 2001; Rojas & Gagnon, 2008). Further, the availability of electronic health information may eliminate unnecessary diagnostic tests, while enhancing the coordination and efficiency of care (Bashshur, 2001).

Quality of care. Telemedicine has the capacity to improve care quality by promoting the coordination and continuity of care through the availability of comprehensive health information, regardless of location. Technology may also

improve patient safety by facilitating communication and decision support between all providers, possibly reducing the risk of medical errors (Bashshur, 2001).

Use of Telehealth Technology for CG Support

Telehealth programs are a relatively novel approach to delivering support to CGs. Telehealth research has largely focused on chronic disease management specifically targeting patients themselves (Marineau, 2005). These programs have been shown to be acceptable by users regardless of age, have improved access to care, decreased healthcare costs and have been shown to positively affect the management of chronic illness (Bowles & Baugh, 2007; Darkins, Ryan, Kobb, et al., 2008).

Very few telehealth interventions have primarily targeted informal CGs. Several telehealth interventions have incorporated CGs into the educational foci, with content ranging from post-stroke recovery to home hospice support (Demiris, Oliver, Wittenberg-Lyles, & Washington, 2011; Lutz, Chumblor, Lyles, Hoffman, Kobb, 2009). Presently, no studies exist evaluating the use of telehealth technology to support CGs of older adults with UI in their role. Using technology to reach community-dwelling elders and their CGs may reduce the burden of the illness by decreasing travel to healthcare sites for treatment, improve UI treatment, and possibly reduce the costs associated with inadequate UI care (e.g., UI supplies, medication costs, health care services as a result of complications, nursing home placement) (Shamliyan, Wyman, Bliss, Kane, & Wilt, 2007). Use of telehealth also has benefits such as allowing the CG access to information as often as needed; and reviewing content more than once. Additionally, current technology will enable the use of engaging video and audio, with the opportunity to demonstrate specific skills.

Purpose

The primary objective of this study was to explore the feasibility and acceptability of an investigator (Student PI) developed, technology-facilitated, multi-component behavioral intervention designed to enhance the home environment of care-dependent community-dwelling older adults with UI, through informal caregiver education, skill development in prompted voiding strategies and individualized supportive assistance to strengthen informal caregiver self-efficacy.

UI is a highly prevalent and burdensome problem facing frail, community-dwelling elders and their informal CGs. According to the National Institutes of Health (2007) further research is needed to establish the best interventions to target this vulnerable population (Shamliyan et al., 2007). Despite this charge, over 40 years of behavioral research related to UI, and the fact that the majority of elders reside in the community rather than nursing home settings, this population remains understudied. Additionally, very few studies have addressed the burden of the disease on family CGs (Dubeau et. al., 2010; Talley et al., 2011).

Assumptions

According to Corbin and Strauss (1991) chronic conditions have a trajectory (i.e., course) that can be managed and shaped through the combined efforts of the individual, family members, and health care professionals. Although many chronic conditions have irreversible courses, with proper management these courses can be improved or stabilized (Corbin & Strauss, 1991). Therefore, chronic UI has a trajectory that is complex, yet amenable to proper management. In a population of frail community-dwelling, care-

dependent elders with chronic UI, proper management includes patient-and family-centered interventions which incorporate the efforts of health care practitioners.

Theoretical Framework

The Chronic Illness Trajectory Theory of Corbin and Strauss (1991) was used to explain how the home environment of the CR can be enhanced to manage the trajectory of chronic UI. The Chronic Illness Trajectory Theory of Corbin and Strauss (1991) assumes that the management of chronic illness is a very complex process which requires a level of nursing care which is equally complex. The theory presupposes that chronic illnesses are on a trajectory which can be managed or shaped. It is through this shaping, that illnesses can be made stable, and/or symptoms of the illness can be controlled through appropriate management (Corbin & Strauss, 1991). In order for the trajectory of the illness to be shaped, the joint efforts of the individual (care recipient), the family (e.g., CG), and the health care practitioner are required (Corbin & Strauss, 1991).

The management of the trajectory is guided by the *trajectory scheme* (i.e., treatment plan) and includes the control and management of symptoms throughout the various phases of illness—the overall goal being maintaining quality of life. The extent to which the trajectory scheme is actually executed, can be influenced by many factors, including: the setting of care (home environment), resources (e.g., access to UI healthcare provider), and relationship between the patient and involved family members (Corbin & Strauss, 1991).

The Home Environment

Within this framework, the home environment is seen as the center of chronic care management (Corbin & Strauss, 1991). Barris et al. (1985) and Cororan & Gitlin

(1992) conceptualized the home environment as encompassing four hierarchically distinct interacting layers: objects (items or tools in the home environment), daily tasks which make up life routines (e.g., toileting), social groups (e.g., family members residing within the household and other social resources), and culture. The belief is that each layer is modifiable, and can be adapted to the demands the environment places on an individual's abilities or competencies (Barris et al., 1985; Cororan & Gitlin, 1992).

This intervention aimed to modify three layers of the home environment: objects, daily tasks, and social groups; through CG education and social support. CGs received education and recommendations which included instructions on removing clutter (i.e., objects) and create an unobstructed path to help facilitate appropriate toileting (Du Moulin, 2009). The task layer was specifically targeted by educating CG skills on the task of properly toileting the CR (i.e., prompted voiding). For example, the CGs were educated on effective toileting techniques, verbal cuing, and positive reinforcement (Du Moulin, 2009; Palmer, 2004). Finally, the social group was targeted through both the telehealth and direct nursing support provided to the CGs (Corcoran & Gitlin, 1992). This framework has been extensively tested in the literature and has been found to be an effective approach to deliver CG-facilitated educational interventions, to improve the care of frail older adults (Gitlin et al., 2006; Gitlin et al., 2008).

Urinary Incontinence: The Chronic Illness

UI can be defined simply, as being any involuntary loss of urine (Abrams, et al., 2003). Although UI in many instances is a treatable condition, in the frail elderly, incontinence is often intractable (Ouslander, 2000). Due to the medical complexities frequently encountered in the oldest old (e.g., cognitive and functional impairments,

multiple morbidity, and polypharmacy), cure is often seen as an unrealistic goal (Teunissen, de Jonge, van Weel, & Lagro-Janssen, 2004). The outcomes of the management of UI in frail elders, therefore should be aimed at ameliorating symptoms, improving overall function, preventing development of adverse medical conditions which may result from the inadequate management of the condition (i.e., skin breakdown), and improved quality of life (Ouslander, 2000). The current study did not aim to necessarily cure of UI, but rather to improve UI related care-recipient (CR) and CG outcomes.

The Person

Within this framework, *the person* is conceptualized as anyone affected by chronic illness. Unless hospitalized, the primary responsibility of managing the illness process on a daily basis lies with the person and their family members (e.g., CG) (Corbin & Strauss, 1991). In this study, *the person* was operationalized as the CG, who is largely responsible for the management of the condition. Given the nature of the intervention, CR outcomes were evaluated as well.

The Trajectory Scheme

Illness-specific, treatment plans (i.e., trajectory schemes) are used to shape the illness course and maintain/improve quality of life, by providing direct assistance with symptom management and disability (Corbin & Strauss, 1991). Within this study, the intervention was designed to facilitate better management of UI within the home environment by modifying: objects, daily tasks, and social groups to improve the quality of life of CRs and CGs.

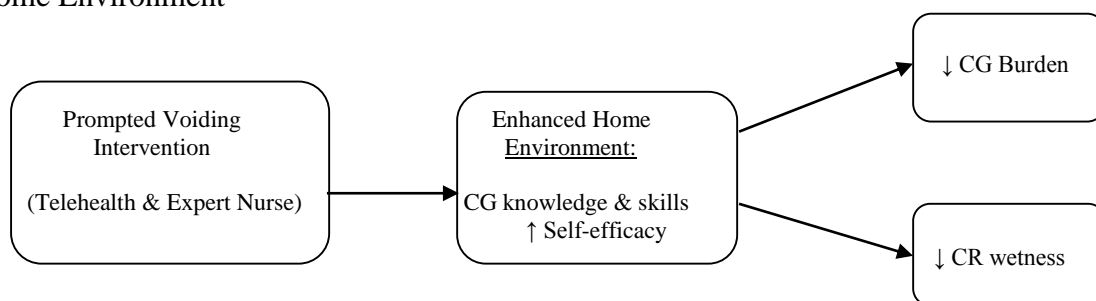
Self-efficacy. Self-efficacy has been a useful framework for research aimed at improving CG outcomes (Gottlieb & Rooney, 2004; Northouse, Katapodi, Song et al.,

2010; Savundranayagam, Montgomery, Kosloski, et al., 2011). In the Social Cognitive Theory (1988) self-efficacy is defined as one's perceptions of confidence in his or her ability to perform a particular task or behavior (Bandura, 1988). Self-efficacy is a modifiable construct, derived from performance accomplishments (i.e., mastering a particular skill), vicarious experiences (i.e., learning beneficial behavior from the observation of others), verbal persuasion, and emotional arousal (Bandura, 1977). Performance-based treatments foster behavioral accomplishments, minimize fear, and validate self-efficacy. Performance successes attained through treatments, strengthen self-efficacy and reduce the negative impact of circumstantial failure (e.g., inability to successfully toilet a family member) (Bandura, 1977). Previous studies have shown, that in the context of family caregiving (irrespective of the domain), high levels of CG self-efficacy have been associated with lower levels of distress (e.g., burden and depressive symptoms) (Gilliam & Steffen, 2006; Gonyea, O'Connor, Carruth, & Boyle, 2006; Gottlieb & Rooney, 2004; Rabinowitz, Mausbach, Thompson, & Gallagher-Thompson, 2007). In one study evaluating the effectiveness of a multi-component, performance-based intervention aimed at reducing dementia CG burden, CGs who received the intervention reported greater mastery, skill enhancement, and greater self-efficacy from baseline to post-intervention (Gitlin, Winter, Burke, et al, 2008). This present study used a similar performance-based treatment approach, with a goal of improving CG self-efficacy related to UI management. By giving CGs the knowledge, skill set, and support needed to successfully toilet their family members, it was hypothesized that performance successes attained through treatment, would strengthen CG self-efficacy related to the

management of UI and reduce the negative impacts of UI (i.e., CG subjective burden, CR leakages) (Bandura, 1977; Corbin & Strauss, 1991).

Self-efficacy: Vicarious experience and modeling. According to Bandura (1977) with self-efficacy, an individual's efficacy expectation is not only influenced by direct experiences of personal mastery, but also indirectly through the observation of others (i.e., vicarious experience) (Bandura, 1977). By observing others successfully perform tasks or surmount stressful situations, the self-efficacy of the observer can be increased. A competent model can teach an observer effective skills and strategies, resulting in higher perceived self-efficacy (Bandura, 1977). This study used modeling to help bolster CG self-efficacy. CGs viewed a video where a CG peer used prompted voiding to assist a CR with toileting. Although vicarious experiences have little resilience when employed alone, when used in conjunction with other strategies, self-efficacy can be enhanced (Bandura, 1977).

Figure 1. Model of UI Chronic Illness Trajectory Management through Modification of the Home Environment



CHAPTER II

REVIEW OF LITERATURE

Although not a life threatening problem, UI is a devastating condition highly prevalent among frail community-dwelling older adults (Chancellor, 1999; Chermansky & Chancellor, 2003; Nitti, 2001). In the United States, an estimated 17 million men and women suffer with bladder control problems—the highest prevalence rates being among the oldest old (Chancellor, 1999; Dubeau, Kuchel, Johnson, Palmer, et al., 2010; Landi et al., 2003). In a sample of 372 randomly selected community-dwelling elders, the prevalence of UI was 36% (Gnanadesigan, Saliba, Roth, et. al., 2004). In a cross-sectional survey of 2,866 elders receiving homecare, Du Moulin et al. (2008) found UI present in 46% of the population—the majority reporting moderate to large degrees of urine loss (Du Moulin, Hamers, Ambergen, Janssen, et al., 2008). In a larger study of 4,010 elderly persons receiving homecare, the prevalence of UI was approximately 33% (Sorbye, Finne-Soveri, Ljunggren, et al., 2009). In yet another study of 5,412 frail elders receiving homecare, Landi and colleagues (2003) found the prevalence of UI to be more than 50% (Landi, Cesari, Russo, Onder, et al., 2003).

UI in frail, community-dwelling elders is not only prevalent, but underdiagnosed and undertreated. In a study of over 2,000 homebound elders, half of the reported cases of UI lacked a sufficient diagnosis. Further, more than 58% of those without a diagnosis, suffered with considerable amounts of urine leakage (Du Moulin, 2008). In another

study of more than 5,000 incontinent elders receiving home care, several common reversible causes of UI were not only present in the population, but were strongly associated with the illness—e.g., urinary tract infections (adjusted odds ratio, 3.20; 95% CI 2.19-4.68) and environmental barriers (adjusted odds ratio, 1.53; 95% CI 1.15-2.02) (Landi, 2003). In a survey of 82,196 US Medicare recipients over the age of 65, Chang et al. (2008) found the prevalence of UI to be 37%—of those, 75% were burdened by it. Of the persons who reported UI related burden, 41% sought professional help for their symptoms; but only 50% of those who sought help actually received treatment from a healthcare provider (Chang, Gonzalez, Lau, & Sier, 2008).

In a cross-sectional descriptive study, Gnanadesigan and colleagues (2004) assessed the quality of care delivered to a random sample of 372 community-dwelling older adults enrolled in two managed care plans. Not only was UI present in 36% of the population, but physician records showed inadequate evaluation and treatment in 75% of new and worsening cases. Although proven beneficial in elder populations, only 13% of the sample were prescribed behavioral treatments. Additionally, patients seen by UI specialists in consult, received more comprehensive evaluation and treatment of the condition. This evidence suggests that UI is not only prevalent (33-50% in community samples) and inadequately evaluated and managed in older adults, but specialist care may be optimal (Gnanadesigan, Saliba, Roth, Solomon, et al., 2004).

Social, Psychological, and Economic Implications

Taking into account the high prevalence and inadequate management UI among community-dwelling frail elders, the psychological, economic and societal implications of the illness cannot be overlooked. UI has been associated with depression, decreased

sexual functioning, social isolation, loss of personal relationships and loss of quality of life (Dubeau, 2010; Farage et al., 2008). In the elderly specifically, UI has been related to decreased overall functioning—frequently present among elders of a higher mortality risk (Batista-Miranda, Molinuevo, & Pardo, 2007; Johnson, et al., 2000). Studies of the elderly population have also found lower urinary tract symptoms—UI specifically, to be an indicator of health, a marker for frailty, and a major indication for institutionalization (Johnson et al., 2000). In a prospective cohort study of 298 elderly residents of a continuing care retirement community (CCRC), Young (2009) explored risk factors for and time of permanent transition from independent living to nursing home over a three year time period. Eleven percent permanently transitioned to nursing home care; with UI as one of the predictive factors (RR 3.8, 95% CI 1.3-11.4) (Young, 2009).

The burdens of UI are not limited to social or psychological sequela. The economic implications of UI on personal and national healthcare expenditures are also troubling. Morrison & Levy (2006) estimated that the annualized cost of US nursing home admission related to UI—taking into account both elderly men and women, approximated six billion dollars in 2000. Langa et al. (2002) found the annualized cost of UI care in the US, including informal caregiving expenses and cost of UI products also averaged six billion dollars (Langa et. al., 2002). Stothers et al. (2005) extended the work of Langa et al. (2002) finding the overall economic burden of UI in males to be 29.4 billion dollars in direct medical costs. They further estimated the annual direct care costs to homebound persons to be over seven billion dollars. Compared with males without the condition, UI increased the annual per person expenditures for ambulatory care and hospitalizations related to incontinence, by approximately \$3,204 to \$7,702 dollars

(Stothers, Thom, & Calhoun, 2005). Subak and colleagues (2006) further found that community-dwelling US women with severe UI pay approximately \$900 annually for routine incontinence care (Subak et al., 2006).

Impact of UI on Caregivers

Over four million elderly persons within US require the assistance of a caregiver to perform one or more activities of daily living (Sorrell, 2007). As the US population continues to age proliferatively, more older adults will be living with chronic health problems (e.g., UI) and even more will require the assistance of informal caregivers to perform the most basic functions (Family Caregiver Alliance, 2012). Considering the fact that UI is not the only condition requiring informal CG attention, its additional burden is concerning. Informal CGs have been shown to be under an extreme amount of stress, without the added component of UI. When compared with those who do not provide care (i.e. non-caregivers), caregiving alone has been associated with increased strain, dyslipidemia, increased cardiovascular risk, and an increased mortality risk (Schulz & Beach, 1999; von Känel et al., 2008). Family caregiving has been further shown to negatively impact CG immune status, wound healing and has been linked to psychiatric morbidity (Lee, Colditz, Berkman, & Kawachi, 2003).

When compared with CGs of elderly persons without UI, CGs of elders with the condition have reported significantly more stress and burden. In a cross-sectional study, Sorbye and colleagues (2009) evaluated the prevalence of UI, associated individual characteristics (e.g., prevalence of catheters, use of pads, toileting assistance), and CG burden; in a random sample of n=4010 frail older adults receiving home care. Respondents were divided into two groups, based on the level of informal care (i.e., care

provided by family, neighbors, friends) required during the preceding week. Sorbye et al. (2009) found that CGs of care-recipients with UI were two times more likely to experience stress or burden, compared with CGs of continent elders (OR=2.2, 95% CI=1.8-2.7, $p < 0.001$) (Sørbye, Finne-Soveri, Ljunggren, et al., 2009). Gotoh and colleagues (2009) evaluated the impact of UI on the psychological burden of informal CGs, caring for frail elderly and disabled family members with UI. Of the 757 CGs included in the analysis, 60% (n=452) provided care to family members with UI. Compared to those with continent care-recipients, UI CGs had significantly higher reports of psychological burden (Gotoh, Matsukawa, Yoshikawa, Funahashi, Kato, & Hattori, 2009).

Langa et al. (2002) examined the impact of UI on informal CG time and also examined UI related costs, in a sample of 7,428 frail US older adults. After adjusting for co-morbidities (e.g., heart disease, DM, dementia, stroke), sociodemographic variables (e.g., net worth, gender, race), and living situation, UI was found to significantly increase the amount of care required, an average of between four and six hours per week in male care-recipients; between two and five hours per week in their female counterparts. The *additional* yearly cost of informal care for elders who suffered with UI ranged from \$700 to \$4,000—translating to over \$6 billion in annual UI-related, national informal caregiving costs (Langa et al., 2002).

Gallagher & Pierce (2002) conducted a phenomenological study evaluating a purposive sample of four caregiver-care recipient dyads, which aimed to evaluate how these dyads dealt with urinary incontinence. The themes which emerged were consistent across the dyads. CGs described multi-factoral coping deficits related to UI management

(e.g., depression, lack of personal time, inability to find adequate support in managing the condition, and the continuous nature of the caregiving role) (Gallagher & Pierce, 2002).

In 2003, Cassells & Watt used a grounded theory approach, to explore the impact of UI on older spousal CGs. A convenience sample of eight participants enrolled, all of whom were over the age of 65, with an average age of 77 years. Care-recipients had a wide array of chronic medical problems, but the reported duration of UI was approximately four years. The authors found several consequences associated with providing care to incontinent persons: sleep issues, social isolation, decreased intimacy, financial cost, and emotional responses. Additionally, CGs expressed a need for, and were appreciative of, practical information regarding incontinence management (e.g., selection of incontinence products) (Cassells & Watt, 2003). Further, in another phenomenological study which explored the meaning of incontinence (both fecal and urinary) in the lives of dementia CGs, the dual presence of incontinence and dementia translated into constant, round-the-clock care (Upton & Reed, 2005).

The burden of UI on family caregivers has also been related to decisions to institutionalize, in an effort to relieve the significant burden. In a cross-sectional study of 109 dementia caregivers aimed at evaluating reasons for institutionalizing care recipients, cognitive disorder was not the main reason. At the time of institutionalization, UI was the most frequent complaint (Thomas, Ingrand, Lalloue, et al., 2004).

Consistent across these studies, is the notion that UI CGs experience multifactoral burdens above and beyond those which are attributable to the general caregiving role. Further, UI CGs feel ill-prepared to assume the additional duties and burdens related to UI, which may lead to care-recipient nursing home placement. Supportive interventions,

therefore, aimed at adequately preparing CGs for the role of managing UI, have the potential to not only be well received, but to offer significant benefit to both CGs and CRs.

