Effect of a Bladder Control Self-Management Program Delivered Through a Health Kiosk

by

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Urinary incontinence (UI) is a chronic yet underreported condition that is negatively impacting the overall health status and quality of life (QoL) of the older adults in our community. People with UI symptoms often delay or abstain from UI-related medical care due to social stigma and the misconception of UI as a part of natural aging. Behavioral interventions are first-line conservative management methods to help people minimize urinary incontinent episodes and related symptoms. Providing behavioral interventions through a self-management delivery program can increase access to care and ease the financial burden on the healthcare system. The purpose of this secondary analysis is to examine the feasibility of delivering a bladder control self-management program through a Health Kiosk and its effect on urinary incontinence and incontinence-specific quality of life. Changes in incontinent episodes were measured by 7-day bladder diaries, and changes in incontinence-specific quality of life were measured with the Incontinence Impact Questionnaire Short Form (IIQ-7). A total of 111 participants from the parent study met eligibility criteria for the current study; 61 of these individuals accessed the six-session Bladder Control Module (BCM). Multivariate analysis revealed that being retired and self-reporting current depression were positively associated with accessing the BCM whereas self-reporting current anxiety decreased participants' likelihood of accessing the BCM. For participants recording incontinent episodes in their baseline bladder diary and completing between three and six sessions of the BCM, there were statistically significant decreases in the median number of

total UI episodes ($p=0.01$), urge UI episodes ($p<0.001$), and stress UI episodes ($p=0.02$). Incontinence-related quality of life also improved significantly ($p=0.03$). Overall, these findings support the potential effectiveness of independently completed self-management programs such as the BCM in increasing access to conservative interventions and improving incontinence-related outcomes for older adults who suffer from UI. Additional research with a larger sample is needed to confirm these findings.

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1.0 INTRODUCTION

Urinary incontinence (UI) is defined as having signs or symptoms of involuntary loss of urine (International Continence Society, 2020). As a common, chronic, yet underreported condition, UI impacts approximately 20 million women and 6 million men in the United States (Irwin, 2019). The population of older adults has rapidly increased in both the United States and globally. By 2030 older adults will make up about 20% of the US population (Kim & Miller, 2017). Although UI is not part of the natural aging process, there are large numbers of people in the older population who are affected by symptoms of UI. According to the Centers for Disease Control and Prevention (CDC), among community-dwelling older adults who are 65 years of age or older, 43.8% reported urinary leakage (Gorina, 2014).

UI is associated with an increased risk for urinary tract infection, falls and fractures, incontinence-related dermatitis, and depression and anxiety. It is also associated with higher hospitalization rates, decreased quality of sleep, impaired social and physical relationships, and worse quality of life (QoL) (Minassian et al., 2017). In a systematic review with meta-analysis, Pizzol and colleagues (2020) reported that compared to controls without UI, individuals with UI had significantly worse general health-related QoL ($p<0.0001$) as measured by the SF-36 total score as well as the mental health and the mental and physical subscale scores. UI is also a costly problem in the United States. According to CDC, in 2000 the cost of urinary incontinence was estimated at $19.5 billion among adults, including $14.2 billion among community residents (Gorina, 2014). The severity of incontinent symptoms is directly associated with increased annual costs.

Due to social stigma, embarrassment, and misunderstanding of UI as a natural part of aging, people who experience symptoms of UI often delay or abstain from seeking medical attention and care. According to previous research, only approximately 38% of women had initiated the conversation about UI with their primary care physicians (Kinchen, 2003). Another study of male and female older adults (N=1104; 65 to 79 years) reported that only 37.6% of the participants had mentioned their UI symptoms to their physicians (Burgio, 1994). Factors that influenced participants' decision to seek treatment were the frequency and volume of UI episodes, the use of protection products secondary to UI, the cost of the products, activity restriction secondary to UI, considering incontinence a problem, reporting that UI had an impact on their feelings, and its duration (Burgio, 1994).

The three most common types of UI are stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed stress and urge urinary incontinence (MUI). SUI develops when a weak urinary sphincter causes involuntary loss of urine when intra-abdominal pressure increases, e.g., when coughing or sneezing or during physical exertion (Irwin, 2019). SUI is common in women. In men, it is not common except following radical prostatectomy. UUI is characterized by an involuntary loss of urine associated with an urge to void and occurs because of the overactivity of the detrusor muscle (Irwin, 2019). It is often accompanied by urinary frequency and nocturia. MUI is a combination of SUI and UUI (Irwin, 2019). In a large epidemiological study of UI in men, among those 65 years and older (n=3646), UUI was the most common type followed by MUI (Diokno et al., 2007). Among younger women, SUI is the most common type of UI. With increasing age, however, MUI and UUI become more common in women (Aoki et al., 2018).

2.0 BACKGROUND

Behavioral interventions are recommended as first-line treatments for stress, urge, and mixed UI. These include lifestyle modifications, pelvic floor muscle training (PFMT), and bladder retraining (Dumoulin et al., 2015). Lifestyle modifications recommended for UI include weight loss, and dietary and fluid intake modifications. Evidence supporting these interventions varies, with the strongest evidence supporting the beneficial effects of weight loss in individuals who are obese or morbidly obese. There is also evidence to suggest that reducing caffeine intake may reduce UI (Dumoulin et al., 2015). PFMT teaches the individual to contract their pelvic floor muscles in order to increase muscle strength, endurance, rapidity, and coordination. The advantages of PFMT as a first-line treatment are that it is non-invasive and relatively low-cost. Based on a systematic review of 16 randomized controlled trials (RCTs) comparing PFMT to alternatives, PFMT was more effective than no treatment, a placebo drug, or an inactive control in treating SUI, UUI, and MUI in women (Dumoulin, 2015). Another conservative treatment method is bladder retraining (BT), which treats UI using a scheduled toileting intervention. There is less research examining the effectiveness of BT in treating UI than for PFMT, but limited evidence suggests that it may be an effective treatment (Dumoulin, 2015).

