British Journal of Healthcare and Medical Research - Vol. 12, No. 03 Publication Date: May 4, 2025

DOI:10.14738/bjhr.1203.18748.

Zhang, A. Y., Kresevic, D., Shoag, J., Aaron, S., Chen, Z., & Bodner, D. R. (2025). Initial Evidence for a Telehealth Behavioral Intervention to Lower Urinary Tract Symptoms in Men. British Journal of Healthcare and Medical Research, Vol - 12(03). 07-16.



Initial Evidence for a Telehealth Behavioral Intervention to Lower Urinary Tract Symptoms in Men

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ABSTRACT

Millions of American men suffer from lower urinary tract symptoms (LUTS) with a prevalence of 30% at age of 60 and older, mainly due to enlarged prostate gland—benign prostatic hyperplasia (BPH). LUTS (e.g., urgency, nocturia, weak stream, and post-void dribbles) diminish men's quality of life significantly in later years. Medical treatments are effective, but inadequate due to poor patient compliance. A widely used behavioral approach comprising lifestyle changes through regulating fluid intake and bladder retraining (e.g., voiding schedule and pelvic floor muscle exercise) has generated promising results, but is delivered through in-person sessions, either individual or in a group setting. This delivery modality restricts intervention access by patients with diverse socioeconomic and disease conditions. Hence, we have developed a telehealth-based behavioral intervention to LUTS and tested it among 8 older men. In this pilot study, the participants received the behavioral intervention over 6 monthly group meetings via Zoom and were assessed on the severity of LUTS, symptom bother and QOL before and after the intervention. T-test showed that LUTS severity measured on the International

Prostate Symptom Score (IPSS) had reduced remarkably in 6 months (mean difference=5.44, one-sided p=.0499), with a large effect size (Cohen's d=0.865). Disease-specific and health-related quality of life assessed on IPSS-8, Visual Analogue Scale and SF20 measures indicated medium effects (Cohen's d >0.5). Further, at the 6 months, self-efficacy (r=.86, p=.013) and adherence to voiding schedule over a 3-hour interval (r=.76, p=.047) significantly and positively correlated with mental health measured on SF-20. The findings suggest that telehealth-delivered behavioral intervention is effective in reducing LUTS and the mediating effect of behavioral change and self-efficacy requires further investigation. The study provided initial evidence to support men's utilization of online behavioral intervention to LUTS.

Keywords: lower urinary tract symptoms (LUTS), behavioral intervention, self-management, men's health, telehealth.

Lower urinary tract symptoms (LUTS) affect 30% of men by age of 60 mainly due to benign prostate hyperplasia (BPH) [1]. Despite the effectiveness of medical treatments, the 12-month adherence to LUTS medications is estimated to be 29% among American men [2, 3]. Unresolved LUTS are associated with increasing urinary retention, infection, hospital visit, healthcare cost, and worsening quality of life of patients [4-6].

The American Urologic Association (AUA) Practice Guideline [7] recommends noninvasive intervention of lifestyle factors for mild and non-bothersome moderate-severe LUTS due to BPH. Because a large portion of older men are affected by bothering moderate to severe LUTS [8-11], rendering behavioral interventions to these medically treated patients promises additional benefits by empowering self -management and patient's sense of control. A meta-analysis of randomized clinical trials (RCTs) supported the effectiveness of behavioral self-management for treating LUTS in men with "reasonable certainty [12]." In the reviewed RCTS, behavioral interventions were delivered to the patients face-to-face between 1 to 6 sessions over 3 months, often individually. The meta-analysis revealed a 7.4-point reduction of the IPSS score in symptom severity at 6 months in reference to usual care (watchful waiting). When compared to drug treatment, a combined self-management and drug treatment reduced symptom severity by 2.3 points over 6 weeks. The meta-analysis evidence suggests a medium to large effect size of behavioral interventions (2.3 to 7.4 points), while a 3-point deduction is considered clinically meaningful [13, 14]. Another systematic review through March 2024 reported similar findings in favor of behavioral interventions [15].