UI in Vulnerable Elders

Urinary incontinence among vulnerable older adults (e.g., those requiring homecare or those with dementia) is prevalent and challenging to treat. Rather than being an isolated condition as seen in younger age groups, in vulnerable elders the condition is complex, with multiple causative factors (Dubeau, 2010). Age related changes to the lower urinary tract and the presence of co-morbid illness (e.g., diabetes, COPD) increase the likelihood that UI will develop. Additionally, polypharmacy, a common occurrence among the frail elderly can exacerbate the condition. Several frequently prescribed medications (e.g., calcium channel blockers, cholinesterase inhibitors, alpha adrenergic agonists) can adversely affect the lower urinary tract and cause UI (Dubeau, 2010). Further, functional limitations commonly seen in frail elders (e.g., limited mobility and transferring) place them at higher risk of UI (Hagglund, 2010; Nelson & Furner, 2005).

One challenging factor in treating the condition in frail elders, is that common medications used in other populations, have a significant risk of adverse events. For example, oxybutynin (i.e., Ditropan) is a medication commonly prescribed for UI treatment, but in frail elders can adversely affect memory—worsening cognitive impairment (DuBeau, 2010). Behavioral interventions for UI (i.e., non-pharmacologic) in this cohort (e.g., prompted voiding) therefore, are considered the mainstay of treatment, because of their known efficacy and low risk profile (DuBeau, 2010).

Caregiver-facilitated Behavioral Interventions for UI

Despite the prevalence and impact of the disease and the known benefits of behavioral interventions, no recent studies have evaluated the use of these treatment approaches in the management of UI in frail community-dwelling elders requiring informal caregiver assistance (DuBeau et al., 2010). In sum, the few studies which have evaluated the effectiveness of caregiver-facilitated toileting interventions, though limited (e.g., low power, small sample sizes, lack of consistent measures of CG burden and positive aspects of caregiving such as self-efficacy) have demonstrated some improvement in UI outcomes—specifically, reductions in the volume and frequency of UI (with treatment effect sizes ranging from 0.2 to 0.97 and prompted voiding demonstrating the strongest evidence).

Given this, the reason for this dearth in the evidence for over a decade is not readily apparent, however, the lack of attention to this population further underscores the need for additional research in this area.

Patterned Urge Response Toileting

Colling and colleagues (2003) evaluated the effectiveness of a 6-week Patterned Urge Response Toileting (PURT) intervention in 78 care-dependent homebound elders. PURT, a behavioral intervention for UI, uses habit training with the assistance of an electronic monitoring device (data logger); which when placed in the incontinence garment of the care-recipient, can log the episode and time of urine leakage. The intervention group (n=43) received in-home instruction on how to perform the intervention by research staff, followed by weekly follow-up phone calls. Research staff was also accessible by pager, at any time, to answer questions. CGs were instructed to

record the frequency and volume of all continent and incontinent voids. If care-recipients were unable to report their own voids, caregivers were instructed to perform and record the results of two-hour wet checks over three consecutive days. CGs were instructed to carry out the PURT intervention during the day and night. The frequency of urine leakages were also recorded simultaneously by the data loggers, using a temperature-sensitive thermistor inserted into the incontinence garment for six 24-hour data collection periods over three weeks. During the 24-hour data collection period, study staff observed the caregiver in the home, ensuring the sensor was placed properly. During this time, staff also reinforced previous teachings about the importance of recording accurate data. Data from the loggers were used to verify caregiver records and to assist in developing individualized toileting schedules. Following a six-week treatment delay, the control group (n=35) received the same intervention. At the six-week post treatment time point, the investigators found no statistically significant difference in UI between the treatment and control groups following the intervention. They did find that the experimental group significantly improved in urine volume loss and UI frequency at the completion of the intervention. The volume of urine loss in the experimental group improved an average of 39% from baseline to follow-up ($p<.05$), compared with an average of 4% in the control group ($p=ns$) (Colling et al., 2003). UI frequency decreased by an average of 0.9 per 24 hour period in 75% of those in the experimental group ($p=0.02$). When describing the management of UI solely, the percentage of caregivers who felt ill-prepared to manage UI decreased from 30% at baseline to 18% by the completion of the intervention. No information regarding CG adherence to the protocol was presented, however when asked to rank the most burdensome caregiving tasks, UI moved from being third most

burdensome (at the beginning of the study) to sixth, at the study's conclusion (Colling et al., 2003)—suggesting that the intervention did not add to pre-existing burden.

Although these changes were not statistically significant, clinical meaning can be drawn from these findings. CG-facilitated behavioral interventions may offer some help in preparing family caregivers for their role in managing UI and may also reduce caregiver burden.

The findings of Colling et al. (2003) also support the outcomes of an earlier study, which examined the benefits of PURT in the nursing home setting (Colling, Ouslander, Hadley, Eisch, & Campbell, 1992). Colling et al. (1992) found that despite only 70% formal CG compliance with the intervention, 86% of frail nursing home elders who received the intervention (mean age 85, all with physical and/or cognitive impairment) showed significant improvement in UI from baseline to the 37-week post-treatment time point (Colling et al., 1992).

Scheduled Toileting

Jivorec and Templin (2001) evaluated the effectiveness of a six-month individualized scheduled toileting intervention to treat UI in 118 homebound elders with cognitive impairment. Participants were randomly assigned to treatment (n=77) and control groups (n=41). CGs in the treatment group were taught to provide toileting reminders to care-recipients based on a schedule developed in consultation with the CG. Voiding schedules were about every two hours for the majority of participants. The treatment group was also taught the importance of adequate and consistent fluid intake, and was taught to encourage care recipients to maintain proper hydration. Additionally, recommendations were offered to improve the home environment to make it easier to

toilet care-recipients. All groups received monthly phone calls from research assistants to maintain commitment to the study. For those in the control group, the phone call was a friendly discussion. Alternatively, the progress of the intervention and notable difficulties were discussed with the treatment group during their phone call. The investigators found that in CGs who received the intervention, the number of persons with improved incontinence was significantly higher than the control group ($Z = -1.83$, $p < .05$). Further supporting the benefits of the intervention, correlational analysis between baseline and post-treatment outcomes showed that less than 9% of the variance in post-treatment incontinence in the treatment group could be explained by baseline UI ($R^2 = .088$, $p = ns$). Analysis of the control group revealed that 58% of post-treatment UI could be explained by baseline UI ($R^2 = 0.58$, $p < .05$) (Jirovec & Templin, 2001). Treatment consistency was assessed at six months and was determined by comparing one-week voiding diaries with CGs' self-reported protocol adherence. If inconsistencies between CG self-report and the voiding diaries were present, the voiding diary was used in the analysis. Although no additional details regarding treatment adherence were presented, the investigators did find that most reasons for failure of the protocol were related to the cognitive status of the care-recipient (i.e. more advanced memory deficits resulted in increased resistance to toileting).

Prompted Voiding

Prompted voiding, a behavioral treatment for UI, has been used in incontinence research for over 20 years and is one of the most common approaches to managing the condition in frail populations (Engberg et al., 2002; Palmer, 2004). Prompted voiding, aims to improve the voiding habits of persons with functional and/or cognitive

limitations, with the use of operant conditioning. Through the use of consistent toileting aided by verbal prompts and positive reinforcement (i.e., verbal praise for successful toileting or dryness), continence is achieved (Roe, Milne, Ostaszkiwicz, & Wallace, 2007).

Several studies evaluating the effectiveness of prompted voiding in the nursing home setting have found it to be efficacious (Fink et al., 2008; Ouslander, Griffiths, McConnell, Riolo, Kutne, & Schnelle, 2005; Schnelle, Leung, Rao, et al., 2010). Schnelle and colleagues (1989) conducted one of the earliest randomized controlled studies in the nursing home setting evaluating the effectiveness of a prompted voiding intervention in 126 incontinent residents. Participants were randomly assigned to treatment (n=63) and delayed treatment group (n=63). The intervention group received hourly checks by research staff during 5-10 day periods, which included prompts to toilet and if successful, social reinforcement. Those who received the prompted voiding intervention were found to have significantly lower percentage of wet checks (17.8%) following the intervention, compared with those who received usual care (34.5%) ($p < 0.001$). In another randomized controlled trial, Hu and colleagues (1989) evaluated the effectiveness of a 13 week prompted voiding intervention in 133 incontinent female nursing home residents. The intervention was noted to be effective after 6 weeks of training. Those who received the intervention (n=65) had 0.57 fewer incontinent episodes compared with baseline ($p < .05$), at post intervention. The control group (n=68) were not found to have a significant improvement in number of incontinent episodes at the completion of the intervention period (Hu, Igou, Kaltreider, Yu, et al., 1989). These studies support the notion that prompted voiding can be a feasible approach to improve

UI in care-dependent elders who can state their name, transfer independently; however the results can only be generalized to the nursing home setting. Unfortunately, at present, little evidence exists evaluating the use of the intervention in community-dwelling, frail elders—particularly those with family caregivers (Dubeau et al., 2010).

In a small, two-group randomized, controlled, crossover trial, Engberg and colleagues (2002) explored the short-term effectiveness of a prompted voiding intervention in 19 cognitively impaired, homebound elders. Treatment consisted of an eight week intervention, which included weekly home visits by a nurse practitioner (NP). Caregivers in the intervention group (n=9) were instructed to prompt participants every two hours during waking hours only and to provide positive reinforcement for appropriate toileting. Treatment response was evaluated by the NP during the weekly visits and voiding intervals were increased to a maximum of three hours if 80% dryness was achieved. In addition to prompted voiding, caregivers were instructed to limit care-recipient caffeine intake, limit fluid intake in the evening, and elevate care-recipients' legs during the day to help with dependent edema. Following an eight-week attention control phase, the control group (n=10) crossed over and received the same intervention. Treatment effectiveness was determined by an investigator created formula, which determined percent reduction in UI frequency and percent reduction in wet checks. Adherence to the prompted voiding protocol was formally assessed at each treatment visit, based upon data from CG documented bladder diaries. CGs were found to be adherent to the prescribed toileting interval an average of 89% of the time (SD=10.4). CR cooperation with the CG prompts and toileting attempts were also determined from

bladder diaries. On average CRs responded to CG prompts by toileting 76% of the time (SD=34%) and voiding 71% of the time (SD=31.6%).

Although the study was only sufficiently powered to detect very large treatment effects ($d=1.14$), clinically significant improvements in leakages were noted among those who received the intervention (average 22% reduction in leakages) compared with their true baseline. Additionally, 80% of caregivers felt their care-recipient's UI had improved. Caregivers reported general satisfaction with the intervention, with a mean adherence of 89%. Although the findings of the study were not statistically significant, this may have been due to the size of the sample (Engberg et al., 2002).

Limitations

Varying design methods, definitions of UI, demographic characteristics of the CGs/care-recipients, outcome measures; as well as the paucity of research in this area make it challenging to draw conclusions across prior informal CG-facilitated behavioral interventions for UI in frail community-dwelling elders. However, several limitations can be identified. Firstly, although these studies were largely caregiver-dependent, very little objective assessments were completed at baseline and post-treatment time points to evaluate CG depression, mental status, functional status, or perceived burden. For example, although Engberg et al. (2002) measured CG perceived burden, satisfaction, impact, and mastery at baseline using validated instruments; they did not repeat these measures at the post-treatment assessment. The investigators did administer a CG satisfaction questionnaire at post-treatment, which yielded descriptive data citing CG perception of benefit in those who received the intervention. Without an additional objective assessment of perceived burden, satisfaction, impact and mastery, it is unclear

whether the described benefit was statistically significant. It is important to objectively quantify CG burden here, because CG's of frail elders are already burdened and additional burden may result in low adherence and poor CG/CR outcomes. Further, in the nursing home setting, where CG-facilitated behavioral interventions for UI have been well studied, CG adherence and burden have been cited in the literature as barriers to effective implementation (Ouslander et al., 2005; Talley et al., 2011).

Positive CG concepts (e.g., mastery or self-efficacy) are important to evaluate as they have been shown to inversely impact CG stress and depression (i.e. low levels of mastery associated with higher levels of stress) (Rozario & DeRienzi, 2008).

This study aimed to address these limitations by measuring CG perceived burden using validated tools and a repeated measures approach. This study also measured CG UI-related self-efficacy.

Health Information Technology & Chronic Illness Management

Telehealth is a term which refers to the delivery of health care from a remote location where the health care provider and the client communicate at a distance, rather than interacting in person. In an effort to improve care delivery, remove the barriers of distance, and decrease the costs associated with high-quality healthcare, an increasing number of projects have employed the use of telemedicine. In 1999, an evaluation of the US healthcare system found nearly 200 active telehealth projects, with an expected growth of nearly 40% annually over the next 10 years (Coleman, 2002; Marineau, 2005).

Telehealth research has largely focused on chronic disease management in patients with diabetes (45%), hypertension (15%), depression (9%), asthma (9%) and congestive heart failure (9%) (Marineau, 2005). Telehealth has proven to be an effective

way to support patients and family caregivers in the management of chronic illnesses (Lutz, Chumbler, et al., 2009). In the elderly veteran population, home telehealth programs have resulted in reports of a 19% reduction in the number of hospital admissions, 25% reduction in bed care days, an average patient satisfaction score of 86%, and substantially lower annual care costs as compared with costs of nursing home care (Darkins, Ryan, Kobb, et al., 2008). Presently, what is not known is whether the use of telehealth to support care-dependent homebound elders with UI and their family caregivers, is a feasible and effective approach to managing this debilitating condition.

Summary

UI is a significant problem facing vulnerable elders and their family CGs. Despite over 40 years of behavioral research related to UI, and the fact that the majority of elders reside in the community rather than the nursing home setting, this population remains understudied. Equally scarce, are evidenced-based programs, designed to address the burden of the disease on family CGs (Talley et al., 2011). Prior studies of the use of behavioral interventions in care-dependent frail community-dwelling elders have lacked consistent measures of CG burden and positive aspects of caregiving such as self-efficacy. This research study aimed to address this paucity in the evidence, test a novel approach to addressing a longstanding problem, and lay the foundation for future studies in the field.

CHAPTER III

METHODOLOGY

This chapter describes the methodological procedures used in this study, which includes the initial study methodology as well as the methodology following a design revision.

Initial Research Design

A randomized, controlled, design was initially proposed, to determine the feasibility and informal CG acceptance of an investigator (Student Principal Investigator) developed behavioral intervention (i.e., Tele-Prompt) and to estimate the effect of the intervention on informal CG and CR outcomes. An initial group of 20 CG-CR dyads were targeted to be randomized to receive either a 6-week multi-component behavioral intervention (n=12), consisting of six educational/skill building sessions and expert individualized, telephone support from a UI nurse expert (Student PI); or a control condition (n=8).

Initial Research Questions

The following research questions (Q) were initially investigated:

- Q1. Will CGs in the Tele-Prompt group use the telehealth technology and perform the intervention?
- Q2. Will CGs who receive Tele-Prompt rate it as acceptable and useful?
- Q3. What are the benefits and problems in using a telehealth-delivered behavioral intervention for UI?

- Q4. Will CGs who received Tele-Prompt report less subjective burden, greater UI knowledge and increased self-efficacy related to UI management, from baseline to post intervention compared with those in the control group?
- Q5. What is the estimated effect size for the average % change in wetness for care-recipients of CGs who receive Tele-Prompt compared with those in the control group, from baseline to 3 weeks and baseline to 6 weeks post-intervention?

Initial Population and Sample

This study initially targeted the informal CGs of community-dwelling older adults with UI who are receiving homecare services and reside within a metropolitan area in the southeastern United States. For the purposes of this study, *informal caregivers* were operationally defined as a family member or friend providing unpaid healthcare services to a community-dwelling older adult. Participants were recruited from the chronic care program in a large home health agency (HHA) in the Southeastern US. An estimated 500-600 patients receive personal care services (e.g., custodial care, companionship) in this agency at any given time—with more than 40% of them suffering with UI. Additionally, between 10 and 12 patients are newly admitted to the program on a weekly basis. Patients and informal CGs currently enrolled or newly admitted to this program, receive no treatment or education regarding UI disease management from the HHA or specific attention to CG support.

Power analysis. A power analysis was conducted to determine the appropriate sample size for the initially proposed study. Two-tailed tests were assumed and alpha was set at .05. An overall sample size of 128 CG-CR dyads (64 in each of two groups)

provides a power level of 0.8 to detect a medium effect ($d=.5$). Taking into account that this was a pilot, feasibility study a conservative sample of approximately 10% of the sample size required for the larger study is considered adequate (i.e., 12 CG-CR dyads, 6 per group) (Lackey & Wingate, 1998). However, a larger sample has the potential to yield greater insight into the feasibility of the intervention. Therefore, 20 CG-CR dyads (12 dyads in the intervention group, 8 dyads in the control group) were targeted representing a 67% increase, with slightly more in the intervention group to allow for potential dropout related to the burden of participation. To allow for possible attrition, oversampling was planned (Gardette, Coley, Toulza, & Andrieu, 2007). Because this was a pilot/feasibility study that would not be sufficiently powered to detect statistically significant differences, it was initially planned for the effects of the intervention to be estimated.

Active Intervention (Initial Design)

Tele-Prompt. *Telehealth-Delivered Prompted Voiding and Educational Intervention to Support Caregivers of Elders with Urinary Incontinence (Tele-Prompt)* is an investigator (Student PI) developed, six-week, multi-component behavioral intervention based upon clinical practice and is similar to the prior work of Enberg and colleagues (2002), who explored the effectiveness of an informal CG-facilitated prompted voiding intervention for homebound older adults with cognitive impairment (described in detail previously). Tele-Prompt extends this previous work by: 1) incorporating the use of emerging technology; 2) providing CGs with practical education regarding UI management (e.g., common myths, stress management, managing cost of

continence supplies, assistive transfers, falls risk reduction, skin care); and 3) uses UI-specific measures of CG outcomes (burden, knowledge, and self-efficacy).

CGs who received the active intervention received an educational/skill building program delivered via technology device that addressed two main objectives: 1) develop CG knowledge about the management of UI in the care-recipient; and 2) enhance the CG skill set in prompted voiding strategies. CGs also received a supportive component in the form of individualized, once-weekly telephone calls from a nurse with expertise in UI specifically in chronically ill older adults (Student PI); where additional education, clarification, reinforcement and expert support were offered based on the assessed needs of the CG.

Tele-Prompt educational foundation. Tele-Prompt drew upon Knowles' Adult Learning Theory (1973) as a basis for CG education. Table 1 describes the application of the theory to content design. According to Knowles (1973) the following principles of adult learning should be taken into consideration when designing learning activities for adult learners: 1) adults have a need to understand the rationale behind learning activities (i.e., the benefits of learning vs. disadvantages of not learning); 2) adults desire responsibility in their decision-making (i.e., self-direction) and need to be seen as being capable of such; 3) adults define themselves by their experiences and bring those experiences to learning; 4) adults learn when they are ready and committed to learn; 5) adults are task- or problem-oriented rather than subject-oriented; and 6) adult learning is motivated by intrinsic (e.g., the need to perform a job well) and extrinsic factors (Knowles, 1973; Knowles, 1996).

Table 1

Knowles' Adult Learning Principles (1973) and their Application in Tele-Prompt

Adult Learning Assumption	Tele-Prompt Application
Adults have a need to understand the rationale behind learning activities.	1. CGS were given details regarding the benefits of proper UI management, as well as the negative sequelae related to poor management of the condition.
Adults desire responsibility in their decision-making.	1. CGS were given the opportunity for self-directed learning where they had the ability to view modules based on their own assessed needs.
Adults define themselves by their experiences and bring those experiences to learning.	<ol style="list-style-type: none"> 1. Content was presented such that CGs were encouraged to relate information to their prior experiences. 2. Discussions generated by the weekly telephone calls with the UI nurse expert (Student PI) allowed them the opportunity to integrate their experiences into the learning process.
Adults learn when they are ready and committed to learn in relation to their assessed needs in their developmental role (e.g., spouse, worker, parent).	<ol style="list-style-type: none"> 1. CGs were required to consent to study participation, carrying with it the assumption that they were interested and willing to participate in the educational intervention. 2. CGS had direct experience managing UI in the CR prior to study enrollment, therefore the timing of this intervention coincided with the tasks of their developmental role – critically important in adult learning (Knowles, 1973).
Adults are task- or problem-oriented rather than subject-oriented.	<ol style="list-style-type: none"> 1. Tele-Prompt content included task-specific content related to UI management. 2. Educational Modules were presented using a problem-oriented approach.

(Table 1 Continues)

(Table 1 Continued)

Adult Learning Assumption	Tele-Prompt Application
Adult learning is motivated by intrinsic and extrinsic factors.	1. Tele-Prompt aimed to increase CG self-efficacy (intrinsic motivator) by increasing CG knowledge and skills related to UI management.