While there is evidence supporting the effectiveness of behavioral interventions for UI, these interventions often require significant clinician time and multiple visits. Given the limited time allotted for a typical office visit and the multiple health care needs of many older adults, there is often not adequate time to deliver behavioral-based interventions. Managing UI requires patients to develop skills to effectively and simultaneously manage their symptoms and behaviors based on treatments and lifestyles (Fu, 2019). Self-management programs for chronic conditions, such

as UI, have the potential to assist patients in making proper decisions about managing their health problems and efficiently utilizing healthcare resources. While positive outcomes have been reported for self-management programs developed for other chronic health problems, studies examining the effect of self-management interventions for UI are limited (Fu, 2019).

In this study, a self-management program for UI is defined as a mobile application or internet-delivered program that conveys UI-related information aimed at helping participants to manage their UI symptoms by engaging in conservative behavioral interventions without a face-to-face component. A literature search was conducted to identify published studies examining self-management programs for UI. Only three research studies were found that met these criteria and evaluated the effectiveness of the self-management program in relation to UI (Asklaud et al., 2017; Brokne et al., 2019; Rygh et al., 2021). The studies used different platforms including websites and mobile applications on smartphones. All three studies were conducted by the same research group in Sweden by the same research group in Sweden, although Rygh et al. (2021) included women from several countries including the U.S. All participants were women and the mean age of the samples varied from 44.4 to 54.4 years. In each of the studies, the effect on UI was measured by the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), a valid and reliable measure of urinary incontinence symptoms and impact (Avery et al., 2004). This questionnaire asks respondents how often they leak urine (from never (0) to all the time (6)), how much urine they usually leak (from none (0) to a large amount (6)), and how much urine leakage interferes with their daily life (from not at all (0) to a great deal (10)), with higher scores indicating worse UI symptoms. All studies reported a significant reduction in UI symptoms following the self-management intervention (see Table 1).

Table 1. Studies examining independent self-management interventions for urinary incontinence

Author	Design	Recruitment Method	Setting/Sample	Intervention	Outcomes	Findings
Asklaud et al., 2017	RCT	Recruitment through study website	Setting: Sweden 27-72 years old, women (M=44.7) SUI; no UUI N for analysis=121 (62 in app group & 60 in control group)	Mobile App focused on PFMT and lifestyle	Symptom severity (ICIQ0UI SF) QoL (ICIQ-LUTSqol) Satisfaction w/ app	Compared to the control group, participants in the app group reported significantly greater improvement in symptoms (p<.001), improvements in UI-specific QOL (p=.005); greater subjective improvement (p<.001); a greater reduction in UI episodes (p=.001); lower pad usage (p=.02) 8.3% of participants in the App group reported being totally satisfied, 58.3% were satisfied (but still had some leakage), and 33.3% not satisfied
Bokne et al., 2019	Pragmatic prospective cohort study	Booklet group: ordered from website or received from a midwife Internet-based treatment: after finding the website without any previous contact with the healthcare system Midwives were informed about & sent the booklet All participants were actively seeking treatment for their UI and self-selected the intervention group they participated in	3 months program, pt. with SUI; 109 women used booklet, 166 women used internet-based program	Two treatment programs on PFMT & life modifications: booklet & internet-based In contrast to the booklet group, those in the internet group did not have contact with a urotherapist for support during treatment	Characteristics of the participants (age & education) Reductions in symptom severity (validated ICIQ-UI SF)	Mean age of booklet users was higher, 59.4 years vs. 54.5 years. More women with post-secondary education, 59% in the booklet group and 67% in the Internet group. The mean reduction in the symptom score was 2.6 points (SD 3.4) in the booklet group, and 3.4 (SD 2.9) in the Internet group. Scores improved significantly in both groups (p<.001) but there were no significant group differences (p=0.08).

Rygh et al., 2021	Prospective cohort study	Anonymous responses to a questionnaire when downloading the Tat app The app is freely available in App store & Google Play in 6 languages	24,602 non-pregnant, non-postpartum women > 18 years old downloaded the app and responded anonymously to the questionnaire. 2672 (11%) responded to 3-month follow-up. Mean age=44.4 (13.5) years The UI types: SUI (53.1%), urge UI (12.1%), mixed UI (30.9%), undefined (3.6%).	App-based treatment (Tat) with PFMT & lifestyle advice for SUI	UI severity measured by the ICIQ-UI SF Self-reported change in UI symptoms	The mean ICIQ-UISF score reduction at follow-up was 1.31 (95% CI: 1.19 to 1.44, p<0.001) with a larger reduction in those with more severe incontinence at baseline. 13% were no longer incontinent at follow-up. The reduction was similar for the subtypes of UI. 65.2% reported that their symptoms improved and 25.9% reported that they were much or very much improved with similar reports for those with slight, moderate and severe UI at baseline and by type of UI.

Although all three studies support the potential effectiveness of self-management interventions for UI symptom management, there are limitations in the generalizability of the findings to community-dwelling older adults, which is the target population of the parent study for this thesis. Additional summarizations about those three studies are presented in Table 1. First, the three studies included participants from a wide range of ages, with the mean age much younger than that of the target population. Second, all three studies only included female participants. While UI is more common in women, with age its prevalence also increases in men. Third, the three studies recruited participants seeking treatment for UI by responding to advertisements or downloading a UI-specific application. In contrast, the parent study for this secondary analysis included multiple self-management modules focused on an array of health topics, with individual modules recommended based on findings from topic-specific screening measures self-administered at a community-based health kiosk. Participants who reported UI symptoms and/or wanted to improve their bladder control were encouraged to complete the Bladder Control module in order to acquire knowledge and self-care behaviors that could mitigate their UI symptoms. Finally, compared to all three published studies that measured improvements in bladder function using self-report symptom questionnaires, the parent study had participants record leaking episodes in a bladder diary, thus enabling detection of quantifiable changes in UI symptoms over time.

The prevalence of chronic diseases increases with age, with many older adults having multiple chronic health problems that can be challenging to effectively self-manage. Technology-based self-management (e-health) programs have the potential to support the self-management of chronic health problems. The slow adoption of telehealth or health-related technology by older adults could be caused, at least in part, by those technologies being less user-friendly for this age

group or insufficient to satisfy older adults' health needs (Heinzelmann, 2005). Age-related changes including cognitive, sensory, and physical impairments as well as motivational issues, particularly when the benefits are not readily and quickly evident during use, were identified as barriers to older adults' utilization of mobile health interventions in a recent scoping review (Wildenos et al., 2018). Lack of access is also a potential barrier to utilization, particularly for older adults with limited financial resources. The health kiosk utilized to deliver and track e-health interventions in the parent study was designed to overcome many of these barriers.