However, there are known barriers to the in-person interventions including time constraints, travel inconvenience, lack of transportation or motivation, physical limitations, and competing demands [16, 17]. Ample evidence has shown that telehealth, namely, remotely delivered healthcare services including consultation using electronic devices, is effective in improving health outcomes [18]. A systematic review of 17 studies reported that group videoconferencing was acceptable and feasible in those who had low digital literacy [17]. Further, social support through group therapy has demonstrated its effects on improving urinary function in men with prostate cancer, but the systematic reviews of LUTS interventions have identified only one study that used social support groups [12, 15, 19]. Telehealth and social support groups are powerful tools for behavioral change but have yet to be incorporated into behavioral interventions to LUTS [15].

Recently our team has developed a telehealth-based behavioral intervention that used both lifestyle change techniques and social support to promote patient's behavioral changes to mitigate LUTS. We tested this behavioral intervention in a pilot study to evaluate its effect on LUTS and quality of life (QOL) and a potential mediating effect of behavioral modification. Based on the social cognitive theory, we believed that as patients' confidence (i.e., self-efficacy) in performing and adherence to the learned behavioral techniques increase, they would experience decreased LUTS severity and improved QOL. By delivering the intervention via Zoom, we expect to ease patient access to behavioral treatment and enroll hard-to-reach men with a diverse background.

METHODS

We conducted a pilot study in 2023-2024 to test a telehealth-delivered behavioral intervention in men that sought medical treatment for LUTS at the University Hospitals Cleveland Medical Center. Subject eligibility included (1) LUTS due to BPH by diagnosis; (2) presence of moderate to severe LUTS (IPSS \geq 8); (3) age \geq 45 according to the AUA guideline; and (4) able to speak or understand English. Exclusion criteria included (1) LUTS independent of BPH (e.g., neurogenic LUTS due to Parkinson's or dementia, LUTS due to cancers, renal diseases, and bladder stones); (2) having other underlying medical conditions including urethral stricture, pediatric voiding dysfunction and/or elimination disorder, chronic prostatitis or bladder pain syndrome; (3) recurrent urinary tract infection; (4) cognitive impairment that compromises the ability to follow study procedures; (5) having a severe condition that requires immediate medical attention; (6) having uncontrolled diabetes, end-stage cardiac and respiratory failure; and (7) those starting a surgical or minimally invasive procedure for LUTS during the study period.

Eight eligible and consenting men were identified from the practice of study physician investigators and their colleagues. They were screened and enrolled by trained research staff and assigned to one of the two social support groups. The group attended a monthly Zoom meeting for 6 months. The meetings lasted an hour and were led by a nurse therapist that specialized in delivering the study intervention. The first group meeting included extra 30 minutes to teach the participants about bladder retraining (e.g., voiding schedule), pelvic floor muscle exercises (PFME), and other behavioral techniques (e.g., toileting techniques, fluid regulation). At each meeting, the nurse therapist reviewed every participant's progress and facilitated group discussion to help study participants brainstorm strategies to maintain the learned behavioral techniques. The participants were assessed before and after the 6-month intervention on LUTS severity, QOL, and behavioral changes using the following instruments. Demographic variables were collected on a checklist at baseline and verified against the medical chart.

LUTS Severity was assessed on the International Prostate Symptom Score (IPSS) that measures 4 voiding (incomplete emptying, intermittency, weak stream and straining) and 3 storage (frequency, urgency and nocturia) symptoms. The items were summed in a total score from 0 to 35; a higher score indicates greater LUTS severity [20].

*Disease-specific QOL*_was assessed on (a) IPSS' 8th item that measures the impact of LUTS on a 1-6 point Likert scale, and (b) a single-item *Visual Analogue Scale (VAS)* (from 0-10) assessing the level of symptom bother for the past week and month, respectively [21]. A higher score indicates more bothersome of LUTS.