Tele-Prompt also addressed the primary styles of learning. According to Fleming & Mills (1992) visual learners acquire knowledge through visual cues (i.e., watching, seeing, viewing); auditory learners acquire knowledge through auditory cues (i.e., listening, hearing); reading/writing learners acquire knowledge through information displayed as words; while kinesthetic learners acquire knowledge through experiencing and doing (Fleming & Mills, 1992). All adults are capable of learning through all three styles, often times however, one style predominates (Fleming, 2006). Tele-Prompt therefore used: 1) videos, slides, and demonstrations to address the needs of predominantly visual and reading learners; and 2) audio voice-over presentations to address the needs of predominantly auditory learners.

Tele-Prompt educational content. The Tele-Prompt educational program consisted of six interactive modules: 1) UI in frail older adults (common causes and myths); 2) practical help to promote toileting safety (i.e., bathroom safety, falls risk reduction, assistive transfers); 3) prompted voiding skills; 4) demonstration of prompted voiding (video); 5) fluid management (i.e., adequate hydration, common bladder irritants); and 6) skin care and UI product costs. Content was developed based on qualitative studies of UI caregiver needs (Upton & Reed, 2005); international consensus treatment recommendations (DuBeau et al., 2010); and empirical evidence on the

negative sequelae of the illness (Gray, 2007; Newman & Wein, 2009). UI product selection was not included in the content because doing so had the possibility of resulting in a change in UI product usage during the active intervention period. Such a change had the potential of influencing CG or CR perceptions of wetness (e.g., switch to more absorbent product)—potentially threatening the internal validity of the intervention. Table 2 describes the learning objectives and content of the six modules.

Content validity. The design and content validation of the intervention took approximately one year to complete. An advisory panel consisting of two geriatricians with clinical and research expertise in the treatment of UI in frail older adults, a nurse practitioner with expertise in behaviorally based interventions for genitourinary disorders, HHA Administrative staff (Director and Director of Nursing), two HHA nurses, an information technology specialist with expertise in instructional technology design and educational interventions, three (3) PhD prepared Professors of Nursing with combined expertise in clinical research, UI, gerontology, family caregiving and caregiver supportive interventions, as well as one (1) informal caregiver volunteer. The Director of Operations and Director of Education from a National Family Caregiver Organization prior to module development also provided recommendations regarding CG educational needs and support. The advisory panel reviewed the content and proposed delivery methods of the intervention and provided suggestions and feedback which were incorporated into the final module content. A similar approach was taken by Lewis et al. (2010) to develop an internet-based psycho-educational supportive program for dementia caregivers (Lewis et al., 2010).

Table 2

*Tele-Prompt Module Learning Objectives and Educational/Skill Building**Content*

<p>Module 1: UI in frail older adults</p> <hr/> <p>Learning Objective: CG knowledge development</p> <ul style="list-style-type: none"> a) UI in care-recipients is not a direct reflection of their caregiving abilities; however they can and should take an active role in the management of the condition. b) Urine loss is an involuntary action, not one of retaliation by the care-recipient, and should not be taken personally (Abrams, P., Cardozo, L., Fall, M., et al., 2003; National Association for Continence, 2011). c) Common causes of UI among frail older adults include: abnormal changes in the urinary system, loss of mental ability, physical disability, uncontrolled or undiagnosed medical condition, constipation, side effect of medications (Vaughan, et al., 2011). d) Five common myths regarding UI in older adults will be discussed, including: 1) UI is a normal part of aging; 2) Very few people have UI; 3) Drinking less fluid will help manage leakages; 4) UI is not treatable; 5) UI in the care-recipient is a direct reflection on CG abilities. e) Stress management strategies: 1) be realistic, 2) improvements may be small, 3) anticipate setbacks, 4) take care of yourself (mind, body, spirit) (Family Caregiver Alliance, 2013) <hr/> <p>Module 2: Practical help to promote toileting</p> <hr/> <p>Learning Objective: CG knowledge development and skill enhancement</p> <ul style="list-style-type: none"> a) The effects of dementia on the CRs ability to understand and respond to voiding urges. b) Observe CRs for toileting cues, such as behavioral disturbance or pulling on clothing (NAFC, 2011). c) Dementia can affect CR's ability to remember the uses of and the ability to find common objects (Specht, 2011). d) Given strategies to promote toileting such as painting bathroom door handle or toilet seat covers a bright color, making them easy to find. Another strategy is to remove common household items that can easily be mistaken for a toilet, such as floor plants and small trash cans (NAFC, 2011). e) Practical aspects of toileting safety presented (e.g. the use of proper body mechanics with transfers, toileting in public settings; using raised toilet seats and installing grab bars) (NAFC, 2011). f) To reduce the risk of falls, CGs taught to respond to CR toileting requests in a timely manner—especially if assistance is need while toileting (Newman & Wein, 2009; NAFC, 2011). <hr/>

(Table 2 Continues)

(Table 2 Continued)

g) Other strategies such as using a non-slip floor mat in the bathroom to reduce the risk of slipping in urine; maintain a well-lighted path to the bathroom that is free of obstacles; and use a bedside urinal or commode if CRs toilets at night (Newman & Wein, 2009; NAFC, 2011).

Module 3: Prompted voiding skills session

Learning Objective: CG knowledge development and skill enhancement

a) Perform prompted voiding on a daily basis, during daytime hours only at 2 hour intervals (Engberg et al, 2002).

b) Approach CRs and focus the attention on continence by asking whether he/she is wet or dry (Engberg et al., 2002).

c) Check to see if the incontinence pad or undergarment is wet or dry (Engberg et al., 2002).

d) If the CR is dry, then the CG will offer positive feedback in the form of praise and social interaction, and then offer toileting (Engberg et al., 2002).

e) If the CR is wet, then the CG would toilet CR without praise or social interaction, therefore giving negative reinforcement, but never punishment (Engberg et al, 2002; Newman & Wein, 2009).

f) If the CR refuses toileting after being offered initially, the CG is to offer toileting 2 additional times (Engberg et al., 2002).

g) The CG will then provide toileting assistance and encourage voiding and provide positive feedback (i.e. praise and social interaction) for appropriate toileting. CG will remind the CR of the next toileting time (Newman & Wein, 2009).

h) At the end of this module, the CG will be referred to view the “Prompted Voiding Video.”

Module 4: Prompted voided video

Learning Objective: CG skill enhancement

a) A 10-minute video demonstrating an actual family CG or healthcare professional successfully performing prompted voiding with a CR, after overcoming a series of stressful circumstances or incorrect toileting techniques.

b) CGs encouraged to review this module as often as needed.

Module 5: Fluid management strategies

Learning Objective: CG knowledge development and skill enhancement

a) CRs should maintain adequate hydration by drinking 6-8 eight ounce glasses of fluid daily. Underhydration can lead to constipation, urinary tract infections, and decreased bladder capacity (Newman, 2009).

b) If getting up at night to urinate is an issue, reduce or eliminate fluids 2-3 hours before bedtime, with the goal of getting the adequate daily fluid intake during the daytime hours (Vaughan, Endeshaw, Nagamia, Ouslander, & Johnson, 2009).

c) CGs shown a list of common bladder irritants (e.g. artificial sweeteners, highly spicy foods) with suggestions to minimize dietary exposure as much as possible (Newman & Wein, 2009). Gradually reduce or eliminate caffeine in the diet to a maximum of 2 cups per day (200mg) (Newman & Wein, 2009).

(Table 2 Continues)

(Table 2 Continued)

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- d) Read food labels and look for hidden sources of caffeine. Research suggests that higher levels of caffeine intake (more than 450 mg per day) are associated with higher incidences of UI (Jura, 2011).
 - e) Decaffeinated beverages are acceptable, but that these are not completely caffeine-free (Newman & Wein, 2009).
-

Module 6: Skin Care and UI costs

Learning Objective: CG knowledge development and skill enhancement

- a) Skin damage in UI and the consequences if left untreated (Doughty, 2006).
 - b) Although skin damage is common in UI, with proper skin care damage can be prevented (Doughty, 2006).
 - c) Goal of skin care is to maintain the health of the epidermis and limit exposure to irritants (Doughty, 2006).
 - d) To keep the epidermis of the CRs healthy, CGS taught to use gentle techniques while cleaning the perineum (e.g. avoid rubbing and scrubbing, use of harsh cleansers and soaps) (Doughty, 2006).
 - e) Additional strategies including: 1) the application of moisturizer to restore the lipids in the skin and 2) the use of moisture barriers to protect the skin from irritants (e.g., lanolin, petroleum, zinc oxide) (Doughty, 2006).
 - f) Develop and maintain a daily routine for skin care (Beeckman, 2009; Gray, 2007). Contact the CR's healthcare provider if new skin breakdown exists, for appropriate evaluation and timely treatment.
 - g) Although UI products can be helpful, cost is a major problem for some. Generally Medicare and private insurers do not cover the cost. In some instances however, if UI is a listed medical diagnosis and products are ordered by a health care provider—they may be covered. CGs will be encouraged to talk with their insurers to see if this would apply to your situation.
 - h) If your CR is entitled to VA benefits, VA does cover the cost of UI supplies, Medicaid may cover some situations, bulk-ordering online can be a cost-effective way to get products (try to look for hospital grade), and there are grants which may be available.
 - i) Contact: Area Agency on Aging, local Medicare /Medicaid Agencies, Social Services for more details.
 - j) South Carolina has a Family Caregiver Supplemental Support Program with a selection process, but CGs may receive \$550 per year for UI supplies (State of South Carolina, Office on Aging, 2013)
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Note. CG=caregiver; CR=care-recipient; VA=Department of Veterans Affairs

Tele-Prompt telephone visits. Telephone visits were conducted by the Student PI, who is a nurse practitioner, board certified in geriatrics, with expertise in clinical and research treatment of UI and family caregiver support, and over 16 years of experience.

Telephone visits occurred according to an established protocol to allow for standardization of the intervention (Appendix D). Telephone visits occurred on a weekly basis, beginning Week 1; and were scheduled at the convenience of the CG. Telephone visits addressed CG questions regarding educational/skill building content; and were also used to troubleshoot any device issues. The Student PI maintained a telephone visit log for each CG telephone encounter, detailing the length of the call and topic(s) of discussion.

Control Condition (Initial Design)

It was initially planned that during the six-week intervention period, CGs randomized to the Control group would receive their **usual care**, coupled with **weekly telephone visits** from the Student PI. The weekly telephone visits would follow a set protocol with standardized weekly discussion topics to include: 1) Durable Power of Attorney (Week 1); 2) Living Trusts (Week 2); 3) Organize your important papers (Week 3); 4) Communicating Effectively with your Healthcare Provider (Weeks 4 and 5); and 5) Preparing for Emergencies or Natural Disasters (Week 6).

Control condition telephone visits. The goal of these telephone calls was to maintain CG interest in the study and control for the level of attention given to the active intervention group. It was planned that special care would be taken by the Student PI, to not discuss any issues related to UI during the telephone visits. At the completion of the six-week study period, CGs in this group were to be given the option to review the same educational/skill building modules as those in the Tele-Prompt group via the telehealth device.

Final Research Design

The initial research design was revised to meet recruitment and enrollment goals. The following sections describe the revised research methodology.

A quasi-experimental, single group, pretest-posttest design was used to determine the feasibility and informal CG acceptance of Tele-Prompt and estimate the effect of the intervention on informal CG and CR outcomes. A group of three CG-CR dyads received a 6-week multi-component behavioral intervention, consisting of six educational/skill building sessions and expert individualized, telephone support from a UI nurse expert (Student Principal Investigator).

Final Research Questions

The following research questions (Q) were investigated:

- Q1. Will CGs use the telehealth technology and perform the intervention?
- Q2. Will CGs rate it as acceptable and useful?
- Q3. What are the benefits and problems in using a telehealth-delivered behavioral intervention for UI?
- Q4. Will CGs report less subjective burden, greater UI knowledge and increased self-efficacy related to UI management, from baseline to post intervention?
- Q5. What is the average % change in wetness for care-recipients from baseline to 3 weeks and baseline to 6 weeks post-intervention?

Final Population, Sample, and Recruitment

This pilot study targeted the informal CGs of community-dwelling older adults with UI who reside within a metropolitan area in the southeastern United States. For the

purposes of this study *informal caregivers* were operationally defined as a family member or friend providing unpaid healthcare services to a community-dwelling older adult. To optimize recruitment efforts, participants were recruited in four ways:

- 1) **Large HHA.** Caregivers were recruited from a large home health agency (HHA) in the Southeastern US. An estimated 1,000 patients receive chronic and short-term services (e.g., short-term rehabilitation, custodial care, companionship) in this agency at any given time—with more than 40% of them suffering with UI. Additionally, between 10 and 12 patients are newly admitted to the program on a weekly basis. Potential participants were identified by the staff at the home health agency and will be referred to the Student PI for screening. HIPPA authorization was obtained.
- 2) **Small HHA.** Caregivers were recruited from a small HHA in the Southeastern US. An estimated 100 patients receive home health agency services at any given time. Home health agency staff were provided with an IRB-approved study flyer. Potential CG participants were identified by HHA staff and encouraged to contact the Student PI for more information about the study, if they were interested. No referrals or Protected Health Information (PHI) were sent to the Student Investigator.
- 3) **Caregiver Advocacy Groups.** Local informal CG advocacy groups were provided with a description of the study and an IRB-approved study flyer. Potential CG participants were encouraged by the advocacy group leaders to contact the Student PI for more information about the study, if they were

interested. Additionally, the Student PI distributed IRB-approved study recruitment flyers at CG support group meetings.

- 4) **Referral.** Local geriatric non-investigator primary care provider colleagues were provided with an IRB-approved study flyer and/or description of the study with the contact information for the Student PI. Potential CG participants were encouraged to contact the Student PI for more information about the study, if they were interested. No PHI was given to the Student PI. Potential participants were required to initiate contact with the Student PI.

Enrollment. After potential participants were identified a baseline telephone pre-screening was conducted by the Student PI to confirm willingness to participate, assess eligibility (care-recipient with UI and dependent), and schedule baseline in-home visit. The in-home screening and enrollment visit, was conducted by the Student PI and included obtaining informed consent from both the CG and CR as previously noted. The Student PI then administered the baseline assessments (see Figure 2) and screened CR's for their ability to state their name or reliably point to one of two objects in the room (Ouslander et al., 1995). At the conclusion of this visit, inclusion/exclusion criteria were reviewed. If the CG/CR dyad met the inclusion/exclusion criteria up until that point, CGs were given the baseline 3-day bladder diary to complete and return at the next in-home visit. At the second in-home visit, the Student PI reviewed the baseline 3-day bladder diary and again review inclusion/exclusion criteria. If CG/CR dyads met inclusion criteria they were continued in the study.

Revised power analysis. A power analysis was conducted to determine the appropriate sample size for the proposed study. Two-tailed tests were assumed and alpha

was set at .05. An overall sample size of 34 CG-CR dyads provides a power level of 0.8 to detect a medium effect ($d=.5$). Taking into account that this is a pilot, feasibility study a conservative sample of approximately 10% of the sample size required for the larger study is considered adequate (Lackey & Wingate, 1998). Because this was a pilot/feasibility study and was not sufficiently powered to detect statistically significant differences, the effects of the intervention were described descriptively.

Final Active Intervention and Control Condition

The Tele-Prompt intervention was developed and delivered to all CGs as previously described. Due to the design change, no CGs received the control condition.

Inclusion and Exclusion Criteria

Inclusion criteria. In order to be included in this study CGs were required to meet the following criteria: 1) informal CG of a community-dwelling older adult with UI; 2) self-identify as being primarily responsible for managing CR's UI and reside with them (in order to perform the intervention); 3) reachable by telephone; 4) able to read and speak the English language; 5) able to visualize the computer screen/images; and 6) willing to participate in study activities (e.g., weekly telephone calls, 3-day bladder diaries, use of Tablet-PC). CRs were required to meet the following criteria for inclusion in the study: 1) adult, age 60 or older; 2) UI present for at least 3 months. This criterion has been used in prior research targeting chronic UI in care-dependent, community-dwelling elders, to help establish the chronicity of the condition (Engberg, et al., 2002). Since this intervention also targeted chronic UI, this criteria was also used in the current study; 3) UI previously evaluated by a healthcare provider (as indicated by the informal CG) or identified previously on the HHA assessment forms (e.g., Outcome and

Assessment Information Set (OASIS) (Centers for Medicare and Medicaid Services, 2012); 4) able to reliably state his/her name or accurately point to one of two objects in the room. This screening parameter was used successfully in a prompted voiding intervention for care-dependent nursing home residents, to screen out CRs with cognitive impairment at a level that would prevent them from participating in the intervention (Ouslander et. al, 2005); 5) Transfer with the maximum assistance of one person moderate assist. This criterion was used to screen out bedridden CRs or persons with a high level of immobility as this may have limited CG ability to assist them with toileting and perform the intervention. This screening parameter was also used successfully in a prompted voiding intervention for care-dependent nursing home residents (Ouslander et. al., 2005); 6) awake at least six hours during the daytime (to participate in the intervention); and 7) require CG assistance for \geq one activity of daily living (ADL) or \geq three instrumental activities of daily living (IADLs).

Exclusion criteria. CG/CR dyads were excluded if the following conditions were present: 1) CG inability to maintain study documents; 2) CG or care-recipient with less than 6 month life expectancy, 3) CR with severe behavioral disturbance as indicated by CG, 4) CR with chronic renal failure and on dialysis; and 5) CR with an indwelling catheter or continuous external catheter use.

Data Collection and Measures

This section describes the instruments that were used for data collection. A summary of variables and measures can be found in Table 3.

Caregiver Outcomes

Self-efficacy in UI management. The Perceived Competence Scale (PCS) (Deci & Ryan, 1985) was used to measure CG self-efficacy in UI management. The PCS is a 4-item, Likert-type scale which has been used in various studies both independently and in conjunction with other constructs from the Self-Determination Theory (1985) to measure perceptions of competence in relation to a particular activity (Deci & Ryan, 1985). The PCS has demonstrated construct validity and internal consistency reliability coefficients above .80 (Williams & Deci, 1996; Williams, Freedman, & Deci, 1998). In this study, the scale was adapted with permission to measure CG perceived competence in managing CR UI. For example, one item read: *I feel confident in my ability to manage my friend/family member's urine leakage*. Items responses range from 1 (not at all true) to 7 (very true). Total scores range from 4-28, with higher scores indicating higher feelings of competence in performing the activity.

Subjective UI burden. The Incontinence Impact Questionnaire Short Form (IIQ-7) (Uebersax, Wyman, Shumaker, et al., 1995) was used to measure CG burden related to the management of UI in the CR. The IIQ-7 is a seven-item, Likert-type scale that has been extensively used to measure the life impact of UI on several personal domains: physical activity, social relationships, travel, and emotional health (Moore & Jensen, 2000). The scale was initially designed for use in populations of women with UI, but has documented validity and reliability in male populations as well (Chan, Choy, Lee,

Pang, Yip, et al., 2010; Moore & Jensen, 2000). The scale has been shown to have a content validity index of 0.88, internal consistency reliability coefficients ranging from 0.87 to 0.92, and test-retest reliability of 0.88 (Chan et al., 2010; Moore & Jensen, 2000). For this study, the instrument was adapted with permission, to measure CG rather than care-recipient burden, with the stem question modified to read *“Has caring for your care-recipient’s urine leakage affected your...”* Subsequent items include: *ability to do household chores; physical recreation such as walking, swimming, or other exercise; feeling frustrated, etc.* Items responses range from 0 (not at all) to 3 (greatly). Potential scores range from 0-21, with higher scores reflecting higher UI impact or burden (Moore & Jensen, 2000).

UI knowledge. The Urinary Incontinence Knowledge Scale (UIKS) (Yuan & Williams, 2010) was adapted with permission, to measure CG knowledge related to the management of UI. The instrument was developed from clinical practice guidelines, and validated in a population of non-healthcare workers (Yuan & Williams, 2010). The UIKS consists of 30 items, which include knowledge of UI risk factors (items 1-5), UI symptoms (items 6-10), impact of UI (items 11-15), prevention of UI (items 16-20), UI treatment (items 21-25), and UI management (items 26-30). Answers choices include: true, false, or don’t know. Items are scored dichotomously, with 1 point given to correct answers and 0 points given for incorrect or “don’t know” answers. Total scores range from 0-30, with scores <18 indicating poor knowledge; 18-24 indicating moderate knowledge; and >24 indicating good knowledge. The instrument was found to have an established content validity index of 0.75 based on expert review and an internal

consistency of 0.69 in a population of older adult, non-healthcare workers (Yuan & Williams, 2010).

