Urinary Incontinence Self-Screening For Healthy Aging

Study Protocol and Statistical Analysis Plan

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o Background

Urinary incontinence (UI) is the involuntary loss of urine that affects 3.5 million Canadians, or nearly 10% of the population.[1] According to the Canadian Urinary Bladder Survey, 16% of men and 33% of women over the age of 40 have symptoms of urinary incontinence.[2] Urinary incontinence prevalence rates have been reported between 9 and 59% in those aged 50 and above.[3] The prevalence of incontinence increases with age with the Canadian Urinary Bladder Survey [3] reporting an increase in urinary symptoms in those 65 years and older.

The impact of UI on older adults can be significant with serious physical, psychological, and social consequences.[4] UI is associated with serious medical consequences such as falls, fractures, institutionalization, and death.[5,6] Embarrassment, isolation,[7] depression,[4] decreased self-confidence, disruption in normal activities [8] and lowered quality of life are pervasive. On average, older adults with UI suffer in silence for four years before they seek health care, instead making adjustments in their daily lives to manage the incontinence. [9]

As many as 50% (or more) of older adults with UI have never discussed or sought help from their general practitioner (GP),[2,9] often due to erroneous beliefs about incontinence, such as the condition being age-related and untreatable. However, older adults with UI seeking help from their GPs have reported negative experiences of being brushed aside, treated with indifference, and not having their UI-related symptoms recognized or prioritized.[10] Preference for self-referral over physician referral emerged in a recent study [11] with a five year (2010-2015) increase of 480% in self-referral to urogynecology, the highest increase in all types of referrals (e.g., specialist, GP).

The importance of early detection and referral is critical. Left undetected and untreated, urinary incontinence is a progressive problem that worsens over time creating greater management challenges for both patients and health providers. Identification of patients with early or less troublesome urinary symptoms may aid in early intervention with simple measures (e.g., lifestyle advice, behavioural therapy), and reduce the need for more complex and costly treatment.[12] Although older adults with UI are receptive to being asked about incontinence,[13] UI screening has yet to become standard practice. As health care has increasingly become patient-centered and shifted responsibility to patients, self-screening has greater potential to reach older adults and promote earlier identification, referral and intervention.

Self-screening has been shown to have several benefits including enhanced privacy in sensitive situations, increased self-awareness, and reaching a wide audience. It has

been used with a variety of populations and health conditions (e.g., cancer) [14] and social challenges (e.g., driving) [15] and is well suited to the study of incontinence because of the stigma, embarrassment and silence that surrounds this health condition. Opportunities for IU self-screening may provide older adults with validation, acceptance, support of a problem shrouded in silence and facilitate help seeking.

o Objectives: The overall aim is to increase awareness of urinary incontinence in community-based older adults and promote timely treatment. To achieve this aim the project objectives will include:

1. To develop a self-screening process for community-based older adults
2. To test the use of a self-screening process with community-based older adults

o Methods

Study Design: This study will use a pilot randomized control trial to test the effectiveness of a self-screening process with older adults. The hypothesis is that older adults exposed to the self-screening process will follow up with health professionals to receive help for the UI condition. There will be two groups of older adults. The intervention group will participate in self-screening and the control will not be exposed to self-screening. Using this approach is necessary to determine whether or not the self-screening works.

Intervention: The intervention will include a combination of self-screening and UI specific information and resources. Older adults in the intervention group will complete a gender specific UI Self-Screening tool. Men will complete the International Consultation on Incontinence Modular Questionnaire (ICIQ) for Males [18] (**See ICIQ-M**) and women will complete the ICIQ for Females.[19] (**See ICIQ-F**). The ICIQ Male and Female are valid and reliable tools, recognized by the International Continence Society, and collect more information about urinary symptoms than other tools, an advantage for referral purposes. In addition, the intervention group will receive a fact sheet with UI specific information, contact information to the local incontinence clinic and a link to a website with patient incontinence resources and education (**See UI Fact Sheet**).

Control Group: Older adults assigned to the control group will receive standard care from their physicians. Standard care may differ from general practitioner to general practitioner. Usual care for urinary incontinence (UI) from general practitioners is generally minimal. Most patients do not tell their physicians about UI, and most physicians do not ask about UI. If this topic does come up during a GP appointment, a patient may be offered no treatment, lifestyle advice (e.g., do not drink before bed), told to do Kegels (but likely not instructed how to do these properly) or in some cases, offered pharmacological therapies (which will be captured in our questionnaire with the participants). But standard of care is unfortunately very often no care.

Setting: Senior's Centers and organizations dedicated to seniors in Kelowna, West Kelowna and Lake Country will serve as the recruitment sites for this study. These Senior's Centers/organizations (e.g., Lake Country Seniors Centre, Lake Country

Health Planning Society, Westside Health Network, Seniors Outreach Bureau) serve large and different populations of seniors (>300 seniors) so overlap in membership is not expected to be an issue.

Sampling and Recruitment: The study sample will include older adults ≥65 years of age (men and women) who attend a local Senior's Centre or organization, report having some UI symptoms, are independent living, ambulatory, with no more than mild cognitive impairment, able to read and write in English or have someone who can assist with reading the data collection information and can complete a paper survey independently. Older adults will be excluded if they have cognitive impairment, require more than minimal assistance with completing the survey, or have any impairment (e.g., vision) that would make self-screening and follow up challenging. They must also never have been referred to a UI specialist or program in the past.

