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Validation of bladder health scales and function indices for women's research

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Abstract

BACKGROUND: Existing bladder-specific measures lack the ability to assess the full range of bladder health, from poor to optimal health.

OBJECTIVE: This study aimed to report evidence of validity of the self-administered, multidimensional bladder health scales and function indices for research in adult women.

STUDY DESIGN: A cross-sectional population-based validation study with random assignment to paper or electronic administration was conducted using national address-based probability sampling supplemented by purposive sampling of women with lower urinary tract symptoms in 7 clinical research centers. Construct validity of the bladder health scales and function indices was guided by a multitrait-multimethod approach using health and condition-specific questionnaires, bladder diaries, expert ratings of bladder health, and noninvasive bladder function testing. Internal dimensional validity was evaluated using factor analysis; internal reliability was assessed using paired *t*-tests and 2-way mixed-effects intraclass correlation coefficient models. Chi-square, Fisher exact, or *t*-tests were used for mode comparisons. Convergent validity was evaluated using Pearson correlations with the external construct measures, and known-group validity was established with comparison of women known and unknown to be symptomatic of urinary conditions.

RESULTS: The sample included 1072 participants. Factor analysis identified 10 scales, with Cronbach's alpha ranging from 0.74 to 0.94. Intraclass correlation coefficients of scales ranged from 0.55 to 0.94. Convergent validity of the 10 scales and 6 indices ranged from 0.52 to 0.83. Known-group validity was confirmed for all scales and indices. Item distribution was similar by mode of administration.

CONCLUSION: The paper and electronic forms of the bladder health scales and function indices are reliable and valid measures of bladder health for use in women's health research.

Keywords

adaptive behavior; construct validity; instrument; lower urinary tract symptoms; multitrait-multimethod

Introduction

Women's lower urinary tract health is affected by life events such as pregnancy and childbirth, hormonal transitions, and acute and chronic medical conditions.[1–3] The high prevalence of lower urinary tract symptoms (LUTS) and the associated economic impact are significant global health concerns. Understanding the progression from a healthy bladder to a LUTS diagnosis is limited by the lack of validated measures assessing the entire

bladder health (BH) continuum. There are many validated self-reported measures of LUTS and pelvic floor dysfunction.[4] However, the symptom severity focus of these instruments limits their ability to comprehensively capture the full range of BH in nonclinical or asymptomatic populations.[1] The goal of the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium is to identify and preserve BH for women.[5] The first step toward this is the development of a measure of BH.

This study aimed to evaluate the empirical evidence supporting the use of a measure of self-reported BH in a national sample (NS) of adult women in both population-based and clinical research via paper or electronic modes of administration. The use of the measure is intended to advance the understanding of the distribution and natural history of BH and aid in identifying risk and protective factors that may serve as the basis for future LUTS prevention and BH promotion research.

Materials and Methods

The full details of the preparatory work have been previously described.[6,7] In brief, the rationale for a novel BH measure was based on the concept that BH is not merely the absence of LUTS and includes the ability to adapt and self-manage.[8] The conceptual model of BH consistent with this definition and developed by the PLUS consortium includes 4 core dimensions: storage (capacity, continence, and sensation), emptying (initiation, stream flow, ease, efficacy, and sensation), bioregulatory (infection), and functional/psychosocial (quality of life, behaviors, and emotional impact) mechanisms, in addition to the adaptive and coping mechanisms used by women. From this starting point, we investigated how bladder function (BF) affects common aspects of day-to-day life. Thus, the conceptual work focused primarily on identification of common everyday activities and/or responsibilities that could be affected by a single aspect of BF (eg, in-continence) or by multiple aspects (storage+incontinence). Transcripts of 30 focus groups with adult women across the United States were reviewed to understand women's experiences related to BH, including symptoms and impact.[9,10] A large item pool (282 items) was generated to assess the range of constructs in the conceptual model across the spectrum of very poor to optimal BH. The items were reviewed and refined using cognitive interviews (CI) for item evaluation. A total of 167 CIs were conducted. In addition, the refined items were included in a survey administered to a nationally representative sample of adult women (n=791) to evaluate response distributions resulting from different versions of item stem format and item response categories.[7]