Care-Recipient Outcomes

Daily frequency of checks wet. Daily frequency of CR UI (i.e wetness) upon physically being checked was measured by the 3-day bladder diary (Appendix E). Bladder diaries have been used extensively in UI research and have been shown to be reliable and reproducible measures of frequency of urine leakage (Colling, 2003; Engberg et al., 2002; Ouslander, 2005; Wyman, Choi, Harkins, Wilson, et al., 1988). Three-day bladder diaries were chosen as the outcome measure for several reasons. Although 7-day bladder diaries are used more commonly in studies of UI and urinary frequency, *3-day bladder diaries* have been shown to be equally as effective and reliable, with significantly higher rates of compliance and better record keeping (Dmochowski, Sanders, Appell, Nitti, & Davila, 2005). Further, 7-day bladder diaries may be too burdensome to informal CGs. In a study evaluating the effectiveness of an informal CG facilitated prompted voiding intervention, 33% of CGs found 7-day diaries to be difficult (Engberg, et al., 2002). Therefore, in this study, CGs completed a bladder diary for three consecutive days, which was adapted with permission from a previous study of prompted voiding in a population of care-dependent homebound older adults (Engberg et al., 2002). CGs were required to record the daily number of CR voids, urine leakages found when physically checking the care-recipient when toileted at their normal interval as well as CR and CG-initiated voids (Engberg et al., 2002; Ouslander, 2005). The average daily frequency of checks wet was determined by first calculating the total number of checks wet for the entire 3-day bladder diary, then dividing that number by the number of diary

days (three). The average daily frequency of checks wet was also be analyzed at the completion of the study, in terms of the percentage of change over the six week intervention period.

Caregiver and Care-Recipient Characteristics

CG and CR general health. The Demographics and Clinical Characteristics Form (DCCF) is an investigator developed tool that was used to document the chronic medical conditions of the CGs and care-recipients. The form also includes inquiries regarding CR conditions which may warrant immediate referral to his/her primary care provider for further evaluation (e.g., CHF exacerbation, undiagnosed obstructive sleep apnea). Additionally, the tool was used to establish the baseline health status of the CGs.

CG depressive symptoms. The Center for Epidemiologic Studies Depression Scale (CES-D) was used, with permission, to descriptively assess for the presence of depressive symptoms in the CG. There is strong evidence that CGs experience high levels of depressive symptoms (Dang, Badiye, Kelkar, 2008; Papastavrou, Charalambous, Tsangari, et al., 2012). The CES-D is a widely used depression measure used in CG research (Bejjani, Snow, Judge, et al., 2012; Losada, de los Angeles Villareal, Nuevo, et al., 2012; Tang, Chang, Chen, et al., 2012) and is a 20-item, self-report depression scale, designed to identify major depressive symptoms. The items assess the frequency of depressive symptoms during the preceding week and are scored using a 0-3 Likert-type scale. Items 4, 8, 12, and 16 are worded positively and were reverse coded by subtracting each score from 3. All items are then summed to obtain an overall score ranging from 0-60, with a score of 16 or higher indicating possible depression (Radloff, 1977). The CES-D has reported alpha coefficients ranging between 0.76 and .90 in

multiple populations. The instrument also has established validity, with sensitivities for detecting depression ranging from 63.9-100% and specificities ranging from 53-93.9% (Myers & Weissman, 1980; Shinar et al., 1986; Weissman et al., 1977).

CG and CR demographics. The Demographic and Clinical Characteristics Form is an investigator developed (Student PI) tool that was used to collect baseline demographic characteristics on the CGs and CRs such as age, ethnicity, co-morbidities, household living situation, number of years as a CG to the CR; household income level, work status, educational level, and prior use of technology/computers.

Clinical Characteristics of Caregiving Situation

CR functional abilities. The Lawton Instrumental Activities of Daily Living Scale (IADL) (Lawton & Brody, 1969) was used, with permission, to measure the **independent living skills of the CRs**. The instrument measures eight domains of function which are assessed for both care-recipient genders and include: 1) the ability to use the telephone; 2) shopping; 3) responsibility for own medications; and 4) ability to handle finances. The instrument has been used extensively to assess the function of care-dependent older adults (clinically and in research); having an interrater reliability of 0.85 and correlation between other measures of functional assessment ranging from 0.41 to 0.61 (Graf, 2008; Lawton & Brody, 1969). Each functional domain was scored trichotomously (1-unable, 2-needs assistance, 3-independent), and summed to form scores of 8-24, with higher scores indicating higher functional ability (Graf, 2008; Lawton & Brody, 1969). The Physical Self Maintenance Scale (PSMS) (Lawton & Brody, 1969) was used, with permission, to measure the **physical functioning and disability of the CRs**. The instrument includes both ADL and IADL scales and was

developed for use in elderly persons residing in institutional or community or chronically ill populations (Lawton & Brody, 1969). Only the six-item ADL scale was used in this study given its proven reliability, validity and extensive use in geriatrics research (McDowell & Newell, 1996; Yilmaz, Turan, & Gundogar, 2009). The ADL scale measures independence in six activities (toileting, feeding, dressing, grooming, physical ambulation, bathing) on a five-point, Guttman scale ranging from total independence to total dependence (1-5). Items are summed for an overall score ranging from 6 to 30, with higher scores indicating higher dependence (Lawton & Brody, 1969). The ADL scale has high reported inter-rater reliability ranging from 0.87 to 0.91 in clinical and research settings, with a Guttman reproducibility coefficient of 0.96 (Lawton & Brody, 1969). The scale has been tested in institutionalized and elderly persons residing at home, showing correlations with physician ratings of functional health, ranging between 0.61 and 0.62 (Lawton & Brody, 1969).

CR continence status. The Demographics and Clinical Characteristics Form as previously described, was used to obtain details regarding the care-recipient's history of UI. The tool also included inquiries regarding the CR's onset of symptoms and previous pharmacologic and non-pharmacologic treatments.

CG acceptance of the intervention. CG acceptability of the intervention was measured as a component of the feasibility analysis. Acceptability of the telehealth technology was measured objectively using a subscale from the Technology Acceptance Model (TAM) (Davis, 1989)—*perceived ease of use* (Davis, 1989). According to Davis (1989) *perceived ease of use* is defined as the extent to which one perceives a particular technology system as being both mentally and physically effortless (Davis, 1989). The

TAM posits that *perceived ease of use* can be used to predict attitudes toward and future uses of technology (Davis, 1989). The TAM has been widely tested in various disciplines and validated in multiple populations (Chutter, 2009). The 6-item subscale has documented strong convergent, discriminant, and factorial validity and internal consistency reliability coefficients between 0.91 and 0.94 (Davis, 1989). In this study, *CG perceived ease of use* will be measured by the Perceived Ease of Use of Tablet PC (PEOU) scale (Davis, 1989). The PEOU scale is a 6-item, Likert-type scales which will be adapted, with permission, to reflect CG acceptance of the tablet PC (Davis, 1993). A simple, objective definition of a tablet PC was added at the beginning of the questionnaire, which read: *“A tablet personal computer is a small computer with a large screen, which can be carried or moved around. Unlike other computers that have keyboards, this device does not. To move from one display to another, you have to touch the screen”*. Individual scale items in the instrument were also adapted to reflect the use of the tablet PC. For example, one item read: *“Learning to operate the tablet PC is easy for me”*. Item responses range from 1 (strongly agree) to 7 (strongly disagree), with total scores ranging from 6-42. Lower scores indicate greater perceived ease of use.

CG perception of intervention benefit. CG perception of benefit was measured subjectively during the **Exit Interview**. At the conclusion of the study, the Student PI administered the Patient Perception and Satisfaction questionnaire, where CGs were asked open-ended questions regarding their perceptions of the benefits of the intervention, content usefulness, and insights into the program. Interviews were conducted face-to-face.

Adherence Assessment

Adherence to the intervention was included as part of the feasibility analysis and was assessed from data regarding CG adherence to prompted voiding and CG use of the technology. Based on reported adherence rates from a previous study of prompted voiding in care-dependent community-dwelling homebound older adults (Engberg et al., 2002) adherence to the present intervention will be operationally defined as: 1) CG performs prompted voiding at the recommended frequency at least 80% of the time; and 2) CG views at least 80% of the modules during Week 1 of the study (i.e., at least 4 modules).

CG adherence to prompted voiding. CG adherence to the prompted voiding intervention was measured using the 3-day Prompted Voiding Diary. The 3-day Prompted Voiding Diary is an investigator developed (Student PI) tool, modeled after prompted voiding diaries used in a similar study in a care-dependent population, with permission (Engberg et al., 2002). CGs were instructed to use the diary to record the frequency and results of daytime prompted voiding attempts and wet checks, including the toileting outcome (Engberg et al., 2002). The diaries were maintained by the CGs on a weekly basis throughout the six-week intervention period. CGs were instructed to complete the diaries during daytime hours only (approximately four prompting attempts per day) (Ouslander et al., 1995). Adherence to prompted voiding was determined at the completion of the study by averaging the percentage of times the CG was adherent to the recommended number of prompting attempts during the six week study period.

CG technology usage. CGs were instructed to maintain a weekly Educational Module Viewing Log where they recorded the frequency and extent to which they

viewed each educational module (i.e., entire, part, etc.). CGs were also given a short evaluation question where they were asked to rate each module's helpfulness. All of these data were reported descriptively and were included as part of the feasibility analysis. CG technology usage was calculated by the number of modules viewed by the CG during the six week study period.

Telephone visit log. For each weekly telephone call, Telephone Visit Logs were maintained by the Student PI detailing CG questions, CG reported challenges in using prompted voiding strategies, and other concerns. These data will be reported descriptively.

Study Procedures

After potential participants were identified, a baseline telephone pre-screening was conducted to confirm their willingness to participate, assess eligibility (care-recipient with UI and dependent), and schedule baseline in-home visit. In-home screening and enrollment (90 minutes), was conducted by the Student PI and included obtaining informed consent from both the CG and CR (see Appendix C for consent documents). If CR did not demonstrate decision making capacity to provide consent (i.e., unable to demonstrate understanding of the intervention and potential risks), the, CG was allowed to consent for CR, if he/she is the legal guardian or is proxy decision maker in a durable power of attorney for health care documents. Following the consenting process, the Student PI completed the **Demographic and Clinical Characteristics** (CR, CG) form. The **CES-D** was then administered to screen the mental status of the CG. CGs with CES-D score ≥ 16 were referred to his/her primary care provider for further evaluation.

The Student PI then administered the **baseline assessments** (see Figure 2) and screened CR's for their ability to state their name or reliably point to one of 2 objects in the room (Ouslander et al., 1995). At the conclusion of the visit, if the CG/CR dyad met the inclusion criteria up until that point, CGs were given the baseline **3-day bladder diary** to complete and return at the next in-home visit.

In-home assessment #2 (Baseline) (60 minutes). The second in-home assessment (T0) visit was scheduled 1 week after the screening visit to allow CGs adequate time to complete the baseline paperwork. At this visit, the **3-day bladder diary** was collected and reviewed for accuracy and completion. If the 3-day bladder diary was inaccurate or incomplete, the visit was rescheduled and the CG was given one additional opportunity to accurately complete it. If a second attempt is again unsuccessful, the dyad was excluded from the study.

Table 3

Summary of Variables and Corresponding Instruments Used for Data Collection

Variables	Instruments	Data Source	Data Collection Time Points
CG Outcomes UI Self-efficacy UI knowledge UI Burden	PCS UIKS IIQ-7	CG CG CG	Baseline, 3 weeks, 6 weeks Baseline, 3 weeks, 6 weeks Baseline, 6 weeks
CR Outcomes % change in wetness	3-day bladder diary	CG	Baseline, 3 weeks, 6 weeks
CG & CR Characteristics CG general & mental health CR general health CR continence status	DCCF CES-D DCCF DCCF	CG/CR CG 	Baseline Baseline Baseline Baseline

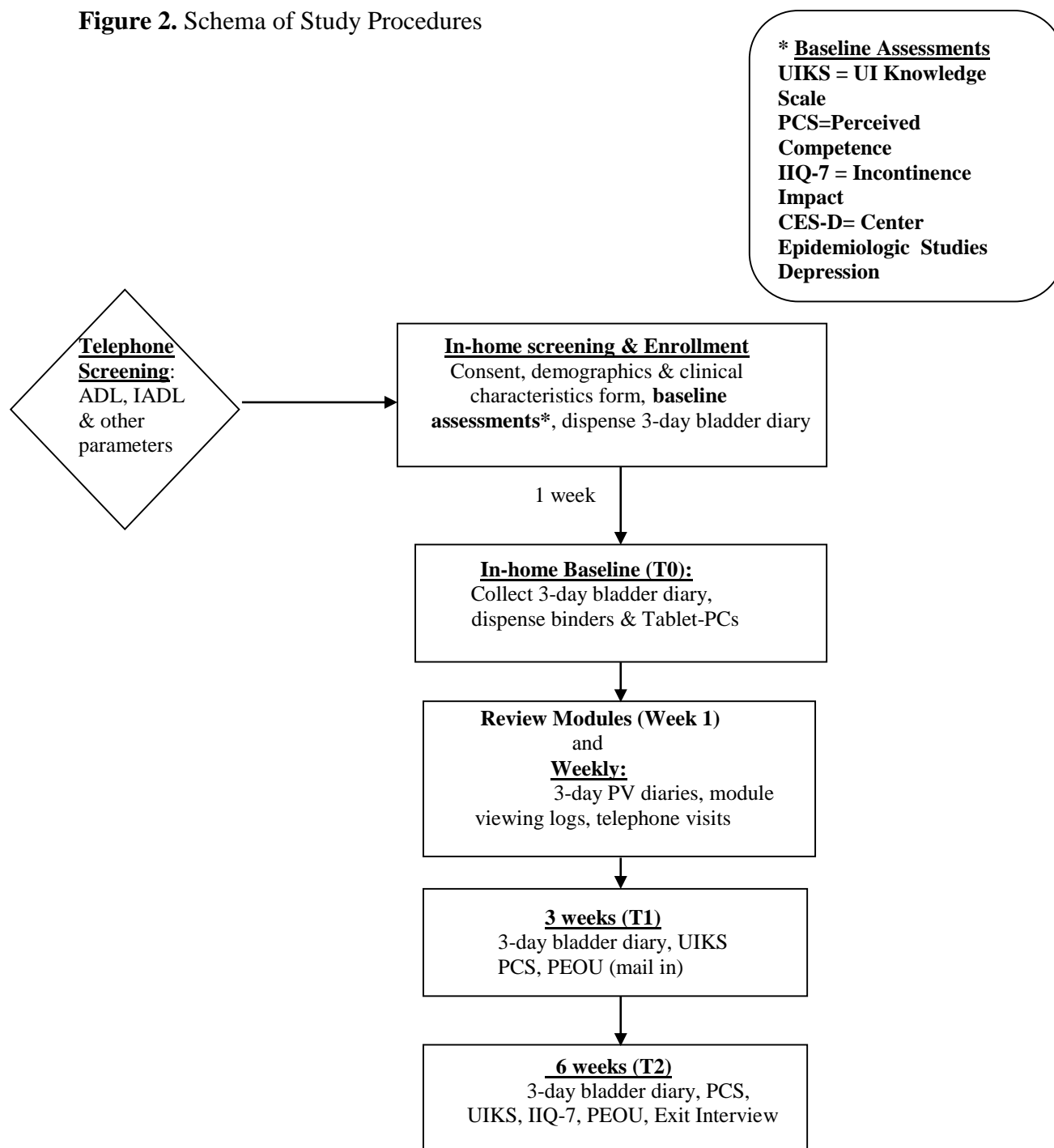
Demographics	DCCF		Baseline
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(Table 3 Continues)

(Table 3 Continued)

Variables	Instruments	Data Source	Data Collection Time Points
CR functional status	PMS Lawton IADL	CG CG	Screening Screening
Intervention Feasibility CG technology acceptance	PEOU	CG	3 weeks, 6 weeks
CG perception of treatment benefit	Exit Interview	CG	6 weeks
CG technology use	Educational Module Viewing Log	CG	Weekly
CG adherence Prompted voiding	3-day PV diary Telephone Visit Log	CG CG/PI	Weekly Weekly
Technology use	Educational Module Viewing Log	CG	Weekly

Note. CG=caregiver; CR=care-recipient; PI=student PI; PCS= Perceived Competence Scale; UIKS= Urinary Incontinence Knowledge Scale; IIQ-7= Incontinence Impact Questionnaire- Short Form; DCCF= Demographic and clinical characteristics form; CES-D = Center for Epidemiologic Studies Depression Scale; PSMS= Physical Self Maintenance Scale; Lawton IADL = Lawton Instrumental Activities of Daily Living; PEOU= Perceived Ease of Use of Tablet-PC; PV diary=prompted voiding diary

Figure 2. Schema of Study Procedures

After the inclusion/exclusion criteria were reviewed again by the Student PI, dyads meeting eligibility criteria received the telehealth device pre-loaded with the educational models at that time and were instructed to watch all modules during the first week, maintaining a viewing of what was viewed and the extent of the module viewed.

Each day, following content delivery, sessions ended with a motivational message about the positive aspects of caregiving and stress management strategies to maintain CG interest. Additional details regarding the evidence-based content present in the modules can be found in Table 2.

Following Week 1, CGs were encouraged to review modules as they felt were needed to reinforce previous teachings. This allowed for CG self-direction in the learning process—an important need of adult learners (Knowles, 1973). CGs were also instructed, via return demonstration, on the use and maintenance of the telehealth device. CGs were also be instructed on the weekly telephone call schedule, and given a study binder with the paperwork to be completed at the designated time. All educational training sessions, including prompted voiding instruction, were delivered via telehealth device, as previously described.

Weekly telephone calls (Weeks 1-6). All CGs were contacted via telephone once per week by the Student PI, during the six-week intervention period. The purpose of the calls was to answer content or device questions. During telephone visits, CGs were reminded when to complete the follow-up paperwork. Telephone visit call length and discussion topics were documented for the feasibility analyses.

3 weeks post randomization (T1). This time point was included as an interim check. Since the CGs were instructed to complete educational modules during Week 1, a UI knowledge assessment at the completion of the study (6 weeks) may not have captured the benefit of the intervention. CGs therefore completed a **3-day bladder diaries, UIKS, PCS, PEOU** and mailed it to the Student PI via pre-paid addressed envelopes (given at baseline visit).

Final visit (Week 6) (T2). At this time point the Student PI schedule a time to retrieve the telehealth device from the CG/CR home, collect the study binder with paperwork and complete the exit interview. All dyads that successfully completed the study were given an **\$80 Visa gift card** and an **educational booklet from the National Association for Continence (NAFC)** (widely recognized and respected patient advocacy group) for caregivers of persons with UI, detailing additional family resources/support, guidance on UI product selection, and management options.

Content design. The interactive education/skill building modules were designed by the Student PI using Camtasia ® Studio and Adobe® Premiere Elements 12 software, which are widely used in the instructional technology (IT) field. Camtasia ® software allowed for the creation of the eLearning content by transforming Microsoft® PowerPoint presentations into dynamic, interactive educational modules with eye-catching themes, animation and interactive elements. The Adobe® software was used to create the video portion by importing video clips and synchronizing them with slides/modules. Modules were then published to the desktops of the tablet-PCs.

Telehealth technology. The telehealth device chosen for this study was the Asus 64MB tablet personal computer (PC). A tablet PC is a small, portable computer with a large touch screen (Oxford Advanced Learner's Dictionary, 2012). This device was chosen because it is lightweight, easy to use, portable, and has multiple touch-screen capability. Since the educational/skill building modules were pre-installed on the tablet PCs, internet access and service contracts with telecommunications entities were not required. All of these features made this approach appealing, particularly in instances where CGs are extremely busy, do not have internet access, or may have difficulty

operating more complex devices. The use of tablet PCs in intervention studies is an emerging approach, however the use of their larger counterparts (traditional computers) in the delivery of health care interventions has been well-established and validated in the literature (Samoocha et al., 2010).

Alternative approaches. In the event that a CG was unable to complete the educational modules or if the telehealth equipment failed, efforts were made to resolve the issue to prevent study compromise. Further, if during any time, a telehealth device became no longer operational, educational content was reviewed during the telephone visit (as needed) and a new telehealth device was delivered to the CG's home the next calendar day.