3.0 PURPOSE

The purposes of the current study were to examine (1) whether community-dwelling older adults who reported urinary incontinence during their baseline assessment for a health kiosk study accessed and completed a Bladder Control Module offered through the kiosk, and (2) whether there was a change in urinary incontinence and/or incontinence-specific quality of life among those who completed the Bladder Control Module.

The research aims were to examine:

1) the proportion of eligible participants that accessed the Bladder Control Module;
2) associations between participant characteristics of participants and accessing the Bladder Control Module;
3) the proportion of participants who completed each of the Bladder Control Module sessions; and
4) changes in incontinent episodes and incontinence-specific quality of life among eligible participants who completed at least three sessions of the Bladder Control Module.

4.0 METHODS

4.1 DESIGN

This secondary analysis utilized data collected for the parent study, the Health Kiosk Project, which was an observational study with embedded health intervention modules. Each module, including the Bladder Control Module, was developed to permit its evaluation using a pre- and post- quasi-experimental design. The parent study was a translational research project funded by the Agency for Health Research and Quality (Self-management via Health Kiosk by Community-residing Older Adults: 5R01HS022889) that aimed to understand the perceptions, motivations, and patterns of usage of a community-based multi-use Health Kiosk available to community-dwelling older adults, especially lower-income individuals who may lack access to e-health resources. Implementation of the Health Kiosk Project in the community provided an accessible and user-friendly platform for the delivery of health-related information. Each kiosk was configured as a desk with on-board computer, chair, and seated scale at which participants could self-monitor their weight, blood pressure, and grip strength, and engage with interactive health modules. The modules were intended to increase older adults' self-management knowledge and behavior for an array of health concerns commonly affecting older adults. The current study, which focused on older adults' UI-related bladder health and the effects of a self-management intervention, utilized data collected by the parent study during participants' interactions with the Bladder Control Module.

Prior to conducting the current study, the principal investigator, Yuchen Zhang, served as a research assistant for the parent study under the auspices of the Undergraduate Research

Mentorship Program at the University of Pittsburgh School of Nursing. The potential for other investigators to use research data collected by the parent study was specified in the consent form and procedures for obtaining informed consent for the parent study. Both the parent study and the current study (STUDY21040086) received approval from the University of Pittsburgh Institutional Review Board (IRB) (see Appendix). De-identified data from the parent study were used in this secondary analysis, and participants' privacy was protected throughout the process. Only the principal investigator of the parent study, Dr. Judith Matthews, has access to the password-protected data sheet with participants' identifiable information.

4.2 THE BLADDER CONTROL MODULE

During the first session of the Bladder Control Module (BCM), "Assessments and Bladder Control Basics," participants completed baseline questions about bladder function and lower urinary tract symptoms, including incontinence and its impact on QOL. Several questions were designed to identify serious lower urinary tract symptoms (e.g., pain, bleeding) requiring medical evaluation. If participants reported any of these potentially serious symptoms, they were contacted by a nurse on the team and referred to their primary care provider, if indicated, before proceeding with the module. The first session also presented information about lifestyle changes that may improve incontinence symptoms. The second session, "Behavioral Treatment of Incontinence," introduced the benefits of doing pelvic floor muscle exercises (PFME) to prevent or lessen UI episodes. Instructions on how to begin a PFM strengthening program and how to practice the exercises were also presented. Participants were asked to specify how many fewer incontinent episodes per week they aimed to achieve within 4 weeks. The third session, "Strategies to Prevent

or Stop Leaking," helped participants develop strategies that could be used to prevent involuntary urine loss during activities that increase intra-abdominal pressure or following an urge to urinate. The fourth session, "What Else Can Help to Stay Dry," delivered information about bladder retraining, including when it can be helpful and how to implement it. The fifth session, "Making New Bladder Habits Stick," reviewed PFME and bladder retraining principles and promoted adherence to the bladder self-management strategies introduced in previous sessions. During the sixth session, "Bladder Control Checkpoint," baseline measures were again self-administered, including the incontinence-specific quality of life measure, the Incontinence Impact Questionnaire-7 Short Form. At the end of each session participants were asked to print a 7-day bladder diary and to enter number of times they leaked any urine and the number of stress and urge incontinent episodes each day. At the beginning of each subsequent session, they were asked to enter the data recorded in their bladder diary (see Measures). Although not included in this secondary data analysis, at the conclusion of session 1 and session 5 participants were also asked to complete a 3-day voiding log documenting each time they urinated in the toilet from the time they got up until the time they went to bed. The feedback during each session consisted of reminding participants of the target they had set for fewer incontinent episodes per week and summarized their recorded bladder diary data as a way to gauge their progress. A minimum interval of seven days separated one session from the next. Participants who wanted to do so could repeat the module as many times as they wished.

To encourage continued self-monitoring and to enable review of the module's educational content, an additional module, "Bladder Ongoing," was offered as often as every seven days for as long as participants were willing to complete it. Similarly, they were encouraged to complete the "Bladder Control Checkpoint" as often as every 28 days following its initial completion.

4.3 SAMPLE AND SETTING

Participants in the parent study were recruited from the 12 sites where kiosks were located: senior centers, low-to-moderate income senior housing, continuing care retirement communities, and a public library. Recruitment was through posters, brochures, and information sessions at the kiosk venues. Those who agreed to participate provided informed consent prior to beginning the baseline assessment.

Participants were eligible for this secondary analysis if they were 60 years old or older, consented to participate in the parent study, and were eligible to complete the BCM. Participants were eligible to receive a recommendation to complete the BCM if they met the following criteria: total score ≥ 4 on the Bladder Control Self-assessment Questionnaire; score ≥ 2 out 10 on the desire to improve bladder control in the next 6 months; bladder control indicated as priority #1 or #2 among health behaviors to improve in the next 6 months; bladder control given the highest rating among the behaviors to improve; and/or an affirmative response to baseline questions asking "Is it difficult to hold urine when you get the urge to go?" or "Do you leak urine?". Participants who accessed the module voluntarily without meeting the above criteria were excluded from the current study.