Study design and setting

National sample—The United States Postal Service Delivery Sequence File provided the sampling frame with multistage probabilistic household sampling to recruit a NS of women. Proportionalsamplingwasusedacross11state groupings stemming from those used by the National Health and Nutrition Examination Survey[11] and divided with equal weight to ensure adequate representation of 4 groupings of the Rural-Urban Continuum Codes.[12] Addresses were randomized to 2 modes of administration: paper-and-pencil interview (PAPI) or electronic computer-assisted self-interview (CASI). The principles of the Tailored

Design Method informed the material design and staging of mailings.[13] The initial NS size (n=6000) was based on estimated response rates from similar national population studies using similar methods[14,15] that would yield a sufficient sample size of completed surveys for psychometric analyses. Women who completed the initial survey were randomized to completion of test-retest follow-up survey (retaining initial mode) within 8 weeks of the initial survey plus a 2-day bladder diary or to completion of a 2-day bladder diary only. Figure 1 presents the study sample plan. Data collection occurred between September 2019 and August 2020.

Clinical-site sample—The supplemental clinical research site sample (CSS) was purposively recruited from the communities surrounding 7 clinical research centers. Women were screened using the Patient Perception of Bladder Condition (PPBC)[16] into 4 categories: healthy (PPBC=1), mild (PPBC=2 or 3), moderate (PPBC=4), or severe (PPBC=5 or 6) to facilitate the representation of a spectrum of severity across 6 different LUTS. Participants also self-reported on 6 LUTS: frequency of urination, leakage, urgency, voiding dysfunction, urinary tract infection, or pain. A minimum of 35 participants were targeted across 4 age groups: 18 to 25, 26 to 45, 46 to 64, and ≥65 years. Those assigned male at birth; having neurogenic or congenital bladder conditions; pregnant at time of recruitment; or unable to toilet independently were excluded. Participants were also randomized to 2 modes of administration: paper (PAPI) or electronic (CASI).

Participants completed the initial survey diaries and attended an in-person visit, all within 8 weeks. The visit included a rating of participants' BH by an expert clinician and objective noninvasive BF testing. Data collection occurred from August 2019 to November 2020, with a 5-month interruption owing to COVID-19 restrictions.

Measures

Data on content validity of the item pool for measurement of both BH and adaptive behavior adjustment (ABA) items were previously published.[7,17] Briefly, expert input, focus groups, CIs, and distributional analysis of items from a large sample of women informed the refinement of the final item pool for psychometric evaluation.

Bladder health scales and function indices—The final 90-candidate BH scale (BHS) item pool for psychometric evaluation was grouped into 4 domains: general BH perception, general day-to-day life impact, activity-specific impact, and emotional-perceptual impact. In addition, an initial 56-item pool assessed BF related to storage, emptying, and dysbiosis (eg, urinary infection). These items were developed and evaluated as BF indices (BFIs) to assess the periodicity, resilience, interference, and relative change in functions.

Adaptive behavior adjustment—It was evident from women's self-evaluation and reports of BH and function that adaptive behaviors (eg, toilet mapping and pad use) can provide a sense of "security" and decrease the self-reported perceived impact of BH on daily activities. Thus, ABA is an important aspect of consideration in assessing the spectrum of BH. For example, a woman may indicate that she perceives no day-to-day impact of BH and may have very high BHS scores for the individual scales; however, she may use adaptive

strategies (eg, wearing pads because of daily urinary leakage) that may signal that her BF and health are not truly optimal. Without an adjustment, the BH score of this woman would be the same as that of another participant who also perceives no day-to-day impact but does not wear pads or have any urine leakage. We anticipate that these subtle differences (eg, from those who have the same scores but no adaptive behaviors) are important to identify and incorporate in the measurement of BH in populations at risk for progression to worse health and populations who may be good targets for prevention intervention strategies. Controlling for the overestimation of BH gained from respondents' adaptative behaviors was approached by using post hoc adjustment to the scoring of each BHS based on respondent report of the frequency of adaptive behavior and the confidence it provided. Therefore, 13 items drafted from a validated instrument on 6 prevalent adaptive behaviors, including preemptive toileting, toilet mapping, use of absorbent products, restriction of fluid intake, and carrying a change of clothing were included.[17]

External measures for construct validation—No "gold standard" external criterion exists for measurement of BH. Therefore, selection of external construct comparators to provide evidence of support of a BH measure was guided by the multitrait-multimethod (MTMM) matrix[18] approach to include comparators from 3 different data sources: self-report, external expert rating, and external clinical tests. Four different data collection methods were used: survey, activity log (diary), visual rating score (subjective), and clinical tests (objective), with a priori hypotheses of association with at least 1 dimension of the BH measurement model (Figure 2). The hypotheses were further refined and mapped to specific scales after identification of a factor structure and subsequent scales of the BHS.