Rationale for data collection time points. Time points were selected based on treatment response rates from prior behavioral interventions targeting care-dependent elders with UI; as well as treatment durations from prior traditional and technology-based informal caregiver research. Six week post-treatment time points have been shown to be sufficient to establish maximum treatment effectiveness and statistically significant benefits of behavioral UI interventions in care-dependent populations (Colling et al., 2003; Enberg et al., 2002). Some literature suggests 3-day trial of prompted voiding as adequate to predict treatment response, however the study these recommendations are based upon was done in the nursing home setting and not validated in non-institutional settings with informal caregivers (Ouslander et al., 1995). Further, in that study, criteria for responders were strict and chosen arbitrarily (e.g., ≤ 1 UI episodes/day). Frail elders may have substantial and clinically meaningful reductions in wetness and not meet this criteria (Ouslander et al., 1995). Additional studies have shown that it may take as long

as six weeks to see maximum benefit of prompted voiding (Lekan-Rutledge, 2000). Given these factors and that this is a pilot, feasibility study of a novel behavioral intervention incorporating prompted voiding, six weeks was chosen as the duration of the intervention.

Data Analysis Plan

Descriptive statistics for all demographic and study variables were completed as appropriate. Data were screened for missing values and if present replaced using standard approaches when appropriate. Data were analyzed using IBM SPSS Statistics version 22. Since this is a pilot, feasibility study with low sample size and power, CG and CR outcomes were reported descriptively.

Q1. *Will CGs use the telehealth technology and perform the intervention?* Due to the exploratory nature of this research question, the analyses to address this question were done descriptively including frequencies, means, and standard deviations. Descriptive data obtained from the prompted voiding diaries and telehealth module viewing logs were reported.

Q2. *Will CGs rate Tele-Prompt as acceptable and useful?* To address this research question means and standard deviations for the following variable: perceived ease of use will be used for analysis at 3 weeks (T1) . Additionally, descriptive statistics, including frequencies, means, standard deviations, and content analysis of qualitative questions from the exit interviews at Week 6 (T2) were reported.

Q3. *What are the benefits and problems in using a telehealth-delivered behavioral intervention for UI?* Due to the exploratory nature of this research question, the analyses to address this question were done descriptively, including frequencies,

means, standard deviations, and content analysis of qualitative questions when appropriate.

Q4. Will CGs report less subjective burden, greater UI knowledge and increased self-efficacy related to UI management, from baseline to post intervention? Due to limitations in recruitment and the size of the sample the analyses to address this question were done descriptively including frequencies, means, standard deviations when appropriate at each time point.

Q5. What is the average % change in wetness for care-recipients from baseline to 3 weeks and baseline to 6 weeks post-intervention? The primary outcome measure of UI (i.e., wetness) in this study was the percent change in wetness over the six-week intervention period and was calculated using the following formula:

$$\% \text{ change in wetness over 6 weeks} = \frac{\text{Average daily frequency of checks wet (baseline)} - \text{Average daily frequency of checks wet (6 weeks)}}{\text{Average daily frequency of checks wet (baseline)}} \times 100$$

The above formula was also used to calculate the percent change in wetness over three weeks. The **daily frequency of checks wet** was defined as the number of times the CR was wet when physically checked by the CG during an individual day (waking hours only). The **average daily frequency of checks wet** was determined by first calculating the total number of checks wet during all three days of the bladder diary, then finding the average for the total number of diary days. To address the research question, descriptive analyses were used including means and standard deviations from each time point when appropriate.

Protection of Human Subjects

This proposal received approval from the Georgia State University Institutional Review Board (Appendix A and B). There was no on-site IRB for either HHA. HIPPA

guidelines were addressed as indicated. CGs and CRs were informed that participation in the study was completely voluntary and that they could refuse to enroll or withdraw at any time, without consequences to them or their family members. Taking into account that the CES-D screens for the presence of depressive symptoms and is a screening rather than diagnostic tool for depression, there was a high likelihood that CGs would have depressive symptoms. Further, since depression was not an outcome measure of the intervention, CGs with a CES-D ≥ 16 were enrolled in the study, but referred to her primary care provider for further evaluation. The CES-D here was used to describe CG mental health characteristics. CRs did not have any medical conditions requiring immediate attention from a primary care provider, therefore no referrals were made in that regard. Participants were told that study records are confidential and that their name or other personal information which could possibly identify them would be kept separate from the study data. Informed consent was obtained from both the CG and the CR prior to the administration of study questionnaires. All participants were given the opportunity to read the consent form and ask questions prior to signing.

Informed Consent and Confidentiality

Informed consent guidelines of the Georgia State University IRB were followed. The Student PI explained the study's goals, procedures, risks and potential benefits, prior to study enrollment. A consent form approved by the IRB was signed by the CGs and CRs to document informed consent (Appendix C). If CRs were unable to restate the purpose of the intervention and potential risks of the intervention, the CG was allowed to consent for CR, if he/she was the legally authorized representative (LAR). According to South Carolina Law, per § 44-66-30 "The Adult Health Care Consent Act", the

following, in priority order, may make health care decisions for individuals unable to give consent (i.e., LARs): a) court appointed guardian; b) attorney-in-fact with durable power of attorney related to health care decision; c) individual authorized by another statute; d) spouse-unless legally separated, with provisions; e) parent or adult child; f) adult sibling, grandparent, adult grandchild; and g) other relative (by blood or marriage) believed by health care professional, to have close personal relationship (South Carolina Code of Laws, 2012).

Information collected in this study was handled as confidential. Study numbers rather than participant names were used on study records. Data were secured in a locked cabinet in the project office and on password and firewall protected computers. Identifying information was kept separate from other study documents. The Student PI monitored patient safety on an ongoing basis. The Student PI facilitated the intervention and interviewed CGs on a weekly basis. No adverse events or unanticipated outcomes were noted during the study period, according Georgia State University IRB guidelines.

CHAPTER IV

RESULTS

This chapter presents the results of this pilot study, which explored the the feasibility and acceptability of an investigator-developed (Student PI), technology-facilitated, multi-component behavioral intervention designed to enhance the home environment of care-dependent community-dwelling older adults with UI and strengthen informal CG self-efficacy in using prompted voiding to manage UI. Details regarding the development of the intervention, content review, as well the results of the descriptive and feasibility analyses are presented.

Intervention Development and Content Review

The evidence-based curriculum for the Tele-Prompt intervention was developed by the Student PI, with foundations in educational theory. The intervention was designed to be a self-contained learning program such that CGs were given Tablet-PC's preloaded with all of the educational modules. Key components of the intervention included instruction on prompted voiding strategies and practical information regarding the management of UI in the CR. The modules also included interactive instruction detailing how to complete prompted voiding diaries (Appendix F) and the educational module weekly viewing logs (Appendix G). Modules concluded with a summary of key points presented, a reminder of how and when to complete viewing logs, and a motivational

quote about family caregiving. Table 2 lists a summary of the content presented in the modules.

In addition to the educational modules, a prompted voiding instructional video was developed using video clips of a male caregiver demonstrating the technique with his elderly mother. The video demonstrated the process of prompting the CR, checking for wetness, toileting and offering praise for successes. Before each clip, the Student PI offered a video introduction and overview of the content that was presented. Following each clip, the Student PI summarized and reinforced key points.

The development of the intervention took approximately four months and included the Student PI learning and mastering the instructional technology and video editing software, creating and editing each interactive module. The Student PI was also responsible for creating the prompted voiding demonstration video script, filming, directing, and editing the video clips which showed two volunteers demonstrating the prompted voiding technique.

Content Review

After the electronic content was reviewed by the Advisory Panel (described in detail in Chapter III), the final interactive modules were reviewed by one family caregiver volunteer who provided detailed feedback on the content. The Advisory Panel generally felt the modules were of high quality, well designed, with excellent content and presentation. A few minor edits were recommended (e.g., grammar, inclusion of a detailed list of financial resources, clarification of the term incontinence); however, no elements were removed. The CG reviewer found the modules clear, relevant, organized and of high quality; stating that she learned a great deal about how to care for her step

mother's UI while reviewing them. The CG reviewer did not recommend any content revisions.

Challenges in Recruitment

Recruitment through a the chronic care program of a large HHA (initial recruitment site) began following several administrative meetings with the Student PI, a Student PI-led staff in-service, and Georgia State University IRB approval. During the in-service, the Student PI discussed the purpose of the study, eligibility criteria, and project requirements. The in-service was attended by administrative leaders, all nursing staff, physical therapy and dieticians. Recruitment flyers were also given to clinical staff for distribution to potential participants. Following a period of approximately one month with very few study referrals, approval was obtained from the IRB to expand recruitment to include all HHA patients, rather than only those specifically assigned to the chronic care program.

The large HHA recruitment expansion resulted in over 200 study referrals sent to the Student PI over the course of eight months. Figure 3 gives the number eligible, the number that refused to participate, and other reasons for not participating. Of the study referrals telephone screened by the Student PI (n=202), only one CG-CR dyad consented/enrolled and completed the study. Some of the reasons for not participating included: CG lack of interest, unreachable by telephone, transitioning of care, and not meeting inclusion criteria (CR age, CR physical ability). The CG-CR dyad that enrolled, was randomly assigned to the treatment group using computer generated numbers. No other participants were enrolled from this HHA or study design.

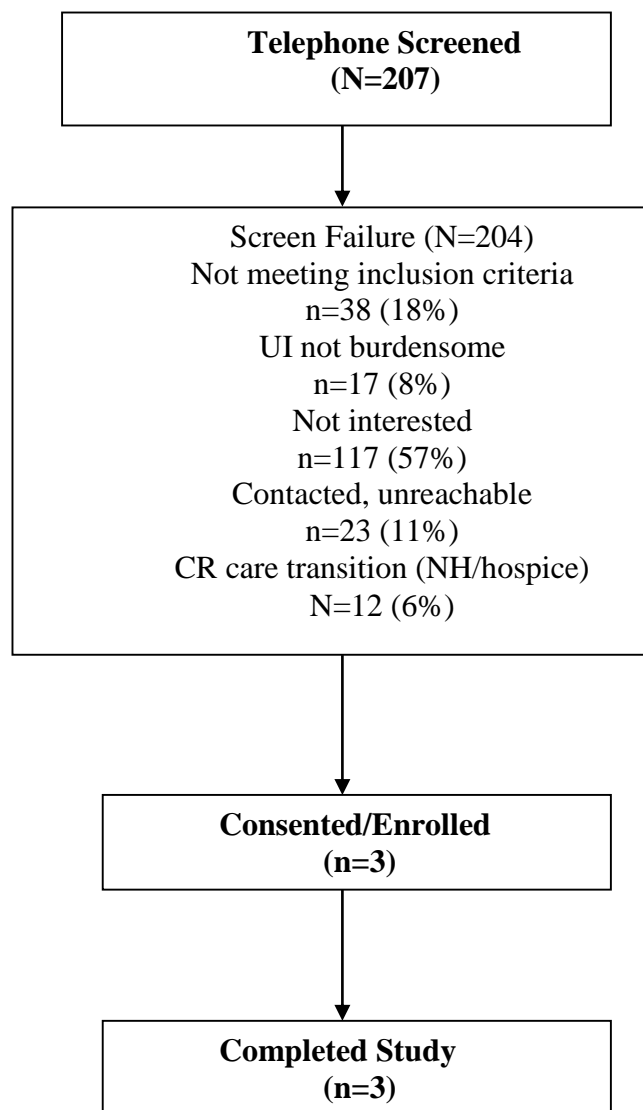
In an effort to increase study enrollment and meet recruitment goals, IRB approval was again obtained to change the study from a randomized, controlled design to a pre- post-design and include recruitment from a smaller HHA, caregiver support groups, and non-investigator healthcare provider referrals. During this time the Student PI gave an in-service to clinicians and leaders at the smaller HHA, met with administrators and support group leaders for the Alzheimer's Association for two local counties, contacted State-appointed CG program leaders, attended local CG support group meetings and discussed the study and distributed flyers, and met with non-investigator healthcare providers with large geriatric practices. With these extensive efforts, five additional potential dyads were identified and telephone screened. Of the five CG-CR dyads screened, two consented/enrolled and completed the study. For the three dyads that failed the screening process, one CG did not think UI in the CR was significant enough to participate in the program (she was more interested in a supportive program for her own UI); another CG was not interested in participating as she and her CR had gone through an extensive work-up and behavioral intervention for UI in the past; and the last CG had to place her CR in a hospice program due to declining health. Figure 3 shows the outcome of the combined recruitment efforts of both the initial and revised designs.

Sample Characteristics

A total of three informal CGs participated in the study; all were female—two spouses of the CR and one adult child. Table 4 describes the general demographic characteristics of the sample. Annual household income levels ranged from less than \$10,000 per year to over \$60,000 per year. No CGs worked outside of the home—one CG was unemployed (unrelated to a disability); while the other two CGs were retired. No

CGs left previous employment to fulfill their CG duties. Time spent in the CG role ranged from 1 year to 6 years—with two of the CGs spending at least 2 years in the CG role. All CGs resided with their CR.

Figure 3. Screening and Flow of Participants in the Study



At baseline, CGs were asked questions regarding their previous use of technology. All CGs reported some prior exposure to technology. All CGs (N=3)

reported previous use of the internet and cell phones. Two CGs reported previous use of a laptop or home computer, while only one reported previously using a tablet-PC. Two CGs reported previously participating in an online discussion or blog, while only one reported using any of these technologies to assist in their CG duties. No CGs reported previous use of electronic diaries or any other technology systems.

Table 4

Demographic Characteristics of the Sample

Characteristics	Caregivers (n=3)	Care-recipients (n=3)
Age (years)		
Mean (SD)	71.67 (15.95)	86.67(8.51)
Range	54-85	77-93
Gender (n,%)		
Female	3(100)	1(33.33)
Male	0(0)	2(66.67)
Race (n,%)		
White	3(100)	3(100)
Level of education (n,%)		
High School	1(33.33)	1(33.33)
College	1(33.33)	1(33.33)
Graduate	1(33.33)	1(33.33)
No, chronic illness		
Mean (SD)	4.33(2.52)	5.0(3.61)
Range	2-7	1-8

Caregiver/Care-Recipient Dyad #1

The Caregiver/Care-Recipient (CG/CR) Dyad #1 consisted of an adult child and her elderly mother. This CG report a personal history of two chronic illnesses—one of which was a history of depression being managed with medication; none of her illnesses affected her physical ability to assist in toileting her CR. The CG had a CES-D score of 24. She reported no acute issues with depression and was instructed by the Student PI to follow-up with her primary care provider. The CR had a history of UI, Macular Degeneration, and did not take any regular medications. The CR was dependent in all Lawton IADLs except in her ability to use the telephone. Based on PSMS, the CR was dependent in three ADLs and ambulated with the assistance of a walker.

Continence history. The CR had a 3 year history of UI—with her CG helping to manage the condition for two of those years. Table 5 describes the baseline continence history and characteristics of the sample. The CR received no prior treatment for UI and the dyad was using incontinence pads to manage the leakages. The CG reported spending an average of 10 minutes per day helping to toilet her CR. She also reported having no direct costs related to the UI, as they received incontinence pads from the HHA. The CR also had a history of nocturia (i.e., urination at night) as well as urinary incontinence at night. The CR did not consume any alcoholic beverages, but did consume approximately one, eight-ounce sized cup of caffeinated beverages (coffee or tea) per day. The CR was a former smoker.

CG self-reported UI-related bother at baseline. On a scale from 0 to 10, with 10 being a ‘great deal’ of bother, the CG reported a high level of bother related to managing her CR’s UI (rating of an 8). On the same scale, the CG also reported a

moderate degree of bother related to nocturia (rating of 6); and a moderate degree of bother from the nighttime urinary incontinence (rating of 6). Both the CR's nocturia and nighttime urinary incontinence affected the CG's sleep.

Caregiver/Care-Recipient Dyad #2

The Caregiver/Care-Recipient (CG/CR) Dyad #2 consisted of an elderly spouse and her husband. This CG reported a personal history of four chronic illnesses. She had no prior history of depression or any illness that could physically affect her ability to assist her CR with toileting. The CG had a CES-D score of 8. The CR had a history of UI, double vision, dysphagia, cardiac arrhythmia with pacemaker, constipation, falls, prostate cancer, hypertension, hypothyroidism, and hypercholesterolemia. The CR was taking several daily prescription and over-the-counter medications, which included: metoprolol 25mg, gabapentin 800mg qid, Synthroid 50 mcg, Plavix 75mg, Lipitor 20mg, aspirin 81mg, Vitamin D₂ 1000 units per week, fish oil 1000mg, Caltrate 600mg, and Toviaz 8mg (overactive bladder). In addition to these medications, the CR was also receiving Lupron injections for the management of his prostate cancer. The CR was dependent in all Lawton IADLs except in his ability to use the telephone and in the management of some of the finances. Based on PSMS, the CR was dependent in four ADLs and ambulated with the assistance of a walker.

Continence history. The CR had a 20 year history of UI—with his CG helping to manage the condition for the two most recent years. The CR received was previously treated with Toviaz 8mg for UI, which he was still taking. No other prior treatments for UI were reported. The dyad was using incontinence briefs and fluid management (timing and amount of fluids) to manage the leakages. The CG reported spending an average of

14 hours per day helping to toilet her CR (10 hours at night; 4 hours during the day). The CG reported having \$200 per month in direct costs related to the UI (cost of products and extra laundering). The CR also had a history of nocturia as well as urinary incontinence at night. The CR did not consume any alcoholic or caffeinated beverages and was a former smoker.

CG self-reported UI-related bother at baseline. On a scale from 0 to 10, with 10 being a ‘great deal’ of bother, the CG reported a high level of bother related to managing her CR’s UI (rating of 10). On the same scale, the CG also reported a high degree of bother related to nocturia (rating of 10); and a high degree of bother from the nighttime urinary incontinence (rating of 6). Both the CR’s nocturia and nighttime urinary incontinence affected the CG’s sleep.

Caregiver/Care-Recipient Dyad #3

The Caregiver/Care-Recipient (CG/CR) Dyad #3 consisted of an elderly spouse and her husband. This CG reported a personal history of seven chronic illnesses. She had a prior history of depression, managed with medications. None of her illnesses prevented her from assisting her CR with toileting. The CG had a CES-D score of 18. She reported no acute issues with depression and was instructed by the Student PI to follow-up with her primary care provider. The CR had a history of UI, Lewy Body Dementia, glaucoma, hypertension, melanoma, benign prostatic hyperplasia (BPH) and overactive bladder. The CR was taking several daily prescription medications, which included: Flomax 0.4mg (BPH), aspirin 81mg, Hyzaar 50-12.5 (1/2 tablet), Ativan 0.5mg (as needed for sundowning), Myrbetriq 50mg (overactive bladder), Lexapro 10mg, Prilosec 20mg. The CR was dependent in all Lawton IADLs except in his ability to do

laundry and housekeeping. Based on PSMS, the CR was dependent in five ADLs and ambulated with the assistance of a walker.

Continence history. The CR had a one year history of UI--with his CG helping to manage the condition for the most recent five months. The CR was previously treated with Flomax and Myrbetriq, both of which he was still taking. No other prior treatments for UI were reported. The dyad was using incontinence briefs to help manage the urine leakages. The CG also reported encouraging the CR to toilet during certain times. The CG reported spending an average of one hour per day helping to toilet her CR. The CG reported having \$75 per month in direct costs related to the UI (cost of products and extra laundering). The CR also had a history of nocturia, but did not have urinary incontinence at night. The CR did not consume any alcoholic beverages, but drank 1-2 eight ounce size cups of half-strength coffee daily. The CR never smoked.

Table 5

Baseline Continence and Clinical Characteristics of the Sample

Characteristics	Overall (<i>N</i> =3)
CR history of UI (years)	
Mean (SD)	8 (10.44)
Range	1-20
CG time spent on UI (min.)	
Mean (SD)	311.33 (479.28)
Range	10-864
UI monthly cost (dollars)	
Mean (SD)	91.67 (101.04)
Range	0-200

(Table 5 Continues)

(Table 5 Continued)

Characteristics	Overall (N=3)
CR urinary history (n,%)	
Daytime UI	3 (100)
Nighttime UI	2 (66.67)
Nocturia	3 (100)
BPH	1 (33.33)
Prostate cancer	1 (33.33)
OAB	2 (66.67)
CR medications (n,%)	
Alpha blocker	1 (33.33)
Bladder relaxant	2 (66.67)
CG UI degree of bother (n,%)	
High	2 (66.67)
Moderate	1 (33.33)
CG nocturia degree of bother (n,%)	
High	1 (33.33)
Moderate	2 (66.67)
CG nighttime UI degree of bother (n,%)	
Moderate	2 (66.67)
CG CES-D*	
Mean (SD)	16.67 (8.08)
Range	8-24

Note. CG=caregiver; CR=care-recipient; UI=urinary incontinence; BPH=benign prostatic hyperplasia; OAB=overactive bladder. *CES-D=Center for Epidemiologic Studies Depression Scale. CES-D scores range from 0-60, with a score of 16 or higher indicating greater symptoms of depression.