Participants who met the eligibility criteria and returned to the kiosk were offered the recommendation to access and complete the "Consider the Bladder Control Module," which described what engaging in the BCM would entail and elicited their agreement to proceed. Participants were included in the analysis for Aim 3 if they completed at least one session of the BCM. To be included in the analysis for Aim 4, participants needed to report at least one incontinent episode during session 2 of the BCM and to complete at least sessions 2 and 3 and/or complete the Incontinence Impact Questionnaire Short Form (IIQ-7) during BCM session 1 and

BCM session 6, the "Bladder Control Checkpoint." Participants who only reported enuresis were excluded from the analysis for Aim 4. If a participant repeated the BCM more than once, data from only the first completion of the module was included in the analysis.

4.4 MEASURES

Access to and completion of the BCM were measured based on session completion at the kiosk. Demographic information collected as part of the baseline assessment in the parent study was utilized to compare sociodemographic characteristics including age, gender, race, marital and socioeconomic status, level of education, and clinical characteristics of participants who did and did not access the BCM.

The change in incontinent episodes (total, stress, and urge) was measured by 7-day bladder diaries. Following the collection of data about participants' current bladder symptoms and lifestyle habits, they were asked to print the bladder diary and complete it for 7 days prior to their next BCM session. At the beginning of each subsequent session, they were asked to enter the data they had recorded in the paper diary. For each day, they were asked to record the number of times they: (a) leaked any urine, even a few drops; (b) leaked urine when coughing, laughing, lifting, or changing positions (classified as stress incontinent episodes); and (c) leaked urine after an urge to urinate (classified as urge incontinent episodes). Wyman and colleagues examined the test-retest reliability of a one-week bladder diary and reported that it is a reliable method of evaluating the frequency of incontinent episodes (Wyman et al., 1988).

The Incontinence Impact Questionnaire Short Form (IIQ-7) (Uebersax et al., 1995) was used to measure the impact of UI on quality of life. This 7-item questionnaire was developed by

identifying items in each subscale of the original 30-item Incontinence Impact Questionnaire (IIQ) that best predicted its subscale score. Participants rated the effect of urine leakage on household chores, physical recreation, entertainment activities, travel more than 30 minutes from home, social activities, emotional health, and feeling frustrated. The response options for each item are: "not at all" (0), "slightly" (1), "moderately" (2), or "greatly" (3). To allow for missing responses and calculate an average score, the scores on items responded to are summed and divided by the number of items answered. This score is then multiplied by 33 1/3 to put the total score on a scale of 0-100, with higher total scores indicating greater impact on QoL. Uebersax et al. (1995) reported high correlations between IIQ-7 scores and the total and subscale scores on the original IIQ (0.88 to 0.97) and significant positive correlations with the number of incontinent episodes, pad test results, and improvements following treatment of incontinence.

4.5 STATISTICAL ANALYSES

Data were analyzed using IBM SPSS version 27 (IBM Corp. Armonk, NY) and Excel version 16.54 (Microsoft Corp, Redmond, WA). Data were screened for normality, missing variables, and outliers. A p-value of ≤ 0.05 was considered statistically significant. Descriptive statistics, based on the distribution of the variables, were used to describe the overall sample as well as the sample for Aim 4.

4.5.1 Aim 1: Proportion of Eligible Participants Who Accessed the Bladder Control Module

The outcomes for Aim 1 were (1) how many participants were eligible to complete the Bladder Control Module, (2) how many eligible participants accessed the "Consider the Bladder Control Module" after receiving the recommendation to do so, and (3) how many eligible participants ultimately accessed the Bladder Control Module. Data for each outcome were analyzed descriptively using frequencies and percentages.

4.5.1 Aim 2: Associations between Participant Characteristics and Accessing the Bladder Control Module

Eligible participants who did and did not access the Bladder Control Module (BCM) were compared by age, sex, race, marital status, household size, education, occupation, difficulty paying for basic needs, difficulty with vision, number of self-reported medical problems, current depression, current anxiety, number of prescribed medications, and use of assisted devices. Given the small sample size, variables with more than two categories were collapsed into two categories. First, bivariate analysis was used to compare the association of each variable with accessing the BCM. The Chi-square test was used to compare categorical variables. The Mann-Whitney U test was used to compare the two continuous variables, age and number of self-reported medical problems, as neither was normally distributed. Logistic regression was then performed to determine which characteristics were independently associated with accessing the BCM. A p-value of 0.20 was used to select variables to include in the regression. We also included self-reported current depression in the model based on a previous study by Burgio et al. (1994) which found that

older adults who reported their UI to a healthcare provider tended to have higher depression scores (p=0.06).

4.5.3 Aim 3: Percentage of Participants Who Completed Each Session of the Bladder Control Module

Descriptive statistics were utilized to address Aim 3. The number and percentage of eligible participants who completed each Bladder Control Nodule were calculated.

4.5.4 Aim 4: Change in Urinary Incontinence and Incontinence-Specific Quality of Life Among those who Completed the Bladder Control Module

The outcomes examined for Aim 4 were changes in urinary incontinence: total urinary accidents (TUI), stress urinary accidents (SUI), and urge urinary accidents (UUI) measured by data participants entered from their bladder diaries during BCM sessions and by changes in incontinence-specific quality of life measured by the IIQ-7. Participants were included in the analyses for changes in TUI if they recorded at least one incontinent episode during BCM session 2 (baseline bladder diary) and if they completed at least sessions 2 and 3. They were included in the analysis for changes in SUI and/or UUI if they recorded at least one SUI and/or UUI episode during session 2, completed at least sessions 2 and 3, and did not have missing data for SUI and/or UUI episodes during the last BCM session completed. For each incontinence outcome (TUI, SUI, and UUI), incontinent episodes/day was calculated at baseline and during the last BCM session completed by dividing the total number of episodes reported by the number of bladder diary days

(maximum 7) that each type was recorded. The percent change in TUI, SUI, and UUI episodes was calculated using the following formula:

% Change in incontinent episodes (UI, SUI and UUI) =

$$(\text{episodes per day}_{\text{baseline}} - \text{episodes per day}_{\text{last completed BCM\_session}}/\text{episodes per day}_{\text{baseline}}) \times 100$$

None of the incontinence variables were normally distributed. Consequently, the median and range were calculated to describe the percent change for each variable. The Wilcoxon signed-rank test was used to compare daily incontinent episodes for each type (TUI, SUI, and UUI) reported at baseline and during the last BCM session completed.