Health-related QOL_was assessed on the 20-item Short Form Survey (SF20) that is sensitive to change and widely used in outpatient populations [22]. SF20 produced six subscale scores, and a higher score indicates better physical functioning, role functioning, social functioning, mental health, current health perception, and severer pain, respectively.

Self-efficacy was assessed on a 0- to-100-point scale [23], ranging in 10-unit intervals, with "0" indicating "not confident" and "100" as "certainly confident," in the following areas: (1) can take 1500-2000 ml (50-67 oz.) of fluid every day, (2) can avoid alcohol and caffeine, (3) can void after 3 or more hours during the day, (4) can reduce nighttime frequency, (5) can avoid dribbles after voiding, (6) can take medication daily as prescribed, (7) can practice PFME every day, and (8) can reduce LUTS at will. The average score of the eight questions was calculated as a measure of the strength of self-efficacy.

Adherence to voiding schedule over 3 hours and adherence to PFME, as mediating variables, were measured on the_4-item Self-Report Behavioural Automaticity Index (SRBAI) using a 7-point Likert scale. SRBAI is a short version of the 12-item Self-Report Habit Index and has good validity and reliability [24, 25]. The average score of each behavior was calculated, with a higher score indicating better behavioral adherence.

We computed Cohen's d to estimate the intervention effect size regarding LUTS severity, QOL, and mediating variables in 6 months. Paired sample t-test was performed as appropriate and the one-sided p values are reported in consideration of the small sample size. Pearson correlation analysis was also performed to explore associations between mediating variables and LUTS and QOL outcomes at baseline and 6 months.

RESULTS

The pilot study sample included 8 men diagnosed for LUTS and aged 61.5 years on average. Majority were White (n=7, (87.5%) and Christian (n=6, 75%), and one was African American. Half of the sample (n=4) were married, one lived with a significant other (12.5%), and three were single or widowed (37.5%). Four participants (50%) had a college degree, two (25%) had a graduate degree, and two had either high school or some college education (25%). Six participants (75%) were still working (75%) and two had retired (25%). The household annual income was below \$50,000 in 2 participants (25%), between \$50,000 and \$100,000 in one (12.5%), and above \$100,000 in three (37.5%) participants (see Table 1 below).

Table 1: Demographic Characteristics

Variable	N	%	Mean (s.d.)	Min/Max.
Age	8		61.5 (8.11)	52 /73
Race				
White	7	87.5		
African American	1	12.5		
Marital status				
Married	4	50		
Significant other	1	12.5		
Single/widowed	3	37.5		
Education				
High school graduate	1	12.5		

Some college	1	12.5
Undergraduate degree	4	50
Graduate degree	2	25
Household Income		
\$15,000 - \$24,999	1	12.5
\$25,000 - \$49,999	1	12.5
\$50,000 - \$100,000	1	12.5
Over \$100,000	3	37.5
No response	2	25
Religion affiliation		
Christianity	6	75
Greek Orthodox	1	12.5
Other	1	12.5
Employment		
Full-time	4	50
Part-time	2	25
Retired	2	25
Religion affiliation		
Christianity	6	75
Greek Orthodox	1	12.5
Other	1	12.5

Table 2 shows that the IPSS total score decreased remarkably (one sided p=.0499) with a large effect size (Cohen's d=0.865) in 6 months. There was a medium effect (Cohen's d>0.5) of improvement on disease specific QOL measures of the IPSS 8th item and Visual Analogue Scale (VAS) of symptom bother for the past week and month. Regarding health-related QOL measured on SF20, there was a medium effect of improved physical functioning (Cohen's d=.545), a small effect of poorer social functioning and mental health (Cohen's d=0.421; 0.458), and no effect on role functioning, health perceptions and pain in 6 months. Regarding mediating variables, there was a small effect of increasing self-efficacy (Cohen's d=0.313) and medium effect of adherence to voiding schedule or PFME (Cohen's d=0.538; 0.726) in 6 months.