CG self-reported UI-related bother at baseline. On a scale from 0 to 10, with 10 being a ‘great deal’ of bother, the CG reported a moderate level of bother related to managing her CR’s UI (rating of 5). On the same scale, the CG also reported a moderate degree of bother related to nocturia (rating of 5). The CR’s nocturia affected the CG’s sleep.

Results for Research Questions

Q1. Will CGs use the telehealth technology and perform the intervention?

As part of the feasibility analysis, CG adherence to the intervention was determined by CG adherence to prompted voiding and CG technology usage. CGs were deemed adherent to the intervention if they: 1) performed prompted voiding at the recommended frequency (every 2 hours during daytime hours) at least 80% of the time during the six week study period; and 2) viewed at least 80% of the modules during Week 1 of the study. Although all CGs were adherent to the module viewing recommendations, only CG#2 was adherent to the prompted voiding recommendations. CG #1 and CG#3 were compliant with the prompted voiding recommendation only 33.33% of the time—the majority of the time prompting their CRs at inconsistent or non-recommended intervals. CG#1, at one point, prompted her CR hourly. CG#2, on the other hand, was compliant with the prompted voiding recommendation 80% of the time. All CGs (N=3) were adherent to the technology usage recommendation, viewing 100% of the modules during the first week of the study. Although not required, all CGs continued to view the modules throughout the remaining weeks of the study. All CGs viewed all or some of the modules for two additional weeks.

Table 6

Caregiver Adherence to Tele-Prompt Intervention and Perceived Ease of Use of Tablet-PC

	Dyad 1	Dyad 2	Dyad 3
Adherence to prompted voiding (%)			
Baseline to 3 weeks	33.33%	50%	0%
3 weeks to 6 weeks	33.33%	100%	66.67%
Baseline to 6 weeks	33.33%	80%	33.33%
Adherence to module viewing (%)	100%	100%	100%
PEOU Tablet-PC*			
3 weeks	6	14	14
6 weeks	6	28	42

Note. *PEOU=perceived ease of use. Scores range from 6-42; lower scores indicate greater perceived ease of use.

Q2. Will CGs rate Tele-Prompt as acceptable and useful?

The PEOU questionnaire was completed at Week 3 (T1) and Week 6 (T2). At both time-points, CG #1 perceived the tablet-PC as easy to use (i.e., acceptable) (see Table 6). CG#2 and CG#3 reported the tablet-PC as easier to use at T1 than at T2, with CR#3 rating it much less easy to use at T2.

On the Education Module Weekly Viewing Logs, all CGs (N=3) rated all of the modules helpful. During the exit interview, CG#1 found the intervention to be extremely helpful. She liked how the information was presented in the modules, including the quotes on caregiving at the end. She felt the intervention was very good and had no additional recommendations on ways to improve it. CG#2 also found the intervention helpful, describing it as “excellent”. Though she felt all of the information presented in the modules was helpful, she thought including additional information on urinary catheter

use and more contact information for community resources might improve the intervention. CG#3 also described the intervention as “excellent”. Particular aspects of the intervention that she found useful were the teachings of the Student PI (in the modules) and the inspirational messages about caregiving included at the end of each module. CG#3 also indicated that while she found all of the modules to be very helpful, Module 4 (Prompted Voiding Instructional Video) was least helpful because she did not feel it applied to her relationship with her CR. She stated that the video would have been more helpful if it had demonstrated a husband and wife going through the steps of prompted voiding, rather than a mother and son.


Q3. What are the benefits and problems in using a telehealth-delivered behavioral intervention for UI?

There were several benefits identified, in using technology to deliver the intervention. Firstly, the technology allowed for the evidenced-based content to be portable. The portability of the intervention allowed for the intervention to be delivered consistently to all participants without compromising the integrity of the content. Secondly, the use of technology allowed CGs to individualize their learning experience by viewing modules at times that were convenient to them. It also allowed CGs the opportunity to review content as often as they felt was indicated. All CGs reported that they were able to view modules at times that were convenient to them (e.g., during times when their CRs were occupied or asleep). Based upon completion of weekly viewing logs, all CGs reviewed content beyond the week that was required.

The modules also included information about how to complete the prompted voiding diaries (see Figure 4). All CGs were able to complete the diaries as instructed.

However, CG#1 had some confusion regarding which diary to complete at each time point, which was addressed during weekly telephone call with the Student PI. Due to the design of the study, 3-week diaries were reviewed at the time of the 3-week mailings. All other diaries were reviewed at the completion of the study. All diaries were interpretable, as caregivers were encouraged to include comments and information which they felt were important to assist with the interpretation of the data (e.g., whether or not this was a typical week). However, one challenge with this approach was that questions regarding any information gathered from the diaries or concerns regarding how the diaries were completed had to be addressed after several had already been completed.

Figure 4. Screenshot of Prompted Voiding Diary Instruction

Time Prompted	Was he/she wet?	Did he/she go to the bathroom when you offered?	Did he/she urinate in the toilet?
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No

Time loved one woke up for the day _____
 Time loved one went to bed _____
 Was this a usual day? Yes ___ No ___
 Comment: _____

Another challenge identified was in working with a population that may not have experience using technology. When using computer technologies, all operating systems at some point require system updates. It is difficult to predict when the need for updates will occur and can be confusing to those with limited experience working with these technologies. Based upon telephone visit logs and information gathered during the Exit

Interview, all CGs began experiencing automatic software updates as they would appear on the tablet-PCs—around the 4-week time point. While CG#1 expressed comfort with and understanding regarding this (she had experienced this before, during her previous technology usage), CGs #2 and #3 expressed unfamiliarity and confusion at times.

Q4. Will CGs report less subjective burden, greater UI knowledge and increased self-efficacy related to UI management, from baseline to post intervention?

Subjective burden. Table 7 presents a summary of CG outcomes from baseline to post-treatment time points. Based on overall IIQ-7 scores, CG subjective burden related to the management of UI in the CR remained essentially the same from baseline to post intervention. Table 8 further details the IIQ-7 subscale scores at baseline and post-intervention. Although the overall IIQ-7 score, physical activity, social, and emotional subscale scores appeared to remain relatively the same; the mean UI –related travel burden subscale score decreased from the midpoint of the subscale to below midpoint—at baseline and 6 weeks post intervention respectively.

UI knowledge. UI knowledge possible total scores ranged from 0 to 30, with scores <18 indicating poor knowledge; 18-24 indicating moderate knowledge; and >24 indicating good knowledge (Yuan & Williams, 2010). Two CGs had poor knowledge at baseline. Two CGs demonstrated an improvement in UI knowledge scores from baseline to post intervention (see Table 7). The items missed by all three of the CGs at baseline were related to the prevention of constipation to help UI; controlling chronic illnesses to help UI (examples given were diabetes, Parkinson’s disease, or dementia); and the use of medication as the only treatment for UI. The only item missed by all three of the CGs at

3-weeks was related to controlling chronic illnesses to help UI. Lastly, no items were missed by all three of the caregivers at the 6-week time point.

Self-efficacy. The Perceived Competence for UI Management score (PCS) potential total scores ranged from 4 to 28 with all CG scores falling at or above the midpoint of the scale at baseline and 6 weeks. Two CGs showed a decrease in scores below the midpoint of the scale at 3 weeks; followed by an increase in scores at the 6 weeks post-intervention time point.

Table 7

Changes in Caregiver and Care-recipient Outcomes from Baseline to Post-Treatment

	<i>Overall (N=3) Mean (SD)</i>	<i>Dyad 1</i>	<i>Dyad 2</i>	<i>Dyad 3</i>
CG UI burden (IIQ-7 score)				
Baseline	10.0 (7.93)	1	16	13
6 weeks	9.33 (8.50)	1	18	9
CG UI knowledge (UIKS score)				
Baseline	15.0 (4.58)	16	10	19
3 weeks	18.33 (7.37)	10	21	24
6 weeks	19.0 (5.20)	13	22	22
CG UI self-efficacy (PCS score)				
Baseline	21.0 (6.25)	28	19	16
3 weeks	18.0 (8.71)	28	12	4
6 weeks	21.33 (6.11)	28	16	20
CR% reduction in wetness compared with baseline (%)				
3 weeks	41.60% (80.62)	100%	+50.38%*	75.19%
6 weeks	65.53% (54.51)	100%	0%	87.59%

Note. CG=caregiver; CR=care-recipient; IIQ-7=Incontinence Impact Questionnaire Short Form; UIKS=Urinary Incontinence Knowledge Scale; PCS = Perceived Competence Scale.

*demonstrates an increase in wetness, rather than a reduction.

Table 8

Changes in Caregiver IIQ-7 Subscale Scores from Baseline to Post-Treatment

	<i>Overall (N=3) Mean (SD)</i>	<i>Dyad 1</i>	<i>Dyad 2</i>	<i>Dyad 3</i>
<i>CG UI physical activity burden (IIQ-7 subscale score)</i>				
Baseline	2.33 (1.15)	1	3	3
6 weeks	2.67 (2.52)	0	5	3
<i>CG UI travel burden (IIQ-7 subscale score)</i>				
Baseline	3 (2.65)	0	5	4
6 weeks	1.67 (2.9)	0	5	0
<i>CG UI social burden</i>				
Baseline	1.67 (1.53)	0	3	3
6 weeks	1.67 (1.53)	0	3	3
<i>CG UI emotion health (IIQ-7 subscale score)</i>				
Baseline	41.60% (80.62)	0	5	4
6 weeks	65.53% (54.51)	1	5	4

Note. CG=caregiver; IIQ-7=Incontinence Impact Questionnaire Short Form. Potential subscale scores range from 0-6 (physical activity); 0-6 (travel); 0-3 (social/relationships); 0-6 (emotional health). Higher subscale scores suggest higher UI impact or burden.

Q5. What is the average % change in wetness for care-recipients at 3 weeks and 6 weeks post-intervention, compared with baseline?

Percent change in wetness at 3 and 6 weeks. Two CRs showed a reduction in the average number of checks wet (i.e., UI) at 3-weeks and 6 weeks post intervention. CR#1 demonstrated a 100% reduction in the average number of checks wet from baseline (mean checks wet_(T0)=0.33) to 3 weeks (mean checks wet_(T1)=0) and baseline to 6 weeks (mean check wet_(T2)=0). CR#3 demonstrated a 75.19% reduction in the average number of checks wet from baseline (mean checks wet_(T0)=2.66) to 3 weeks (mean checks wet_(T1)=0.66); and an 87.59% reduction at 6 weeks (mean checks wet_(T2)=0.33) compared

with baseline. CR#2 had a 50.38% increase in the average number of checks wet at 3 weeks (mean checks wet_(T1)=2) compared with baseline (mean checks wet_(T0)=1.33); and did not demonstrate a change in the average number of checks wet at 6 weeks (mean checks wet_(T2)=1.33) compared with baseline (mean checks wet_(T0)=1.33).

Additional Findings

Telephone Visits. Telephone visits were completed on a weekly basis between the Student PI and all CGs. Calls lasted approximately 10-15 minutes on average. Discussion topics included: what Modules were viewed during the week, progress updates with prompted voiding (e.g., how CR was responding to prompting, CG ability to prompt successfully), troubleshooting challenges with prompted voiding (e.g., CR not interested at time of prompting), discussing technical challenges with the tablet-PC (e.g., navigating to appropriate screen to view modules, questions regarding charging the device and software update alerts, and reminding CGs when and how to complete the diaries and other paperwork. For example, during Week 2, CG#3 had a question regarding how long she should allow her husband's skin to "air out" at night (i.e., not be exposed to constant moisture from the incontinence garment) as a follow up to information presented in one of the modules.

CG perceptions of satisfaction with the intervention. The results of the Exit Interview are in Table 9. During the exit interview, CGs offered additional insight on how UI impacted their lives. One CG shared that her degree of bother was related to her life totally being changed because of her CRs urinary condition. In the past, she had been very actively involved in community and social organizations holding various leadership positions. However, during the past year, she had not been very active because of her

CR's UI. As a result of this, she felt that she does not have much of a life or friends anymore.

At the completion of the study, CG#1 reported that she felt that her CR's urine leakages were 'much better', compared to before they started the study, but the number of UI products/garments was about the same. The other two CGs reported using less UI products/garments. Two CGs reported that managing the CRs' UI was less bothersome with no change in bother for one CG. Additionally, CG #1 was 'completely satisfied' with her CR's progress in the program, but found it 'somewhat difficult' to stick with the treatment because of her need to travel and other responsibilities. She rated her use of the tablet-PC to be very easy (10). All CGs felt comfortable enough to continue prompted voiding indefinitely, however only two would use the tablet-PC for learning in the future. When CGs were asked to rate on a scale of 1- 10 whether they would do the program again and recommend the program to a friend, scores indicated they would be likely to do the program again and said they 'would definitely recommend this program to a friend'. When asked about the most difficult part of the treatment, CG#1 she stated that keeping track of her CR's urination was the most difficult because she felt they both were on different schedules. She stated, "It was hard tracking". CG#2 felt the most difficult part was her feeling too tired and as though she did not have enough time to complete the activities were the most difficult parts. The last two weeks of the study were particularly challenging for them because there was a death in the family, and they had many difficult times dealing with hospice, the funeral, etc. CG#3 felt that working with the technology was the most difficult part of the treatment stating, "I wish I could have operated the tablet-PC better". She reported some frustration with how she managed the device during

the beginning and the last few weeks of the study. She expressed that she would like to learn how to manage computers better.

The best part of treatment for CG#1 was when she asked her CR about needing to urinate during prompted voiding and she did need to go. For CG#2, the best part of the treatment was the Student PI. She stated, “If they eliminate [the Student PI] it wouldn’t be fun at all”. She also felt how the study was presented to her and her husband in the beginning was “very good”. The best parts of treatment for CG#3 were: having someone to discuss things with, being able to talk with a professional, the detail given, and how thorough the modules were.

All CGs all educational modules to be very helpful, liked how the content was presented, and enjoyed listening to them. CG#2 reported that after the first two modules, she realized that she was not alone in dealing with her CR’s leakages (i.e., there are other CGs facing the same challenges). CG#3 stated that the modules were “as good as support group meetings, but at home”. All CGs especially liked the inspirational quotes at the end of each module. One described the quotes as “inspirational” and the Student PI’s voice on the modules calm and professional. Another CG stated, “The inspirations at the end were fantastic”. Another CG reported that the Modules helped her to, “try new things”, which she felt helped her to understand that their current situation could be different. One CG found the Prompted Voiding Instructional Video less helpful as she felt that the language used by the son in prompting his mother would only apply in the nursing home setting—specifically, him telling his mother he would be back in “2 hours”. She also felt that the video would have been better if it were a husband and wife. No CGs identified any modules which they considered not helpful at all.

When asked to identify information which they felt should have been discussed in the modules, CGs#1 and #3 did not identify any additional information that should have been discussed. CG#2 felt that more specific information about community resources that could possibly offer advice and supportive services, would have been helpful. Another CG stated that information about more absorbent UI products to use at night and information about how urinary catheters are used would have added to the treatment. When asked about how to improve the program, CGs felt that overall, the program was excellent. One CG stated, “I think you have a good program. I don’t have any suggestions really. Three times a week doing the diary wasn’t difficult”. At the completion of the intervention, CGs felt comfortable enough to continue prompted voiding indefinitely, though two CGs did not feel the technique really applied to their situation since their CRs’ urine leakage was mainly at night. CGs would ‘definitely’ recommend the program to a friend.

Table 9

Caregiver Perceptions and Satisfaction with Tele-Prompt

	<i>Dyad 1</i>	<i>Dyad 2</i>	<i>Dyad 3</i>
CR urine leakage	Much better	Better	Better
CR use of UI products	Same	Less	Less
Satisfaction with CR progress	Completely satisfied	Somewhat satisfied	Somewhat satisfied

(Table 9 Continues)

(Table 9 Continued)

	<i>Dyad 1</i>	<i>Dyad 2</i>	<i>Dyad 3</i>
CG UI bother*			
Baseline	8	10	5
6 weeks	0	7	5
Difficulty adhering to treatment	Somewhat difficult	Somewhat difficult	Very easy
Easiness using tablet-PC**	10	7	5
Continue prompted voiding indefinitely	Yes	Yes	Yes
Use tablet-PC for future learning	Yes	Yes	No
Participate in study again	10	8	10
Recommend to friend	Definitely	Definitely	Definitely

Note. CG=caregiver; CR=care-recipient; UI=urinary incontinence. *Scores range from 0 'not bothersome' to 10 'extremely bothersome'. ** Scores range from 0 'not easy at all' to 10 'very easy'. *** Scores range from 0 'definitely not do it again' to 10 'definitely do it again'.

CHAPTER V

DISCUSSION AND CONCLUSIONS

This chapter presents a discussion of the results of this pilot/feasibility study, as well as its limitations and implications for future practice and research.

Discussion/Conclusions

UI is a significant problem affecting vulnerable community-dwelling older adults and their informal CGs. Though considered ideal, only three previous studies conducted over a decade ago, explored the use of behavioral interventions for UI within this cohort. Equally scarce are studies exploring the effects of these interventions on CG outcomes such a UI-related burden and positive aspects of caregiving, such as self-efficacy. Since these studies were conducted, health IT has emerged as an effective approach in the management of chronic illness and has been highlighted as a central factor in the delivery of effective, patient-centered care. Currently, no studies have explored the use of these technologies to support UI caregivers in their role. This pilot/feasibility study addressed this paucity in the evidence by exploring the use of telehealth to deliver an evidence-based, multi-component educational and prompted voiding intervention for UI to the informal CGs of community-dwelling older adults with chronic UI.

Main Findings

One of the main findings of this study is that recruiting and accessing this population is extremely challenging. Despite this, the development and implementation

of the evidence-based intervention, as well as its delivery via health IT to informal CGs, did prove feasible. An in-depth discussion of the findings/lessons learned from the development and execution of the intervention follows. Additionally, due to the limitations in the availability of current research evidence regarding the use of behavioral interventions within this cohort; the findings of this study will be compared to earlier studies.

Feasibility of Tele-Prompt: Difficulties in Recruiting Participants

The largest challenge to the feasibility of this study was in the recruitment of participants, which resulted in an inability to meet recruitment goals as well as a small sample size. Once in the study, CGs were willing to participate and complete the intervention (the attrition rate was 0%); however, the challenge was getting participants to enroll past the initial screening process. Over 200 potential CGs were screened by telephone following HHA referral, with slightly more than half of those referred declining to participate because of lack of CG interest and almost one-fifth did not meet inclusion criteria (e.g., lack of informal CG or CR physically unable to participate). One explanation for this could be that the home health population may be so frail that they are ineligible to meet the functional requirements for participation in a prompted voiding intervention, CGs are so burdened with care they are not interested in adding any additional burden, or in the absence of an informal CG, the HHA provided the necessary toileting support. In a study of prompted voiding which recruited solely from the home health population, Engberg et al. (2002) also faced recruitment challenges and an inability to recruit a large enough sample to sufficiently power the study—the main reason for exclusion being the lack of a full-time CG (Engberg, et al., 2002). Colling

et al. (2003) also experienced recruitment challenges in a community-dwelling sample of older adults with UI where over 50% of potential participants were excluded for lack of a CG. Engberg et al. (2002) relied on referrals from one HHA for potential participants, while Colling et al. (2003) recruited informally through community networks at multiple study sites. The present study used two HHA sites as well as community resources (e.g., CG advocacy groups) and referral from non-investigator primary care health care providers. Of the methods used, recruitment through local advocacy groups yielded two additional participants for the study and this setting may have more individuals that will meet inclusion criteria.

The recruitment of vulnerable elders and their CGs into UI research studies remains an ongoing challenge, which may be the reason why this population remains understudied. Future studies should consider potential challenges in accessing this vulnerable population as well as potential barriers to enrollment (e.g., perceptions of increased burden by informal CGs). Additional recruitment considerations include: local newspaper and radio advertisements and recruitment through specialty practices (e.g., urology, gynecology).