Participants were included in the analysis for changes in UI-specific quality of life if they completed the IIQ-7 during BCM session 1 and during the "Bladder Control Checkpoint." IIQ-7 scores were not normally distributed. Consequently, the median and range were used to describe scores at the two-time points and the Wilcoxon signed-rank test was used to compare them.

5.0 RESULTS

5.1 SAMPLE CHARACTERISTICS

One hundred thirteen (46.7%) of the 242 participants from the parent study were eligible to be asked to consider completing the BCM. Two participants were excluded due to being younger than 60 years of age. Thus, 111 (45.9%) of the 242 participants were eligible to be included in this secondary analysis. Their mean age was 72.8 years, most were female (n=95, 85.6%), and 81 (75.7%) identified themselves as Caucasian. Thirty-eight (34.2%) identified themselves as currently married or living with a significant other, and 57 (51.8%) lived alone. Most (n=79, 71.2%) had at least some college education. More than half (n=60, 54.5%) reported having some difficulty paying for their basic needs.

In terms of health status, participants reported having a mean of 3.5 medical problems. The prevalence of medical problems reported by 10% or more of the participants is summarized in Table 2. The most common medical problems were arthritis (n=87, 79.1%), hypertension (n=72, 64.9%), and dyslipidemia (n=47, 42.7%). Most participants (n=102, 91.9%) reported taking prescription medications regularly, with 22 (19.8%) taking one or two, 40 (36.0%) taking three or four, and 40 (36.0%) taking five or more. More statistical data are reported in Table 2.

Table 2. Sample characteristics (n=111)

Characteristic	Findings	Missing
	n (%)	(n)
Age in years: mean (SD); median (range)	72.8 (7.9); 72.0 (60-92)	0
Female: n (%)	95 (85.6)	0
Caucasian race: n (%)	81 (75.7)	4
Some college education: n (%)	79 (71.2)	0
Retired: n (%)	95 (85.6)	0
Currently married/living with significant other: n (%)	38 (34.2)	0
Live alone: n (%)	57 (51.8)	1
Caregiver for another person: n (%)	18 (16.2)	0
Somewhat or very difficult to pay for basic needs: n (%)	60 (54.5)	1
Use assistive device during ambulation: n (%)	19 (17.3)	1
Difficulty seeing (even with glasses/contacts): n (%)	14 (12.6)	1
Use a hearing aid: n (%)	23 (20.7)	0
Number of self-reported medical problems: mean (SD); median (range)	3.5 (2.1); 3.0 (0-12)	0
Self-reported medical problems: n (%)		
Anxiety	32 (29.9)	4
Arthritis	87 (79.1)	1
Asthma/Bronchitis	23 (22.1)	2
Cancer	14 (12.8)	2
COPD (chronic obstructive pulmonary disease)	10 (9.2)	2
Depression	20 (18.3)	2
Diabetes	17 (15.5)	1
Dyslipidemia	47 (42.7)	1
Heart disease	21 (19.3)	2
History of stroke	12 (10.8)	0
Hypertension	72 (64.9)	0
Osteoporosis	33 (30.0)	1
Thyroid disease	24 (23.8)	1
Number of prescription medications taken on a regular basis: n (%)		0
None	9 (8.1)	
1-2	22 (19.8)	
3-4	40 (36.0)	
5-7	27 (24.3)	
8-10	9 (8.1)	
> 10	4 (3.6)	

5.2 RESULTS RELATED TO AIMS

5.2.1 Aim 1. Proportions of Eligible Participants Who Access the Bladder Control Module

Of the 111 participants eligible to complete the BCM, 76 (68.5%) completed the "Consider the Bladder Control Module." Sixty-one (61) of these participants accessed the BCM, which is 55.0% of those classified as eligible participants and 80.3% of those who completed the "Consider the Bladder Control Module."

5.2.2 Aim 2. Associations Between Participants' Characteristics and Accessing the Bladder Control Module

On bivariate analyses, the one variable examined that was significantly related to accessing the BCM was the retirement status (p=0.04). Fifty-six participants who reported being retired (58.9%) accessed the BCM compared to five (31.3%) of those who reported currently being employed or actively engaged in volunteer activities. Anxiety was the other characteristic that met the p=0.20 criteria for being included in the multivariate analysis. Among participants who reported anxiety, 40.6% (n=12) accessed the BCM compared to 60.6% of those who did report anxiety (n=45, p=0.07). The results of the bivariate analyses are presented in Table 3.

Table 3. Characteristics of those who did (n=61) and did not (n=50) access the Bladder Control Module

Characteristic	Missing cases	Accessed the BCM	Did not Access the BCM	Test statistic p-Value
Age in years, median (range)	0	72.0 (60-92)	73.0 (60-90)	U^1=1589.5 p=0.70
Sex, n (%)	0			χ^2= 0.43
Female		51 (53.7)	44 (46.3)	p= 0.51
Male		10 (62.5)	6 (37.5)	
Race, n (%)	4			χ^2= 0.005
White/Caucasian		43 (53.1)	38 (46.9)	p= 0.95
Others		14 (53.8)	12 (46.2)	
Married/living with significant other, n (%)	0			χ^2= 0.002 p= 0.96
Yes		21 (55.3)	17 (44.7)	
No		40 (54.8)	33 (45.2)	
Household size, n (%)	1			χ^2= 0.18
Living alone		30 (52.6)	27 (47.4)	p= 0.68
Living with other people		30 (56.6)	23 (43.4)	
Education, n (%)	0			χ^2= 0.36 p= 0.55
Less than high school through vocational		19 (59.4)	13 (40.6)	
Some college through graduate school		42 (53.2)	37 (46.0)	
Employment status, n (%)	0			χ^2= 4.24
Employed/volunteer		5 (31.3)	11 (68.8)	p= 0.04
Retired		56 (58.9)	39 (41.1)	
Difficulties in paying for basic needs, n (%)	0			χ^2= 0.44 p= 0.51
Yes		35 (58.3)	25 (41.7)	
No		26 (52.0)	24 (48.0)	
Serious difficulty seeing even with glasses or contact lenses, n (%)	0			χ^2= 0.03 p= 0.86
Yes		8 (57.1)	6 (42.9)	
No		53 (54.6)	44 (45.4)	
Number of self-reported medical problems, median (range)	0	3.0 (0-10)	3.5 (1-12)	U^1=1389.5 p=0.42
Current depression, n (%)	2			χ^2= 0.34
Yes		12 (60.0)	8 (40.0)	p= 0.56
No		47 (52.8)	42 (47.2)	
Current anxiety, n (%)	4			χ^2= 3.39
Yes		13 (40.6)	19 (59.4)	p= 0.07
No		45 (60.0)	30 (40.0)	