The following measures, not part of the BHS items, were included in the survey to serve as external constructs consistent with a priori hypotheses of convergence or divergence with BHS. These measures are all based on self-report using survey methods: 18 items drawn from the Medical Outcomes Study (MOS), a health-related quality of life measure[19]; 17 items from the King's Health Questionnaire (KHQ)[20]; 3 voiding items from the Bristol Female Lower Urinary Tract Symptoms (BFLUTS)[21]; and 20 items from the Pelvic Floor Distress Inventory.[22] Self-reported bladder diaries recorded events over a 48-hour period.[6]

CSS participants underwent an unstructured interview conducted by an expert before any clinical testing. A numeric BH rating using a visual analog scale from 0 (worst) to 10 (best) was assigned by clinical experts working in women's health or pelvic medicine. To control for potential experimenter expectation effects of consortium members, a balanced number of ratings were done by nonmembers.[23] Each expert completed ratings for at least 8, but up to 18, participants.

External quantitative measures/clinical tests during the clinical visit included: quantified standing (cough) paper towel test for stress incontinence,[24] maximum flow (Qmax) captured by noninstrumented seated uroflowmetry with a minimum prevoid volume of 150 mL,[25] and noninvasive postvoid residual measurement.[26]

Statistical analysis

Response rates were determined using the response rate definition from the standards of the American Association for Public Opinion Research (AAPOR) for mail surveys of unnamed persons (RR4).[27] Items were evaluated for ceiling and floor effects and missing values; item distributions with ≥10% response at the floor or ceiling or missing values were flagged for further evaluation. Internal dimensional validity of scales was evaluated using factor analysis (FA). Overall acceptance of the factor structures was based on the measure of sampling adequacy (Kaiser–Meyer–Olkin [KMO] value, >0.70) and the Bartlett sphericity test to identify item redundancy.[28] Retention of factors adhered to the Kaiser–Guttman rule (eigenvalues>1.0), and for the retention/rejection of items, the standard 0.60/0.40 or 0.20 difference in factor loading was used.[29,30] Iterative FA used both orthogonal and oblique rotations. Initially, exploratory FA of item grouping within the 4 domains was conducted with the grouping constraint relaxed (but not fully removed), followed by a confirmatory FA within each of the 4 domains. The final factor loadings are a result of the confirmatory analysis. Internal consistency was evaluated with Cronbach's alpha.[31] Items with factor loadings ≤0.40 were dropped for low convergent validity; items with loadings >0.9 were reviewed for redundancy and dropped as appropriate.

The BFIs were simple summative indicators of BF, and thus evaluation of internal variables such as consistency and dimensional validity was not appropriate. BFI development followed a traditional magnitude scaling approach[32]; the full sets of symptom-specific items were evaluated relative to the health–disease continuum. An iterative process of item distribution and analysis of variance was used to determine item retention.

Reliability analyses included individuals who completed the retest survey within 8 weeks. Two items were used to screen out individuals who experienced major changes in BH between the test and the retest. Test-retest reliability was evaluated with paired *t*-tests and chi-square tests at the item level and 2-way mixed-effects intraclass correlation coefficient (ICC) models at the scale level, with a 95% confidence interval of the estimate using the following guideline[33]: poor (< 0.5), moderate (0.5–0.75), good (0.75–0.9), and excellent (>0.90).

Comparisons of item response by mode were done within the NS with either chi-square or Fisher exact (ordinal, categorical), or *t* tests (numeric rating scale), as appropriate for the item response options. Construct validity was evaluated using Pearson correlation of BHS/BFI. Published scoring algorithms were used whenever available (eg, KHQ, BFLUTS). General MOS items were scored using a simple mean. Diary and clinical test thresholds for healthy to unhealthy were based on published normative values and expert opinion where normative values are not well established.[25,34–39] BHS and BFI scores are continuous and based on summed means of scale items, with higher values indicating better health and function. The clinical-site sample size was selected for known-group comparisons and a restricted set of external criterion evaluation and evaluated with Welch *t*-tests, with unequal variance between the national and clinical-site samples.