Feasibility of Tele-Prompt: CG Adherence and Perceptions of Technology

Usefulness

Low adherence to prompted voiding recommendations. Although CGs performed all aspects of the intervention and were adherent to the recommendations for technology usage, only one was adherent to the recommended two-hour prompted voiding interval. According to diary data, CGs performed prompted voiding, but not at the recommended interval. During follow-up telephone calls with the Student PI, one CG

did report not consistently adhering to the prompted voiding recommendations—citing that she and her CR were on different schedules. No CGs reported confusion with or issues regarding the prompted voiding technique. Given this, one reason for the non-adherence could be that the two-hour recommended interval was not consistent with the CRs' natural voiding patterns. CGs may have allowed the CR's regular voiding patterns to guide the prompting, rather than the recommended two hour schedule. This raises questions regarding whether or not a more individualized approach may have increased adherence. In a similar study of prompted voiding, Engberg et al. (2002) started participants on a two-hour prompting schedule, but individualized the strategy by re-evaluating CR response on a weekly basis—adjusting the recommended voiding schedule accordingly. In Engberg et al. (2002) it is unclear what percentage of participants were ultimately prompted at intervals other than every two hours as this was not reported, however this approach resulted in an average adherence rate of 89% (Engberg et al., 2002). Jivorec & Templin (2001) measured CG adherence to their protocol, controlling for it in the discriminant final analyses. While adherence was not found to be a significant predictor of success in their intervention, the investigators cited CR refusal to toilet as the main factor influencing low adherence. This appears to be in contrast with the present study, since CR refusal did not appear to be a factor. The size of the sample of the present study however limited the ability to perform more in-depth statistical analyses of factors influencing and predictors of adherence. Future studies of prompted voiding should consider whether or not an individualized approach is warranted and also include details regarding predictors of CG adherence to the intervention.

High adherence to technology. Even though CGs were of diverse educational backgrounds, income levels and age; with limited experience in using the tablet-PC, all were willing and able to be trained to use the technology. CGs used the technology beyond what was required and consistently rated the educational modules as extremely helpful and well done. Additionally, the majority of CGs found the intervention very easy to follow, reported that they would participate in the intervention again, and would definitely recommend it to a friend. With regard to the use of technology, the majority of CGs rated the tablet-PC as easy or moderately easy to use at three weeks and six weeks. These findings support the notion that CGs found the intervention acceptable and useful.

Decreased perceptions of technology usefulness. All CGs at three weeks had scores on the computer usability below the midpoint of the scale suggesting greater perceived ease of use of the technology. At six weeks however, two CGs had scores above the midpoint of the scale suggesting lower perceptions of usefulness. Changes in scores at six weeks were reflective of CGs rating it less easy to get the tablet-PC to do what they wanted it to do; less clear and understandable; less flexible to interact with; less easy to become skillful at using; and overall less easy to use—compared with 3 weeks. During the exit interviews, these CGs expressed some confusion and frustration with the automatic software updates which occurred after three weeks; which may be the cause of this change. Future studies using tablet-PCs should consider educating CGs regarding the potential for these system updates and troubleshoot ways to manage them before they actually occur.

Feasibility of Tele-Prompt: Intervention Development and Study Procedures

Intervention development. An interactive, technology-facilitated, evidence-based intervention for informal CGs of older adults with UI was developed that is self-contained and has the potential to be translatable to other technology platforms (i.e., web-based technology). Participant assessment of the intervention during the exit interview and their perceptions of the helpfulness of the modules on the weekly viewing logs suggest that the development of the intervention was successful. All CGs consistently rated the content and presentation of the content extremely high and helpful—going as far as reviewing the content beyond what was required. All of the caregivers specifically mentioned access and interacting with the Student PI, an expert in UI, as beneficial. During nursing interventions, participants may have access to experts which may be an unintended, but important part of some interventions. Access to experts was addressed as a potentially unrecognized intervention component in a critical synthesis of interventions for stroke survivors (Bakas, Clark, et al., 2014).

The development process included the use of Camtasia® software in conjunction with Microsoft® PowerPoint and Adobe® Premiere Elements to develop the interactive educational modules. The initial plan was to use Camtasia and PowerPoint alone, however editing video clips with the software proved extremely challenging—thus requiring the additional software. The use of these software packages proved very effective in developing a high quality intervention. Figure 5 illustrates a screenshot of one of the interactive modules. Learning and mastering these software packages did require additional time, however the Student PI was able to develop the educational

modules independently, without the assistance of an Information Technology specialist (as initially thought).

The software and approaches used in the development process are widely used in the Instructional Technology field to develop electronic learning content. The results of this study indicate that this approach is also accessible to healthcare professionals and may be used to create or translate evidence-based interventions in the future. When planning future studies, investigators should consider additional time needed to learn unfamiliar software as well as potential cost savings with regard to developing the intervention themselves.

Figure 5. Screenshot of Prompted Voiding Module



The content review by the expert advisory panel, coupled with the review of the informal CG volunteer were key steps in the validation process and strengthened the internal validity of the study. The advisory panel included geriatric healthcare providers, researchers, administrators, Information Technology specialists, as well as caregiver support program leaders. Future studies should consider using non-clinical experts in the

process of content validation as they may offer a unique and important perspective. The approach used within the present study, helped to ensure that the content, as well as decisions made regarding content were relevant to the target population and relevant to the context in which the intervention was delivered.

The telehealth device used for this study was a tablet-PC, which was chosen for its portability, ease of use, and touch-screen capability. The device allowed for easy installation of and access to the educational modules. CGs specifically noted benefits in the portability of the intervention and in their ability to access modules at their convenience. To access the modules, CGs were required to use the touchscreen and select an icon on the home screen, which took them to a list of the modules. Each module had its own icon and CGs were then taught to use the touchscreen to select the icon for the module they wished to view. The selected module would then appear and begin to play on the screen. While the modules were playing, CGs had the option to use the touchscreen to play, pause, advance, stop, and rewind the modules. CGs were taught by the Student PI how to navigate the device, troubleshoot problems, and access the modules, by return demonstration during the baseline home visit. The operation of the device proved complex during the latter weeks of the study for one CG who became confused in the process of navigating to the modules. This resulted in one unscheduled telephone call with the Student PI and one additional trip to the CG's home to deliver a new device. When designing future studies using a similar device, investigators should consider adding system or software controls to allow a more streamlined approach to accessing the modules—particularly for CGs unfamiliar with these types of technologies, to minimize the potential for confusion.

Bladder diaries and questionnaires. CGs were given a study binder which contained all of the required paperwork divided into study weeks and mailing supplies for the three week time point. To help minimize the potential for confusion, 3-day bladder diaries and prompted voiding diaries were printed on different colored paper to help CGs easily distinguish between the two. One CG found the diaries the most difficult part of the intervention and had confusion at times, about how to complete them (addressed during the telephone visits with the Student PI). The other CGs found them easy to complete. One CG expressed that she enjoyed completing the diaries as the process helped her to understand her husband's patterns and condition better. All CGs completed all required viewing logs and questionnaires. The schedule, timing, and quantity of viewing logs and questionnaires were not reported as burdensome.

Home visits and telephone visits. In-home assessments were easily scheduled and completed at the convenience of the CG and Student PI. CGs resided within a 20-mile radius of the Student PI. Baseline visits typically lasted about 90 minutes to allow for completion of the informed consent process and baseline study paperwork. CRs were present during the assessments and actively involved in the interviews. Occasionally, CGs were called away to briefly assist their CRs with minor things, such as meal set up; but visits for the most part flowed easily with minimal interruptions. Telephone visits were also easily scheduled and completed, requiring minimal time.

Mailings. All CGs were compliant with three weeks mailings. All CGs were reminded what study paperwork to include in the mailings during the 2-week telephone visit with the Student PI. Two of the CGs required an additional reminder during the

scheduled telephone visit with the Student PI. No previous studies of CG-facilitated behavioral interventions for UI used mailings as part of their intervention protocol.

Demographic and Clinical Characteristics of the Sample

CG demographic characteristics and baseline depressive symptoms. Though limited by the size of the sample, the findings of this study offered some insight into the current demographics surrounding community-dwelling elders with UI and their CGs. All CGs within the present study were female relatives of the CRs (two spouses and one adult child), which is consistent with previous reports of informal caregiver characteristics. Studies have shown that within the US, the majority of informal CGs are women, representing between 59 and 75% of all caregivers (Family Caregiver Alliance, 2012). Not surprisingly, two of the three CGs in the study were over the age of 75, as a great number of CGs of older adults are also themselves elderly. According to studies, the average age of US CGs for those aged 65 or older is 63 years (Family Caregiver Alliance, 2010). These findings are also consistent with the sample characteristics of other studies evaluating CG-facilitated behavioral interventions for UI. In a study evaluating the effectiveness of an informal CG facilitated prompted voiding intervention, targeting community-dwelling older adults, Engberg and colleagues (2002) also reported a predominantly female sample (69%), with all CGs being relatives (44% spouses) of the CRs (Engberg et al., 2002). Jivorec & Templin (2001) also reported a predominantly female sample of CGs, who were mostly White, and 80% spouses of children.

CGs within the present study reported an average of four chronic illnesses, with two having a history of depression. Those with a baseline history of depression also screened positive by CES-D for the presence of depressive symptoms. These findings are

consistent with other studies demonstrating a high prevalence of depressive symptoms among informal CGs (Garcia-Alberca, Lara, et al., 2011; Seeher, Low, et. al., 2013). The presence of these symptoms among the study sample however, did not limit CG participation – as all CGs actively participated in the intervention, performed study duties (e.g., diaries, mailings, questionnaires, telephone calls), and completed the study.

CR demographic and continence characteristics. Overall, CRs were fairly educated with a minimum of a high school diploma, all White, and mostly male, with moderate levels of comorbidity. CR functional characteristics were very similar to the findings of Engberg et al. (2002) in that CRs in the present study were also dependent in all except one IADL and required the use of an assistive device and/or physical assistance to toilet. Functional characteristics of the sample in the present study were also similar to Colling et al. (2003), who also had a treatment group almost completely dependent in IADLs.

Based upon diary data, CRs in the present study had mild UI at baseline, as well as a wide range in the reported UI history—one CR had a 1 year history of living with the condition; another had a history spanning 20 years. Other studies exploring the use of behavioral interventions for UI in care-dependent community-dwelling older adults also reported the presence of mostly mild UI among their samples at baseline and the presence of daytime and nighttime UI and nocturia (Colling et al., 2003; Engberg et al., 2002; Jirovec & Templin, 2001). The majority of CRs within the present study were on at least one medication which could affect their urinary status. Colling et al. (2003) found that their participants took an average of 4.4 medications, 35% of them being daily diuretics.

Engberg et al. (2002) also found that their participants on average were taking 5.5 medications, with 47% on diuretics.

In the present study, while no formal testing was conducted with regard to cognitive status, all CRs met the baseline cognitive screen for inclusion. One CR had a diagnosis of Lewy Body dementia at baseline, while the other CRs did not have a formal dementia diagnosis. This differed from previous studies where CRs were required to have an official diagnosis of dementia at baseline or screen positive for cognitive impairment on baseline cognition screens (Engberg et al., 2002; Jivorec & Templin, 2001). The findings of the present study suggest that benefits in urinary status may be appreciated in care-dependent functionally impaired community-dwelling elder populations—even in the absence of a formal diagnosis of dementia.

With regard to UI burden, CGs reported spending between 10 minutes and 14 hours daily at baseline, managing their CR's UI. This variation may possibly be related to CG ability and/or the severity of the condition. CG's further reported moderate to high levels of bother at baseline related to managing their CR's UI (day and night) and nocturia. All CGs reported that managing their CR's nocturia negatively affected their sleep. Lastly, the majority of CGs reported financial burden, spending over \$90 per month on UI related products and extra laundering. Similarly, after adjusting for regional location of CGs, Colling et al. (2003) estimated the monthly cost related to supplies, laundry and CG time, to be approximately \$90 on average. In Engberg et al. (2002) approximately half of their sample reported some or a great deal of strain related to managing their CR's UI and related to the cost of incontinence briefs/pads. The present study did not explore the effects of cost and UI product selection directly. However,

detailed information regarding ways CGs could receive reimbursement for UI related costs was included in the educational modules—which all CGs rated as helpful on viewing logs. Special care was taken by the Student PI not to discuss UI product selection in the modules or during interactions with the CG as it was felt that this could affect the internal validity of the study.

In sum, the demographic and clinical characteristics of this sample are consistent with prior CG studies. Even though two of CRs were on bladder medications and UI within this sample was mild, CGs still reported high levels of UI related burden at baseline. The results of the present study also showed that nocturia and nighttime UI were not only present in the majority of CRs, but also when present, burdensome to CGs. The nature of prompted voiding is such that nocturia and nighttime UI are not directly addressed. Further, prompted voiding has been shown to be less effective in helping nocturnal urinary symptoms. One study of prompted voiding in care-dependent older adults in the nursing home setting, found nighttime prompted voiding to be ineffective in managing nocturia and nighttime UI—even when care was taken to minimize the disruption of sleep (Ouslander et al., 2001). Although the focus of the intervention was not nocturia, some discussion was included in the educational modules regarding behavioral strategies for nocturia (e.g., timing of fluids around bedtime) and ways to promote toileting safety during the night (e.g., maintaining a lighted, clear path to the bathroom), which CGs found to be helpful. Future studies within this population should include strategies targeting nocturia specifically, given the prevalence of the condition and its effects on CRs and CGs.

Changes in Caregiver and Care-Recipient Outcomes

Minimal change in UI-related burden (IIQ-7 scores). Within the present study, the mean CG UI-related burden score as measured by the IIQ-7, remained essentially the same from baseline to six weeks post intervention. One CG's scores improved slightly, while one's worsened slightly. Review of the IIQ-7 subscale scores revealed that the CG whose overall score improved, showed a substantial decrease in UI-related travel burden (i.e., CG ability to travel within a certain distance from home and ability to attend entertainment activities) at six weeks. The CG whose scores worsened showed a slight increase in UI-related physical burden (i.e., CG ability to perform household chores and physical recreation activities). The reason for this increase may be related to the CG's worsened health situation. She revealed during the exit interview that her physical ability to care for her husband in general, decreased during the course of the study because of acute medical issues she was dealing with. Generally speaking, a minimal change in mean scores overall may suggest that at a minimum, the intervention did not worsen CG UI-related burden. Lastly, these findings are consistent with prior CG-facilitated behavioral interventions and further underscores the notion that even mild UI can be perceived as burdensome to informal CGs. Colling et al. (2003) and Engberg et al. (2002) also reported a great deal of UI-related CG burden at baseline.

Improvement in UI knowledge and self-efficacy. Previous studies of prompted voiding or behavioral treatments for community-dwelling older adults did not evaluate UI-related CG knowledge or UI-related self-efficacy specifically. The majority of CGs within the present study demonstrated an improvement in UI knowledge and UI-related self-efficacy scores from three weeks to six weeks post intervention. While two CGs

showed a worsening of self-efficacy scores from baseline to three weeks, they did show an improvement in subsequent scores at the 6 week time point. This decrease, followed by an increase in scores may be reflective of CG overestimation of their UI-related self-efficacy at baseline coupled with the time required to learn the intervention. This overestimation may be related to years of CG experience. CGs reported having between 1 and 6 years of experience in the CG role (Mean=6.33, SD=4.51). Given the number of years within their roles, CGs may have overestimated their confidence in caring for their CR's UI, until additional information was presented to them during the intervention—reflecting the decrease in scores at three weeks. Exploring UI-related CG self-efficacy in the future may be warranted, however future investigators should consider exploring reasons for possible trends in UI-related self-efficacy scores as well as factors which may influence self-efficacy (e.g., years of CG experience, CG age).

Improvement in wet checks. Two of the three CRs demonstrated a reduction in urine leakages at three and six weeks, as determined by the percentage of physical checks made by the CG where the CR was wet. During the exit interview, all CGs reported improvements in their CR's urine leakages and UI product usage. CRs in the present study, demonstrated a 62.53% mean reduction in wet checks at the completion of the study. These findings are consistent with Engberg et al. (2002) who found a 50% mean reduction in daytime percent wet in those who completed the prompted voiding protocol (Engberg et al., 2002). These findings indicate that even with inconsistent prompted voiding by CGs there may be a benefit to CR.

Conceptual framework of the study. The Corbin and Strauss Chronic Illness Trajectory Theory (1991) was used to explain how the home environment of the CR

would be enhanced to manage the trajectory of chronic UI. This study also used the construct of self-efficacy from Bandura's Social Cognitive Theory (1988) as a framework to explain how the intervention would help CGs develop confidence in managing UI (Bandura, 1988; Palmer, 2004). It was hypothesized, that by giving CGs the knowledge, skill set, and support needed to successfully toilet their family members, performance successes attained through the intervention would strengthen caregiver UI self-efficacy and reduce the negative impacts of UI (i.e., CG subjective burden, care recipient wetness) (Bandura, 1977; Corbin & Strauss, 1991). This study was also the first of its kind to use modeling behavior, to help enhance CG UI-related self-efficacy—CGs viewed a video demonstrating another CG using prompted voiding to assist their CR with toileting (Bandura, 1977).

With regard to modeling behavior specifically, while all CGs found the demonstration video helpful, one CG felt that the gender and age of the CG in the video made it less relatable. Considering that the majority of family CGs are elderly women (Family Caregiver Alliance, 2012) a video demonstrating an elderly female CG performing the steps of prompted voiding, may have been more helpful. Overall, the findings of this study suggest that the application of this theoretical framework is partially supported. The present study provides preliminary evidence that the intervention may be effective in reducing wetness and improving CG confidence and knowledge in managing UI. Future studies applying modeling behavior should consider including an additional example of an elderly CG to make the video more relatable.

Implications for clinical practice

Behavioral treatments for care-dependent community-dwelling older adults.

This study adds to the current body of knowledge which supports the use of behavioral interventions to manage UI in vulnerable populations of older adults (DuBeau, 2010; Talley et al., 2011). This study also highlights the limitations in the availability of these evidence-based interventions to CGs and CRs. At baseline, CR leakages were primarily managed with UI products and/or bladder relaxants. No dyads had received any instruction regarding behavioral treatments for UI, despite the fact that CGs were still burdened and were able and willing to take an active role in the management of their CRs UI. Clinicians should consider behavioral interventions for UI in their treatment plans and engage informal CGs in their delivery. Additionally, telehealth technology may be an option to increase patient/provider accessibility to these interventions or clinical experts in the field.

Predictors of prompted voiding success. Ouslander et al. (1995) found that in a sample of nursing home residents with UI, a three-day trial of prompted voiding was sufficient to predict which residents would respond best to the strategy (Ouslander et al., 1995). In the present study, which evaluates the technique in a community-dwelling population, with prompted voiding being facilitated by informal CGs (rather than trained research staff), it is difficult to ascertain whether or not this criteria applies. During the first three days of the study, CG adherence to the recommended toileting interval was lower compared with subsequent weeks of the study. One explanation for this may be that CGs were learning and attempting to master the technique during the first week of the study, becoming more consistent with the technique as the study progressed. With

the limitations in adherence and the size of the sample, it is difficult to draw conclusions regarding whether or not CRs truly responded to the prompted voiding strategy during the three-day timeframe. Further, unlike Ouslander et al. (1995) the present study incorporated educational and supportive components which may have impacted UI outcomes. Future studies should explore predictors of success in care-dependent community-dwelling older adults, as a means of identifying those (CGs and CRs) who would readily respond to the intervention. Such information would be helpful to clinicians and CGs when considering potential cost and time savings.

Limitations

The main limitation of this study was the challenge with recruitment, which subsequently resulted in a small sample size—therefore, limiting the generalizability and the statistical analyses. Also, the sample was too small to determine the characteristics of CGs or CRs who would respond better or be more compliant with the program. Although some improvements were noted among the sample, it is unclear whether the differences observed in the outcome measures from baseline to post-intervention were statistically significant; however they may have been clinically meaningful. The size of the sample also limited the ability to validate the instruments in this population.

Implications for Future Research

Despite the limitations of this study, the findings suggest that future research exploring the use of telehealth to deliver evidence-based interventions to community-dwelling older adults with UI and their CGs is warranted. Future studies should use a randomized, controlled design with a larger sample and consider ways to optimize recruitment (e.g., multi-site studies, use of print or social media outlets). Lastly, further

exploration and validation of instruments to measure CG UI-related burden and UI-related self-efficacy is also needed.

Summary

This pilot/feasibility study explored the use of telehealth to deliver an evidence-based intervention to support the informal CGs of older adults with UI. The main finding of the study is that it is feasible to develop a technology based intervention and deliver it via tablet-PC. Lessons learned during the recruitment process suggest that recruiting UI CGs remains challenging and may be an obstacle for future investigations. Further, the home health population may be too frail to recruit for an outpatient prompted voiding intervention, suggesting that prompted voiding should be reserved for specific community-dwelling elder groups. Despite recruitment challenges and a small sample size, findings indicate that CGs liked the intervention and found it helpful. CGs demonstrated slight increases in UI-related self-efficacy, UI knowledge, and decreases in UI reported bother at the conclusion of the study. Mean CG UI-related bother (i.e., IIQ-7 scores) remained essentially unchanged. CRs demonstrated a mean 62.53% reduction in wet checks (Range=0-100%) at the conclusion of the study. This application of the Corbin and Strauss Chronic Illness Trajectory Theory (1991) which suggested that by increasing informal CG self-efficacy through enhancing the home environment of the CR, CG UI-related burden and CR wetness would improve, was partially supported.