Usage of assisted devices, n (%) **Yes** **No**	1	 11 (57.9) 49 (53.8)	 8 (42.1) 42 (46.2)	χ^2= 0.10 p= 0.75
Numbers of prescribed medicines, n (%) **0 - 4** **5 or above**	0	 38 (53.5) 23 (57.5)	 33 (46.5) 17 (42.5)	χ^2= 0.16 p= 0.69

BCM=Bladder Control Module
[1]Mann Whitney U test

Three predictor variables, current anxiety, employment status, and current depression were entered into the logistic regression model. Current anxiety and employment status were chosen because their p-value met the <0.20 selection criteria and current depression was selected based on previous research (Burgio et al., 1994). The total number of participants included in the regression model was 106, with 5 participants excluded because of the missing values on one or more of the three predictor variables. The model correctly classified 91% of participants who accessed the BCM, but only 43% of those who did not. Overall, 69% of the participants were correctly classified. The logistic regression model was statistically significant (p<0.001), which indicates the model including these variables was significantly better than the null model. Being retired (OR=6.2, p=0.007) and reporting current depression (OR=7.9, p=0.007) were associated with increased odds of accessing the BCM, whereas reporting current anxiety reduced the odds of accessing the BCM (OR=0.10, p=0.001). The regression findings are summarized in Table 4.

Table 4. Logistic regression analysis of predictor variables (n=106)

Predictor Variables	Odds Ratio	p-value	95% Confidence Interval
Currently retired	6.15	0.007	1.65 – 22.95
Current Anxiety	0.10	0.001	0.03 – 0.41
Current Depression	7.88	0.007	1.76 – 35.37

5.2.3 Aim 3. Percentages of Participants Who Completed Each Session of the Bladder Control Module

Sixty-one of the eligible participants completed BCM session 1. Seven (11.5%) of these individuals only completed session 1. Among the remaining participants, 74.1% (n=40) completed the 5 intervention sessions (there was no intervention delivered during session 6, the "Bladder Control Checkpoint"), while 3.7% (n=2) only completed four, 5.6% (n=3) only completed three, and 16.7% (n=9) only completed two sessions.

5.2.4 Aim 4. Change in Bladder Control Symptoms among Those Who Completed the Bladder Control Modules

Self-reported data collected during BCM session 1 was used to describe the bladder-related characteristics of the Aim 4 sample. Participants who reported at least one incontinent episode during session 2 of the BCM and completed at least sessions 2 and 3 and/or completed the IIQ-7 during BCM session 1 and BCM session 6 ("Bladder Control Checkpoint") were included in the analyses for Aim 4. Their characteristics are summarized in Table 5. Among the 37 eligible participants, 25 (67.6%) reported mixed UI, 11 (29.7%) reported urge UI only, and one (2.7%) reported stress UI only. Six (16.7%) also reported enuresis. The normality of all measured variables was examined and, as none of the continuous variables were normally distributed, results were summarized using both the mean and median. Participants reported a median of two incontinent episodes (range: 0-8) during the daytime and one during the night (range: 0-6). Seventeen (45.9%) reported incontinence episodes both during day and night. Sixteen (43.2%) reported the use of absorbent products during the day and 15 (40.5%) reported use of them at night.

The median number of daytime voids was five times per day, and median nocturia episodes per night were two. Participants were asked how many, on average, glasses or cups of noncaffeinated and caffeinated beverages they consumed each day. The median for noncaffeinated drinks was five (range: 0-16) and two (range: 0-10) for caffeinated drinks. The median score on the IIQ-7 was 9.6 with a range from 0 to 76.2. Five participants (13.5%) reported that they were doing pelvic floor muscle exercises.

Table 5. Bladder-related characteristics of participants eligible for inclusion in analysis for Aim 4 (n=37)

Characteristic	Mean (SD)	Median (range)	n (%)
Type of urinary incontinence[1]			
Stress only			1 (2.7)
Urge only			11 (29.7)
Mixed stress and urge			25 (67.6)
Enuresis[2] (missing: n=1)			6 (16.7)
Incontinent episodes[1]			
During the day	2.3 (2.1)	2.0 (0-8)	
At night (missing: n=1)	1.2 (1.7)	1.0 (0-6)	
Absorbent products used			
During day			16 (43.2)
At night (missing: n=1)			15 (40.5)
Daytime voids/day (missing: n=1)	5.4 (1.6)	5.0 (3-9)	
Nocturia episodes/night (missing: n=1)	2.1 (1.6)	2.0 (0-5)	
Cups (glasses) of caffeinated drinks/day (missing: n=2)	2 (1.9)	2 (0-10)	
Cups (glasses of noncaffeinated drinks/day (missing: n=2)	5.0 (2.9)	5.0 (0-16)	
Incontinence-related quality of life (IIQ7)	15.0 (16.5)	9.5 (0-76.2)	
Currently doing pelvic floor muscle exercises			5 (13.5)
For those doing pelvic floor muscle exercises (missing: n=1); typically done:			
Times per week	4 (2.3)	5.0 (0-6)	
Sessions per day	1.8 (1.3)	2.0 (0-3)	
Repetitions per session	8.2 (4.3)	6.0 (5-15)	