Table 2: Effect Size of Study Variables Over Six Months

Variable	Mean diff.	Standardizer ¹	Cohen's d	One-sided p ²
IPSS Score	5.44	6.289	0.865	0.048
IPSS Item 8 - QOL	1.000	2.000	0.500	0.117
VAS1 – Bother over 7 days	1.786	3.557	0.502	0.116
VAS2 – Bother over 4 weeks	2.000	3.416	0.586	0.086
SF20 – Physical Function	-7.143	13.106	0.545	0.100
SF20 – Social Function	17.143	40.708	0.421	0.154
SF20 – Mental Health	7.429	16.236	0.458	0.136
SF20 – Health Perception	-0.357	7.401	0.048	0.451
SF20 – Pain	-2.857	43.861	0.065	0.434
SF20 – Role Function	0	No change		
Self Efficacy	-6.543	20.877	0.313	0.219
Adherence to 3hr Voiding Schedule	-15.536	28.879	0.538	0.102
Adherence to PFME	-32.750	45.115	0.726	0.090

¹: The denominator used in estimating the effect sizes, based on the sample standard deviation of the mean difference. ²: One-sided p value from a paired sample t-test.

Pearson correlation analysis indicated associations between mediating and outcome variables. At baseline, higher self-efficacy significantly corelated with better disease specific QOL on the IPSS 8^{th} item (r=-.887, p=.003). Correlations between self-efficacy and LUTS severity indicated by the IPSS total score (r=-0.656, p=.078) and VAS symptom bother (r=-.669 and -.691, p=.07 and .058 for the past week and month, respectively) were marginally significant. Better adherence to a 3-hour voiding schedule significantly correlated with better SF20 physical functioning score (r=-.825, p=.012). At 6 months, more self-efficacy (r=.86, p=.013) and 3-hour voiding schedule (r=.76, p=.047) significantly corelated with better SF20 mental health score.

Table 3: Correlation Between Mediating and Outcome Variables Over 6 Months

Variables	Self Efficacy	Adherence to 3hr	
	<i>r</i> (p)	Voiding Schedule	PFME
		<i>r</i> (p)	<i>r</i> (p)
Baseline			
IPSS Score	656 (.078)*	088 (.84)	073 (.91)
IPSS Item 8 - QOL	887 (.003)**	035 (.94)	.645 (.24)
VAS1 – Bother over 7 days	669 (.070)*	135 (.75)	.115 (.85)
VAS2 – Bother over 4 weeks	691 (.058)*	264 (.53)	.063 (.92)
SF20 – Physical Function	.262 (.53)	825 (.012)**	518 (.37)
SF20 – Social Function	.509 (.20)	479 (.23)	139 (.82)
SF20 – Mental Health	104 (.86)	.604 (.11)	.683 (.20)
6 Month			
IPSS Score	623 (.14)	476 (.28)	100 (.83)
IPSS Item 8 - QOL	449 (.31)	216 (.64)	170 (.72)
VAS1 – Bother over 7 days	409 (.36)	300 (.44)	.304 (.51)
VAS2 – Bother over 4 weeks	417 (.35)	375 (.41)	.261 (.57)
SF20 – Physical Function	166 (.72)	.229 (.62)	.251 (.59)
SF20 –Social Function	015 (.98)	.358 (.43)	.411 (.36)
SF20 -Mental Health	.860 (.013)**	.760 (.047)**	.535 (.22)

^{*:} Two-sided $p \le .10$.

DISCUSSION

This pilot study provided new evidence to show that a telehealth (zoom)-based behavioral intervention has mitigated the severity of LUTS. A 5.44-point reduction (p<.05) on the IPSS score is larger than a 3-point reduction for being considered clinically meaningful. Although this study intervention was not tested against usual care controls, the study participants included those having poor health conditions and the literature suggests that 49% of moderate LUTS cases continue to progress, quicker than mild LUTS [26]. Hence the observed reverse trend of LUTS is promising. Further, disease-specific QOL measured by IPSS-8th item and VAS has showed an improvement in a half standard deviation (Cohen's d >.05), indicating a reduced impact of LUTS on patient's well-being. The evidence supports the provision of telehealth-based behavioral intervention to LUTS and future clinical trials to better quantify this intervention's effectiveness.