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APPENDIX A

IRB Approval for Initial Randomized Controlled Design



INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999 In Person: Alumni Hall
Atlanta, Georgia 30302-3999 30 Courtland St, Suite 217
Phone: 404/413-3500
Fax: 404/413-3504

November 14, 2013

Principal Investigator: Patricia Clark

Student PI: Nicole Davis

Protocol Department: Nursing

Protocol Title: Using Telehealth to Support Informal Caregivers of Elders with Urinary Incontinence

Submission Type: H14180

Review Type: Expedited, Category 7

Approval Date: November 14, 2013

Expiration Date: November 13, 2014

The Georgia State University Institutional Review Board (IRB) reviewed and approved the above referenced study in accordance with 45 CFR 46.111. The IRB has reviewed and approved the research protocol and any informed consent forms, recruitment materials, and other research materials that are marked as approved in the application. The approval period is listed above. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution.

Federal regulations require researchers to follow specific procedures in a timely manner. For the protection of all concerned, the IRB calls your attention to the following obligations that you have as Principal Investigator of this study.

1. For any changes to the study (except to protect the safety of participants), an Amendment Application must be submitted to the IRB. The Amendment Application must be reviewed and approved before any changes can take place
2. Any unanticipated/adverse events or problems occurring as a result of participation in this study must be reported immediately to the IRB using the Unanticipated/Adverse Event Form.
3. Principal investigators are responsible for ensuring that informed consent is properly documented in accordance with 45 CFR 46.116.
 - The Informed Consent Form (ICF) used must be the one reviewed and approved by the IRB with the approval dates stamped on each page.
4. For any research that is conducted beyond the approval period, a Renewal Application must be submitted at least 30 days prior to the expiration date. The Renewal Application must be approved by the IRB before the expiration date else automatic termination of this study will occur. If the study expires, all research activities associated with the study must cease and a new application must be approved before any work can continue.
5. When the study is completed, a Study Closure Report must be submitted to the IRB.

All of the above referenced forms are available online at <https://irbwise.gsu.edu>. Please do not hesitate to contact Susan Vogtner in the Office of Research Integrity (404-413-3500) if you have any questions or concerns.

Sincerely,



Cynthia A. Hoffner, IRB Vice-Chair

Federal Wide Assurance Number: 00000129

APPENDIX B

IRB Approval for Final Quasi-Experimental Pre-Post Design

INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999
Atlanta, Georgia 30302-3999
Phone: 404/413-
3500 Fax: 4
04/413-3504

In Person: Dahlberg Hall
30 Courtland St, Suite 217

October 06, 2014

Principal Investigator: Patricia Clark

Key Personnel: Clark, Patricia; Davis, Nicole

Study Department: GSU - B.F. Lewis School of Nursing

Study Title: Using Telehealth to Support Informal Caregivers of Elders with
Urinary Incontinence - 2

Funding Agency: John A. Hartford Foundation, John A. Hartford

Foundation Review Type: Expedited 7

IRB Number:

H15144 Reference

Number: 329829

Approval Date: 10/06/2014 Expiration Date:

10/05/2015

The Georgia State University Institutional Review Board (IRB) reviewed and approved the above referenced study in accordance with 45 CFR 46.111. The IRB has reviewed and approved the study and any informed consent forms, recruitment materials, and other research materials that are marked as approved in the application. The approval period is listed above. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution.

Federal regulations require researchers to follow specific procedures in a timely manner. For the protection of all concerned, the IRB calls your attention to the following obligations that you have as Principal Investigator of this study.

1. For any changes to the study (except to protect the safety of participants), an Amendment Application must be submitted to the IRB. The Amendment Application must be reviewed and approved before any changes can take place
2. Any unanticipated/adverse events or problems occurring as a result of participation in this study must be reported immediately to the IRB using the Unanticipated/Adverse Event Form.
3. Principal investigators are responsible for ensuring that informed consent is properly documented in accordance with 45 CFR 46.116.
 - The Informed Consent Form (ICF) used must be the one reviewed and approved by the IRB with the approval dates stamped on each page.
4. For any research that is conducted beyond the approval period, a Renewal Application must be submitted at least 30 days prior to the expiration date. The Renewal Application must be approved by the IRB before the expiration date else automatic termination of this study will occur. If the study expires, all research activities associated with the study must cease and a new application must be approved before any work can continue.
5. When the study is completed, a Study Closure Report must be submitted to the IRB.

All of the above referenced forms are available online at <http://protocol.gsu.edu>. Please do not hesitate to contact the Office of Research Integrity (404-413-3500) if you have any questions or concerns.

Sincerely,


Ann Kruger, IRB Chair

Federal Wide Assurance Number: 00000129

APPENDIX C
Informed Consent Documents

Georgia State University
Department of Nursing
Informed Consent

Title: Using Telehealth to Support Informal Caregivers of Elders with Urinary Incontinence (Caregiver)

Principal Investigator: Patricia C. Clark, PhD, RN, FAHA, FAAN

Student Principal Investigator: Nicole J. Davis, RN, MSN, ANP, GNP

Sponsor: John A. Hartford Foundation's National Hartford Centers of Gerontological Nursing Excellence Award Program

I. Purpose:

You are invited to participate in a research study. The purpose of this study is to see if a tablet-personal computer can be used to teach caregivers how to manage urine leakage. We would like you to participate because you help an older person manage their urine leakage. We would also like you to participate because you are over the age of 18. A total of 20 participants will be recruited for this study. Participation will require about 14 hours of your time over 7 weeks.

II. Procedures:

If you decide to take part in the study, you will be asked to read and sign this consent form. You will then go through the following steps:

Visit 1:

You will be asked to take part in an in-home visit with the Student Principal Investigator. The following procedures will be done during Visit 1:

- You will be asked to fill out a form with general questions about you and the person you care for, your living situation and other details about you. This may take 20 minutes to complete.
- Your health history, the health history of the person you care for, and their current medications will be reviewed.
- You will also be asked to answer some questions about what you know about urine leakage, how you feel about taking care of someone with urine leakage. This may take 20 minutes to complete.
- You will be given a bladder diary to keep track of how many times the person you care for goes the bathroom and has an accident with urine leakage, for 3 days before your next visit. You will be given instructions on how to complete it.

This visit will last about 60 minutes. The Student Principal Investigator will visit your home in about 1 week to complete Visit 2.

Visit 2:

You will be asked to take part in a second in-home visit with the Student Principal Investigator. The following procedures will be done during Visit 2:

- The bladder diary will be collected and reviewed by the Student Principal Investigator
- ***If you meet requirements for the study:***
 - You will be given a small computer and will be taught how to use it (about 15 minutes).
 - You will be asked to look at 6 educational sessions on the computer at least once during the first week of the study. Sessions give information about taking care of someone with urine leakage.
 - You will be asked to keep track of when you view each session and answer a question about how helpful it was.
 - You will be asked to write down how many times the person you care for goes the bathroom and has an accident with urine leakage in a bladder diary. You will do this for 3 days each week.
 - You will be asked to take part in one telephone visit each week for 6 weeks (about 30 minutes per telephone visit). Visits will be with the Student Principal Investigator. Telephone visits will be scheduled at your convenience.
 - During the telephone visits, the Student Principal Investigator will answer any questions that you have about the information in the educational sessions or about how to care for someone with urine leakage.

This visit will last between 60-90 minutes. At the end of this visit, you will be scheduled for your first telephone visit with the Student Principal Investigator.

Telephone Visits 3-7:

The following procedures will be done during each telephone visit with the Student Principal Investigator. There will be 5 visits over 5 weeks. Each visit will last visit about 30 minutes. At the end of each visit, the next telephone visit will be scheduled.

- The bladder diaries and questionnaires for all visits will be reviewed.
- Any questions you have about the educational sessions or caring for someone with urine leakage will be answered.
- For Visit 5, you will be asked to mail in the bladder diaries and questionnaires using a pre-paid envelope.

Visit 8 (Final Visit):

You will be asked to take part in an in-home visit with the Student Principal Investigator. The following procedures will be done during Visit 8:

- The bladder diaries and health questionnaires will be collected and reviewed. (about 10 minutes)
- The tablet-personal computer and will be collected.
- You will be asked questions about how satisfied you were with the education and the tablet-personal computer. (about 40 minutes)

This visit will last about 60 minutes. At the end of this visit, participants in Group 2 will schedule a time when the tablet-personal computer can be returned to the Student Principal Investigator.

Compensation

There will be no cost to you for taking part in this study. When you finish the study, you will receive a \$40 Visa gift card. You will also receive an educational booklet on caring for someone with urine leakage. Your care-recipient will also receive a \$40 gift card at the end of the study. If you both do not finish the study, each of you will receive a gift card totaling \$5 for every week that you completed.

III. **Risks:**

You will not have any more risks than you would in a normal day of life. Answering questions and keeping diaries may be time consuming.

IV. **Benefits:**

Taking part in this study may or may not benefit you. You may learn how to better manage your friend or family member's urine leakage. Overall, we hope to learn about ways to teach caregivers how to manage urine leakage in the elderly.

V. **Voluntary Participation and Withdrawal:**

Taking part in this study is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop being in the study at any time. Whatever you decide, you will not lose any benefits or assistance to which you are otherwise entitled.

VI. **Confidentiality:**

We will keep your records private to the extent allowed by law. Dr. Patricia Clark and Nicole Davis will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection (OHRP) and/or the Food and Drug Administration (FDA), and the sponsor). We will use a study number rather than your name on study records. The information you give us will be secured in a locked cabinet and on password and firewall protected computers. Identifying information will be kept separate from other study documents. Your name and other facts that might point to you will not appear when we present this study or publish its results.

VII. **Contact Persons:**

Contact Dr. Patricia Clark at (404) 413-1180 or Nicole Davis at (770) 639-1501; pclark@gsu.edu and njdavis76@yahoo.com if you have questions, concerns, or complaints about this study. You can also call if you

think you have been harmed by the study. Call Susan Vogtner in the Georgia State University Office of Research Integrity at 404-413-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

VIII. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant

Date

Signature of Principal Investigator or Researcher Obtaining Consent

Date

Based on the results of this study, we may conduct future studies. You do not have to participate in a future study if you participate in this study. Please tell us if you agree for us to contact you about possible participation in future studies.

May we contact you in the future about other studies? (Please check next to your answer)

_____ Yes

_____ No

Georgia State University
Department of Nursing
Informed Consent

Title: Using Telehealth to Support Informal Caregivers of Elders with Urinary Incontinence (Care-Recipient)

Principal Investigator: Patricia C. Clark, PhD, RN, FAHA, FAAN

Student Principal Investigator: Nicole J. Davis, RN, MSN, ANP, GNP

Sponsor: John A. Hartford Foundation's National Hartford Centers of Gerontological Nursing Excellence Award Program

I. Purpose:

You are invited to participate in a research study. The purpose of this study is to see if a tablet-personal computer can be used to teach caregivers how to manage urine leakage. We would like you to participate because you have urine leakage and are age 60 or older. We would also like you to participate because you live with and get help from a caregiver to manage your urine leakage and other daily health needs. Your caregiver is also being asked to volunteer for this study. This study will help us learn how we can help your caregiver take better care of you. A total of 20 participants will be recruited for this study.

During this study your caregiver will fill out some questionnaires about your health. Your caregiver will also be asked to write down how many times you go to the bathroom and have an accident with urine leakage. You will not be asked to do anything for this study, but how your caregiver manages your urine leakage may change.

Your participation in this study will be about 7 weeks.

II. Procedures:

If you decide to take part in the study, you will be asked to read and sign this consent form. Your caregiver will then go through the following steps:

- Your caregiver will be asked to fill out forms with general questions about you.
- Your health history and the medicine you take will be reviewed.
- Your caregiver will be asked to keep track of how many times you go to the bathroom and have an accident with urine leakage.
- *If you and your caregiver meet requirements for the study*, your caregiver will be given a small computer and receive education about taking care of someone with urine leakage.
- Your caregiver will be asked to take part in one telephone visit each week for 6 weeks. Visits will be with the Student Principal Investigator.

Compensation

There will be no cost to you or your caregiver for taking part in this study. When you finish the study, you will receive a \$40 Visa gift card. Your caregiver will also receive a \$40 gift card and an educational booklet on caring for someone with urine leakage. If you and your caregiver do not finish the study, you each will receive a gift card totaling \$5 for every week that you completed.

III. Risks:

You will not have any more risks than you would in a normal day of life.

IV. Benefits:

Taking part in this study may or may not benefit you or your caregiver. This study may help us learn new things that may help people in the future.

V. Voluntary Participation and Withdrawal:

Taking part in this study is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop being in the study at any time. Whatever you decide, you will not lose any benefits or assistance to which you are otherwise entitled.

VI. Confidentiality:

We will keep your records private to the extent allowed by law. Dr. Patricia Clark and Nicole Davis will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection (OHRP) and/or the Food and Drug Administration (FDA), and the sponsor). We will use a study number rather than your name on study records. The information you give us will be secured in a locked cabinet and on password and firewall protected computers. Identifying information will be kept separate from other study documents. Your name and other facts that might point to you will not appear when we present this study or publish its results.

VII. Contact Persons:

Contact Dr. Patricia Clark at (404) 413-1180 or Nicole Davis at (770) 639-1501; pclark@gsu.edu and njdavis76@yahoo.com if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Call Susan Vogtner in the Georgia State University Office of Research Integrity at 404-413-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

VIII. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Participant's Legally Authorized Representative

Signature of Participant's Legally Authorized Representative

Date

Signature of Principal Investigator or Researcher Obtaining Consent

Date

Based on the results of this study, we may conduct future studies. You do not have to participate in a future study if you participate in this study. Please tell us if you agree for us to contact you about possible participation in future studies.

May we contact you in the future about other studies? (Please check next to your answer)

_____ **Yes**

_____ **No**

APPENDIX D

Telephone Visit Protocol

Using Telehealth to Support Informal Caregivers of Elders with UI

Telephone Visit Protocol

Materials:

1. Blue or black ink pen
2. Telephone visit Log

General Approach:

1. CGs will be called by the Student PI on a weekly basis during the 6-week study period.
2. At the beginning of each call, the Student PI will introduce herself and remind the CG of the purpose of the telephone call. (see Telephone Script)
3. The Student PI will explain the content that will be discussed and time required, at the outset of the telephone call.
4. The Student PI will be sensitive to CG time and the need to reschedule the call for a more convenient time, as indicated by the CG.
5. The Student PI will maintain a log of the duration of the call and content discussed.
6. The telephone log will also indicate the outcome of the call (e.g., call completed, no answer/message left, no answer/no message, wrong number, asked to call back later, refused) and number of previous attempts to contact the CG.
7. At the conclusion of the telephone call, CGs will be asked to schedule the date and time of the next weekly telephone visit.
8. CGs will be thanked for their time and ongoing commitment to the study.

Telephone Script

Hello Mr/s. _____, this is Nicole Davis from the Tele-Prompt research study. I am calling to complete your weekly telephone visit. How have you and your _(care-recipient)_____been? (Pause for response). I realize you must be very busy, so this should only take about 20 minutes of your time. Is now an ok time for our visit?

Yes: Wonderful, let's go ahead and get started. Today we will be discussing_____ (topics listed below)

No: Ok, no problem. When would be a better time to call you (later today or another time this week)? Thank you and I look forward to talking with you later.

Discussion Topics

1. **Tele-Prompt Group Topics** (*order to be followed for each CG during every weekly telephone visit*)

- a) Modules viewed during this week
- b) Answer any question CG may have regarding information covered in the modules
- c) Discuss and troubleshoot challenges in viewing modules
- d) Discuss progress with prompted-voiding
- e) Discuss and troubleshoot challenges with prompted-voiding
- f) Answer questions CG may have about the prompted-voiding technique
- g) Discuss technical issues with Tablet-PC

Tele-Prompt Group Script: 1) *Have you viewed any modules this week?*; 2) *Do you have any questions about any of the information that was given to you?*; 3) *Were the modules helpful to you?*; 4) *Was there anything that prevented you from watching all or some of the modules?*; 5) *How are things going with the Prompted voiding?*; 6) *Do you have any*

questions about the technique or is there anything you'd like for me to review?; 7) Have you had any problems with the Tablet-PC?

2. Control Group – Topics (*Special care will be taken by the PI to not answer any CG questions regarding UI or anything that could impact UI (e.g., fluid intake, incontinence products, if they arise)*)

- a) Week 1 – Durable Power of Attorney**
- b) Week 2 – Living Trusts**
- c) Week 3 – How to organize your important papers**
- d) Week 4 – Communicating Effectively with your Healthcare Provider I**
- e) Week 5 – Communicating Effectively with your Healthcare Provider II**
- f) Week 6 – Preparing for Emergencies or Natural Disasters**

APPENDIX E

3-day Bladder Diary

Bladder Diary

Instructions: For the next 3 days, use this diary to keep track of the urination and urine leakages of the person you care for during the day and night.

1. For each day, start first thing when your loved one wakes up in the morning.
2. Every time your loved one urinates in the toilet, check his/her pad or clothing and circle whether or not he/she is wet.
3. Also circle whether or not he/she decided to use the toilet on their own.
4. For any other urine leakages during the daytime, write the time in the box.
5. At the bottom of the page, write down the time your loved one woke up and the time he/she went to bed that night.
6. Also write down whether or not it was a usual day and the number of pad or clothing changes.

Example:

Time Urinated in Toilet	Was he/she wet?	Did he/she decide to go to the toilet on his/her own?	Time of other urine leakages
	Yes No	Yes No	
	Yes No	Yes No	
	Yes No	Yes No	

Time loved one woke up for the day _____

Time loved one went to bed _____

Was this a usual day? Yes _____ No _____

of pads used _____ # clothing changes because of accidents _____

Adapted with permission from: Engberg, S., Sereika, S.M., McDowell, J., Weber, E., Brodak, I. (2002). Effectiveness of Prompted Voiding in Treating Urinary Incontinence in Cognitively Impaired Homebound Older Adults. *Journal of the Wound, Ostomy, and Continence Nursing*, 29(5), 252-265.

APPENDIX F


Prompted Voiding Diary

Prompted Voiding Diary

Instructions: For the next 3 days, use this diary to keep track of when you perform prompted voiding with your loved one. Only perform prompted voiding and keep this diary during the daytime hours only.

1. For each day, start first thing when your loved one wakes up in the morning.
2. Every time you perform prompted voiding write down the time.
3. When you check your loved one's pad or clothing, circle whether or not they are wet.
4. Also circle whether or not he/she went to the bathroom when you offered and if they urinated in the toilet.
5. At the bottom of the page, write down the time your loved one woke up and the time your loved one went to bed that night.
6. Also write down whether or not it was a usual day.
7. Continue to keep track all day, until your loved one goes to bed for the night and then start the diary again the next morning when he/she wakes up.

Example:

Time Prompted 	Was he/she wet?	Did he/she go to the bathroom when you offered?	Did he/she urinate in the toilet?
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No

Time loved one woke up for the day _____


Time loved one went to bed _____

Was this a usual day? Yes _____ No _____

Comment: _____

Adapted with permission from: Engberg, S., Sereika, S.M., McDowell, J., Weber, E., Brodak, I. (2002). Effectiveness of Prompted Voiding in Treating Urinary Incontinence in Cognitively Impaired Homebound Older Adults. *Journal of the Wound, Ostomy, and Continence Nursing*, 29(5), 252-265.

Day 1 Date _____

Time Prompted 	Was he/she wet?	Did he/she go to the bathroom when you offered?	Did he/she urinate in the toilet?
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No

Time loved one woke up for the day _____

Time loved one went to bed _____

Was this a usual day? Yes _____ No _____

Comment: _____

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APPENDIX G

Educational Module Weekly Viewing Log

Educational Module Weekly Viewing Log

Instructions: During this week, use this form to keep track of when you view each learning module on the Tablet-Personal Computer. Put a check mark in the boxes below, when you see all or just a part of each module. Also circle whether or not you felt each module was helpful.

Module	Viewed <u>all</u> of the Module (put a check mark each time)	Viewed <u>some</u> of the module (put a check mark each time)	Was it helpful? (circle your answer)
#1: UI in frail older adults			Yes No
#2: Practical help to promote toileting			Yes No
#3: Prompted voiding skills session			Yes No
#4: Prompted voiding video			Yes No
#5: Fluid management strategies			Yes No
#6: Skin Care and UI costs			Yes No