Planned sample sizes were based on psychometric analysis principles of 5 to 10 participants per item.[40] All analyses were conducted using SAS, version 9.4 (SAS Institute, Cary, NC)[41]

and R, version 2.1.9 (R Core Team, Vienna, Austria),[42] with R package psych.[43] The protocol was registered (ClinicalTrials.gov; NCT04016298) and approved for the NS and CSS through a single institutional review board (ADVARRA: Pro00032238).

Results

There were 5001 eligible households from 6000 survey invitations sent to the NS; 999 were ineligible because of a bad address, a deceased resident, or no female in the household. Completed surveys were returned by 605 respondents (11.4% [AAPOR RR4] overall; 16.6% and 8.7% for PAPI and CASI, respectively). The response rate for the NS retest survey version was 68.2% overall (n=277), with 67.1% (PAPI) and 69.4% (CASI) completion rates. The diary completion rate was 69.5% overall (n=261) (Figure 1). The cooperation rate for CSS participants was 63.4%, yielding 467 completed surveys, 344 diaries, and 337 clinical visits.

Sample demographics are presented in Table 1 (and Supplemental Table 1). By design, more respondents in the CSS had sought bladder care compared with respondents in the NS. Evaluation of item nonresponse of returned surveys did not indicate need to remove any items. Floor and ceiling effects were evident, wherein those with high levels of health were at the ceiling, but the items still proved to be valuable in differentiating levels of health in those with less than perfect health.

Factor analysis

Separate factor analyses were done for the sets of items within each of the 4 domains (Table 2). All scales met or exceeded the KMO minimum measure of sampling adequacy and the Bartlett test, and the a priori rules for factor retention were all met. One item from Scale 10 Freedom (“Fear of odor restricts activities”) demonstrated factor loadings on its primary factor and another factor that exceeds the 0.20 threshold by 0.0182. Theoretically, this is an important item in a scale that represents the relationship between BF and resultant behavior change. Therefore, the decision was made to retain it for evaluation.

Within each of the 6 distinct BFIs (urinary tract infection [UTI], frequency, sensation, continence, comfort, emptying), 5 items were retained (function recency, chronicity, resilience, interference, and health transition).

Of 277 retest respondents, 214 reported no changes in BF since the initial survey completion. Of these, 178 completed retest surveys were returned within the 8-week window. Item-level retest indicated nonsignificant differences in item response distributions between test and retest. The 95% confidence intervals of ICC for all scales ranged from moderate to excellent.

Construct validity

Tables 3 and 4 show the correlations of BHS and BFI with external measures. In the case of the MOS 36-Item Short Form Health Survey, these correlations ranged from 0.44 to 0.52, whereas the absolute values of the correlations with the KHQ I, KHQ II, and KHQ symptom scales (SS) were excellent. As expected, correlations of the BHS/BFI with

LUTS questionnaires (KHQ SS, Urinary Distress Inventory, and BFLUTS) were moderate. Divergence was assessed with the BHS and the Pelvic Organ Prolapse Distress Inventory and Colorectal-Anal Distress Inventory scores, with low to moderate correlations overall, as expected (data not shown). Expert BH ratings correlated strongly with the global scale (0.72) and well with the other scales (0.61–0.66), but only moderately with BFI (0.30–0.49). Clinical tests had very weak absolute correlations with the scales (0.13–0.34). Appendix C includes a modified MTMM matrix.

The comparison of BHS and BFI scores of the NS and CSS demonstrated that the NS had significantly higher values on all scales and indices compared with the CSS (all comparisons, $P \leq .001$), supporting known-group validity (Table 5).

Mode evaluation

The BHS and BFI demonstrated no difference in mean between the PAPI and CASI modes of administration within the NS, except for very small differences in the BH Urination scale and the BF Sensation Index, where CASI administration resulted in marginally higher endorsement of healthy bladder. We did not attempt specific adjustments for these 2 items on the basis of the overall equivalence between modes of administration.