[1]Based on response to "How many times do you typically leak urine even a few drops during the day and night?" [2]Enuresis reported separately from urge, stress, and mixed UI
IIQ7: Incontinence Impact Questionnaire Short Form

Thirty-two participants reported one or more incontinent episodes in their baseline bladder diary (BCM session 2) also completed BCM 3. Most of these participants (n=27, 84.4%) completed all five BCM sessions, while three (9.4%) completed four (sessions 1, 2, 3, and 4) and two completed three sessions (1, 2, and 3). The median total incontinent episodes per day decreased from 2.1 at baseline to 1.4 at the last BCM session completed (p=0.01). There was a 34.6% median percent reduction in total incontinent episodes, with 14 participants (43.7%) reporting more than 50% improvement and 3 reporting no accidents at their last completed BCM session. Only 17 of the 32 participants were eligible to be included in the analysis examining changes in stress UI. Among these participants, there was a median decrease from 1.6 to 0.6 episodes per day (p=0.02) with a 49.2% reduction in stress incontinent episodes. Eight participants (47.1%) reported more than 50% improvement and 4 reported no stress accidents at their last BCM session. Of the 22 participants eligible to be included in the analysis examining changes in urge incontinence, episodes per day improved from a median of 1.1 to 0.2 ($p<0.001$), with a median 61.8% decrease. Most participants (n=17, 77.3%) reported more than 50% improvement, and 5 participants reported no urge accidents at their last BCM session. Thirty-two participants (86%) completed the IIQ-7 during BCM session 1 and during the Bladder Control Checkpoint. Among these participants there was a significant improvement in incontinence-related QoL, with the median IIQ-7 score decreasing from 9.5 to 4.8. At both time points there was wide variability in IIQ-7 scores (from 0 to 76.2). The findings in relation to Aim 4 outcomes are summarized in Tables 6 and 7.

Table 6. Outcomes: Incontinent episodes and incontinence-specific quality of life (n=32)

Outcome	n	Median	Range	p-value[1]
Incontinent episodes/day	32			0.01
Baseline		2.1	0.1-10.0	
Final BCM session		1.4	0.0-9.6	
Stress incontinent episodes/day	17			0.08
Baseline		1.6	0.1-5.2	
Final BCM session		0.6	0.0-4.0	
Urge incontinent episodes/day	22			<0.001
Baseline		1.1	0.1-4.8	
Final BCM session		0.2	0.0-2.9	
IIQ-7 score	32			0.03
Baseline		9.5	0-76.2	
Final BCM session		4.8	0-76.2	

[1] Wilcoxon Signed Rank test
BCM: Bladder Control Module
IIQ-7: Incontinence Impact Questionnaire Short Form

Table 7. Participants' reduction in percentage of incontinent episodes (n=32)

Type of Incontinent Episodes	Median (percent)	Range (percent)	Reported >50% improvement (n)	Cured[1] (n)
All incontinent episodes (n=32)	34.6	-441.8-100.0	14 (43.7%)	3
Stress incontinent episodes (n=12)	49.3	-133.3-100.0	8 (47.1%)	4
Urge incontinent episodes (n=22)	61.8	-12.5-100.0	17 (77.3%)	5

[1] Reported no accidents at the last completed BCM session

6.0 DISCUSSION

Whereas the parent study investigated the feasibility of implementing the Health Kiosk, this secondary analysis focused on the effect of the BCM on community-residing older adults' urinary incontinence and incontinence-specific quality of life. Based on the baseline assessment in the parent study, out of the 111 eligible participants who had the opportunity to receive a recommendation to consider the BCM, 68.5% (76 participants) completed the "Consider the Bladder Control Module." Eighty percent of those individuals accessed the BCM and completed at least one session. Among those who accessed the BCM, 11.5% only completed session 1, with the remaining participants completing between two (16.7%) and all five (74.1%) of the intervention sessions. The reasons behind why some participants did not access or finish all modules remain unknown due to the nature of secondary analysis and the inability to further follow-up with the participants. If possible, future studies should explore the reasons participants do not access and/or complete self-help interventions such as the BCM. This knowledge can be used to develop strategies to increase the utilization of these interventions.

We examined participant characteristics associated with accessing the BCM. Previous studies that examined characteristics associated with seeking treatment for urinary incontinence focused primarily on incontinence-related characteristics. In the parent study, however, data related to these characteristics were not collected until participants completed the first BCM session, and they were not available for participants who did not access the Module. Consequently, the comparison of those who did and did not access the BCM was limited to sociodemographic and clinical characteristics assessed during the baseline assessment of all participants in the parent study.

In the multivariate analysis, three characteristics were associated with accessing the BCM: current anxiety, current depression, and being retired. Participants who reported that they were currently depressed were significantly more likely to access the BCM than those without current depression. On the other hand, those who reported current anxiety were less likely to access the BCM than those who did not report anxiety. While studies examining characteristics associated with UI reported that higher rates of anxiety and depression in participants with UI than those without UI (Cheng et al., 2020), we only identified two studies that examined anxiety or depression in association with treatment-seeking for UI. Our finding that depression was associated with higher odds of accessing the BCM is consistent with the findings of Burgio et al. (1994) that older adults who sought treatment for UI tended to have higher depression scores. Only one study was identified (Waetjen et al., 2015) that examined the association between anxiety and seeking treatment for UI. In that study, anxiety was not associated with treatment-seeking in the multivariate analysis, which is inconsistent with our findings. Possible reasons for inconsistencies may include differences in how anxiety was measured or in the ages of the two samples. Waetjen et al. measured anxiety as the number of years with anxiety, while participants in the current study were asked if they currently had anxiety. All participants in the current study were 60 years of age or older, with a mean age of 73.2 years. In contrast, Waetjen et al. only included women between 42 and 52 years of age. In the current study, participants who were retired were significantly more likely to access the BCM than those who were currently working or engaged in regular volunteer activities. We did not identify any other studies that examined employment status in relation to treatment-seeking for UI. One possible explanation for our finding in relation to retirement is having more time to visit the kiosk.