^{**:} Two-sided *p*≤.05

Health-related QOL measure presented mixed results when SF20 physical functioning showed a medium-size improvement (Cohen's d=0.545), decreasing SF20 scores showed slight worsening of social functioning and metal health (Cohen's d=0.421 and 0.458), and no change was observed on pain, role functioning and current health perception over 6 months. A closer look revealed that an outlier affected the findings. The table 2 shows that the average mean difference between baseline and 6 month was 17.143 for social functioning and 7. 429 for mental health; however, mean difference of a participant alone was 100 for social functioning and 20 for mental health. His social function had dropped from baseline "no limitation" to "limitation all of the time" in 6 months and his unhappy mood from "none of the time" to "most of the time" despite an improvement in physical functioning in 6 months. Clearly, health-related QOL is influenced by a wide range of factors besides LUTS, and this participant might have experienced other worsening health conditions or life stress. The findings suggest that the relationship between diseases-specific and health-related OOL in this elderly population needs careful studies that warrant large samples to mitigate outlier's influence.

The self-efficacy of self-management, adherence to voiding schedule over a 3-hour interval and PFME exhibited growth (Cohen's d=0.313, 0.538, 0.726, respectively) post intervention. Correlation between increasing self-efficacy and decreasing LUTS severity was sizable at baseline (r=-.656, p=.078) and 6 months (r=-,623, p=.14) but statistically insignificant, suggesting a possible role of the self-efficacy in reducing LUTS severity and necessity of statistical detection of the effect in large samples. Correlations between the self-efficacy and disease-specific QOL measures were sizable at baseline (r \geq -.669), especially on the IPSS-8th item (r=-.887, p=.003), but decreased at 6 months (r \leq -.449). It is possible that other factors might be associated with LUTS impacts on QOL and should be explored. Lastly, a significant correlation between mental health and self-efficacy or adherence to a 3-hour voiding schedule at 6 months shows that mental health, for better or worse, matters; those with better mental health had greater self-efficacy and adherence to 3-hour voiding schedule, vice versa. Thus, participant's mental health should be cared during the intervention for improving self-management of LUTS.

Despite our belief that telehealth-based intervention can ease patient access to a behavioral treatment, we encountered challenges during the recruitment phase. Some patients reported "no interest" in learning behavioral techniques despite ongoing moderate to severe LUTS, some had technological difficulties with zoom or online completion of study assessments, and others were too sick (e.g., a recent hospitalization) to participate. However, once enrolled, 6 participants (75%) completed 5 to 6 meetings, and two participants (25%) completed 4 meetings due to business travels or a medical condition. Throughout this process we have learned good lessons. First, establishing rapport with potential subjects from the get-go is crucial and communicating clearly about the study purpose and tasks are important for aiding patient's decision making. When such communication is impossible over the phone, in-person enrollment may be considered. Secondly, providing continuous technical support is critically important. This includes but not limited to setting up zoom access, simplifying electronic version of study instruments to ease completion, and keeping communication channels open during the study period.

The study findings, though novel, should be viewed within the context of study limitations including a small sample, a lack of control group, one-sided p-value being reported, and possible

biases due to participant's self-selection and other factors. These methodological shortcomings speak to the urgent needs for large-scale clinical trials. Given the initial and encouraging evidence from this study, it is imperative that we continue the investigation in this direction to establish a new delivery mode of behavioral therapy in order to benefit men with LUTS from all walks of life.

Acknowledgement

Case Western Reserve University France Payne Bolton School of Nursing provided funding support. Authors acknowledge their appreciation of Ms. Samantha DeSimio and Ms. Jasmine Wang for their technical support on data entry and processing.

Conflict of Interest Statement

The authors have no conflict of interest to report.

Ethical Conduct of Research

The study protocol was approved by a hospital s Institutional Review Board. Informed consent was obtained from all study participants.

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