Following ethics approval, eligible older adults will be recruited through a letter of invitation sent through e-mail distribution lists of our participating seniors centres/organizations (**see Letter of Invitation**). Based on other UI studies, in which there was a 14% self-referral rate without an intervention, we hypothesize a 61% incremental increase in self-referral in the arm receiving the intervention. [11] The sample size required to detect an improvement in self-referral (with 80% power, $p<.05$) to a health professional (e.g., UI specialist) is 24 participants (12 older adults per arm). Drop-out or attrition is common in research studies. [16] In factoring the potential for a drop-out rate of 50%, a sample size of 36 participants will be recruited. Excel randomization function will be used to assign participants to one of the two arms (the arm receiving the self-screening process or the arm not receiving this process). The randomization assignments (allocations) will be placed in individual sealed envelopes. After informed consent is obtained, the Research Assistant (RA) will choose the next available envelope to reveal which arm the study participant will be assigned.

Data Collection:

Pre-test: Prior to implementation, the self-screening tool will be pre-tested with 5 older adults attending participating seniors centres/organizations. The purpose of the pretest will be to identify any implementation issues such as recruitment, administration, understanding and ease of use of the self-screening tools.

Procedures: Older adults assigned to both groups will receive follow up from the RA who will provide details about the study and answer any questions. Prior to randomization, consenting older adults from both groups will complete a demographic (e.g., age, sex, highest level of education, household income), health history profile (e.g., co-morbidities, history of previous referrals for UI, medications) (**see Demographic and Health History Profile**) and a quality of life questionnaire [17] (**see The King's Health Questionnaire**).

Three months following study entry participants from both groups will receive a phone follow-up to obtain information about actions they have taken re IU (e.g., self/physician

referral), UI symptoms, [18,19] treatments received, satisfaction with care (**See Three Month Follow up Questionnaire**), and changes in quality of life.[17] The follow up phone call will be recorded. It is expected the baseline and 3 month follow up data collection will take approximately 20-30 minutes to complete.

The primary outcome will be the numbers of older adults who take action to receive help for their UI during the 3-month follow-up from study entry: self-referral to the local UI clinic, appointment with GP about their UI, and/or referral to a specialist (urologist or urogynecologist or gynecologist), or other action. Secondary outcomes will include: treatments received, satisfaction with care, changes in quality of life. [19]

Post-Intervention Focus Groups: To obtain feedback on the self-screening process, focus groups (n=2) will be conducted with older adults (10-12 participants) who were in the self-screening group. At the end of 3-months from study entry, in conjunction with survey completion, participants will be invited to participate in a focus group. Those expressing an interest in focus group participation will be contacted with details of the date, time of the focus group and will receive a copy of the semi-structured interview questions. Questions will address participants' comfort with the self-screening process, rationale and influences on choice to self-refer or not, barriers/facilitators to self-referral, recommendations to make the self-screening process easier (**See Focus Group Interview Questions**).

Data Analysis:

Description of Sample:
Frequency analysis will be conducted on all demographic (age, sex, highest level of education, household income), health history profile (co-morbidities, history of previous referrals for UI, medications) and quality of life. For continuous variables, means with associated standard deviations (SD) will be calculated for parametric variables or medians with associated interquartile ranges will be calculated for nonparametric variables. For categorical variables, percentages with 95% confidence interval (CI) will be calculated. These calculations will be calculated for the total study population as well as for participants in each study group.

Primary analysis:
The study hypothesis is that older adults exposed to the self-screening process will follow-up with health professionals to receive help for their UI condition more often than the control group. To test this hypothesis, investigators will calculate the proportion (with 95% CI) of participants who self-report as having self-referred to a health professional (binary yes/no response) during the study period for each group. A chi-square test will be conducted to determine if the self-screening process is associated with self-referral to a health professional. In addition, a logistic regression analysis will be conducted to model the odds of self-referring among people who have undergone self-screening, adjusting for demographics, and health history variables. Bivariate analysis will be conducted and variables significantly associated with self-referral will be entered into the model. Since the study sample size will only allow for having 3 variables in the

model, more than one regression model may be necessary. If this is the case, a Bonferroni adjustment will be used to account for multiple comparisons.

Secondary analysis:

Quality of life scores will be compared within and between groups. For the within group comparison a two-sided dependent t-test will be conducted using the pre-study and 3-month quality of life scores for each group. To determine if a change in quality of life (difference between pre-study and 3-month quality of life scores) is statistically significant and mixed between-within subjects analysis of variance will be conducted.

All participants will complete a Urinary Symptoms questionnaire (ICIQ-FLUTS) which consists of ordinal categorical responses to questions related to urinary symptoms. Each question has five response options. For each question, each response category will be assigned a numeric value depending on the severity of the symptom (1= no symptoms; 5=severe symptoms). For each participant, improvement in symptoms will be determined by a reduction in the ordinal value. Improvement in UI symptoms will be compared between groups using a chi-square test.

Investigators are also interested in knowing if self-screening results in a higher proportion of participants initiating medication of UI during the study period. Therefore, the proportion of participants in each group who started medication for UI during the study period will be compared using a chi-square test.

Limitations: It is possible that screening for eligibility for the study may make a person more likely to self-refer. If this occurs in the control arm, it may bias the results toward the null hypothesis (i.e. it may be less likely to detect a difference between study arms).

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