Of the studies that examined self-management interventions for UI, the only study that examined characteristics associated with accessing the program was reported by Bokne et al. (2019). They compared the ages and education levels of those who signed up and completed their internet-based self-management program to those who signed up but did not complete the program and reported no significant differences. Our findings in relation to age and educational level and accessing the BCM module were consistent with the findings of Bokne et al.

Thirty-two participants were eligible to be included in the analyses examining the effect of the BCM on urinary incontinence, while 22 met eligibility criteria to be included in an analysis examining changes in urge incontinence and 17 met eligibility criteria for examining changes in stress incontinence. There was a significant reduction in the median number of total incontinent episodes per day from 2.1 at baseline (BCM session 1) to 1.4 during the last BCM completed. For episodes of SUI per day, the median number decreased from 1.6 at baseline to 0.6 at the last completed session, while the median number of UUI episodes per day decreased from 1.1 at baseline to 0.2 during the last completed BCM session. The significant reduction in total UI episodes is consistent with the other studies that utilized e-health delivered UI interventions (Asklaud et al., 2017; Brokne et al., 2019; Rygh et al., 2021) even though different measuring tools were used in these studies than in the current study. The significant reduction in episodes of SUI and UUI is also consistent with the findings of Rygh et al. While the current study used a 7-day bladder diary to measure urinary incontinence, the three comparison studies used the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), a self-reported questionnaire. Consequently, we were unable to compare the percent reduction in incontinence to previous studies examining self-management interventions.

There was also a significant improvement in incontinence-related QoL, which decreased from a median score of 9.5 at baseline to 4.8 during the last accessed BCM session. This statistically significant improvement in incontinence-related QoL in the current study is consistent with the study results from Asklaud et al. (2017), which measured incontinence-specific QoL using the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-LUTSqol) instead of IIQ-7 used in this secondary analysis. Although the median IIQ-7 scores in this secondary analysis suggested that UI did not have a large impact on participants' QoL, the range of measurements varied from 0 to 76.2 (out of 100) both before and after the intervention. This wide range of variability suggests that the effect varied across participants, with some reporting a larger impact of UI symptoms. Future studies should include qualitative data to obtain a more in-depth understanding of critical elements in improving incontinence-related QoL.

6.1 STUDY LIMITATIONS AND FUTURE RECOMMENDATIONS

Several limitations exist in this secondary analysis. First, participants in the parent study were recruited via convenience sampling, thus limiting the generalizability of the findings to individuals with characteristics similar to those of the participants. There are also limitations related to the design of the current study. Because data related to the continence history were not collected until BCM session 1, a comparison of the continence characteristics of those who did and did not access the BCM could not be performed.

Secondary to the design of the parent study, there was no contact with participants during the completion of the BCM and no feedback on the data they entered from their bladder diaries.

As a result, there was no opportunity to clarify missing data and inconsistencies between reporting of incontinence during the continence history (BCM session 1) and the first bladder diary data (BCM session 2). This resulted in excluding participants from the analyses examining the effect of the Module on changes in incontinence. Like all self-report measures, using a bladder diary to measure incontinence could be associated with reporting bias. Finally, the single group, pre-post quasi-experimental design of the intervention modules in the parent study limited our ability to make causal inferences about the effect of the BCM on UI and UI-specific quality of life. Without a control group and randomization of participants to either the BCM or a control condition, we cannot rule out other potential explanations for the findings in this study.

Despite these limitations, this study had a number of strengths. First, this is the first study that focused on UI-related self-management in community-dwelling older adults. The previous studies mainly focused on younger individuals. Also, both male and female participants were included in this study instead of just focusing on the women. In addition, the study design of the parent study allowed a wide range of target populations including people who have less opportunity or limited access to UI-related health resources to access of UI-related intervention module. Lastly, in contrast to previously published studies, participants in this secondary analysis were not actively seeking treatment for UI.

Additional research is needed to confirm the effectiveness of the BCM in reducing UI and improving incontinence-specific QoL. Future studies should include a comparison control group. A larger sample should be included to permit the examination of predictors of the response to the intervention. Assessing incontinence-related characteristics prior to initiating the BCM and collecting data on both sex and gender will allow a more complete examination of factors associated with accessing the BCM. Future studies should also include other measures of changes

in incontinence in addition to the bladder diary. This should include participants' perspectives of the effectiveness of the BCM. While the BCM was delivered via a Health Kiosk in the parent study, future studies could explore the delivery of the Module via the internet or a smartphone app.

6.2 CONCLUSION

Although additional research is needed to confirm the effectiveness of the BMC in improving urinary incontinence and quality of life, the findings suggest that self-care programs such as the Bladder Control Module may be an effective way to increase access to conservative interventions and to improve urinary incontinence among community-residing older adults. Using e-health delivery methods, this UI self-management intervention could reach and benefit a wide range of community-residing older adults who endure UI symptoms and their related negative impact on quality of life due social stigma or lack of access to behavioral approaches to improve managing and monitoring their health.

APPENDIX A. IRB APPROVAL FORM

University of Pittsburgh | Institutional Review Board
Office of Research Protections

EXEMPT DETERMINATION

Date:	May 28, 2021
IRB:	STUDY21040086
PI:	Yuchen Zhang
Title:	Effect of a bladder control self-management program delivered through a health kiosk

The Institutional Review Board reviewed and determined the above referenced study meets the regulatory requirements for exempt research under 45 CFR 46.104.

Determination Documentation

Determination Date:	5/28/2021
Exempt Category:	(4) Secondary research on data or specimens (no consent required)

Approved Documents:	• Exempt Application Form: Secondary Analysis, Category: IRB Protocol; • Parent Study: 3-day Voiding Log, Category: Other; • Parent Study: 7-day Bladder Diary, Category: Other; • Parent Study: Bladder Control Self-assessment Questionnaire, Category: Other; • Parent Study: Consent Form, Category: Other; • Parent Study: Incontinence Impact Questionnaire - Short Form - IIQ-7, Category: Other; • Parent Study: Interview Schedule, Category: Other; • Parent Study: Urinary Incontinence Assessment, Category: Other;

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Carolyn Ivanusic.

Please take a moment to complete our Satisfaction Survey as we appreciate your feedback.

Human Research Protection Office 3500 Fifth Avenue, Suite 106 Pittsburgh, PA 15213 www.hrpo.pitt.edu

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