Scale administration and scoring

Each of the 10 BH scales is valid for use independently. We recommend that investigators use all scales within a given domain because this provides a broader assessment of the relevant domain. The final full 10 subscales comprising the BHS contain 38 items, with no skip patterns and is found in Appendix A. According to best practices within the survey methods research community, these 38 items will take approximately 9.5 minutes on average to complete. Estimated time to complete individual scales varies from <1 to 1.5 minutes. Scoring for the 10 BHS, 6 BFI, and ABA requires that at least 51% of the items within a scale be completed. The ABA value was the sum of the behavior item and confidence indicator associated with the behavior. Scoring for each BH scale was based on the individual scale scores multiplied by the ABA. This adjusted score was transformed to a range of 0 to 100. As demonstrated in Figure 3, application of the ABA lowered BH scores across the spectrum of BH. The BFIs were scored as the sum of index item means, with higher values indicating better BF. The global index was created by taking the mean of the 6 indices, with higher scores indicating better health. BHS, BFI, and ABA items along with coding and scoring instructions are included in Appendix B.

Comment

Principal findings

We present a rigorously validated BH-scale and function-index (BHS/BFI) instrument for use in women’s health research that considers BH on a continuum from poor (0) to optimal (100) health and can account for overestimation of BH owing to adaptive behaviors. The BHS/BFI may be used to estimate the distribution of BH and to identify factors associated with the continuum of BH in either paper or electronic modes of administration. Although

currently recommended for cross-sectional studies, future efforts evaluating sensitivity to change and item reduction and minimum clinically important differences are planned.

Results in the context of what is known

The BHS scoring incorporates adjustments for self-management behaviors often adopted to manage LUTS (eg, pad use).[44,45] Systematic measurement error in self-report of function can be directly and indirectly influenced by adaptive behaviors.[46,47] This error is often associated with response formation processes, including depth of cognitive processing, heuristics, topic salience, and social desirability.[47] Confidence alters the cognitive context when participants interpret a question, evaluate the response categories, and process response formation editing, resulting in overestimated reports of health. Therefore, we recommend the use of ABA in scale scoring, with the exception of analyses that model adaptive behavior as an independent or predictor variable.

Clinical and research implications

The BHS/BFI are designed for population and clinical research of BH and may be used to measure BH along a spectrum from very healthy to very unhealthy. The instrument is designed to identify protective factors for BH and potential risk factors for LUTS. Future studies will be designed to identify women at risk and who may benefit from prevention intervention trials.

Strengths and limitations

There is no “gold standard” to evaluate construct validity of BH. Reliance on available objective clinical indicators used to confirm LUTS in significantly affected women is subject to the contextual effects of a clinical environment and does not represent how a woman experiences her BF over the course of a day, in different environments with varying levels of activity, toilet access, and bladder storage and emptying stressors. In addition, the reliability of a bladder diary is affected by both missing data and what is termed the “parking lot” effect, whereby multiple diary entries are made at a single point in time.[48,49] The strengths of this study lie in the rigorous study design and use of external expert raters and validated self-report instruments for criterion validation. High correlations with expert raters’ global assessment of BH are encouraging.

Conclusions

Paper and electronic forms of the BHS and BFIs are reliable and construct valid measures of BH for use in women’s health research. The BHS/BFIs have broad generalizability for use in population or clinically based research as an outcome to identify risk and protective factors associated with the continuum of BH and reflect a measure of BHin accord with the World Health Organization’s definition of health as not merely the absence of disease. By measuring BH, we aim to identify factors that may be targeted to prevent all types of LUTS, not just isolated conditions such as incontinence or UTIs. The development of a validated BH instrument is the first step in shifting the paradigm of LUTS prevention research. Future efforts evaluating sensitivity to change and item reduction and minimum clinically important differences are planned.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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AJOG at a Glance

Why was this study conducted?

Existing bladder-specific measures lack the ability to assess the full range of bladder health.

Key findings

Using rigorous psychometric principles, we validated bladder health scales and bladder function indices, in paper and electronic formats, to assess bladder health in women.

What does this add to what is known?

This instrument aids in understanding the full range of bladder health and how to best develop interventions and strategies to support it.

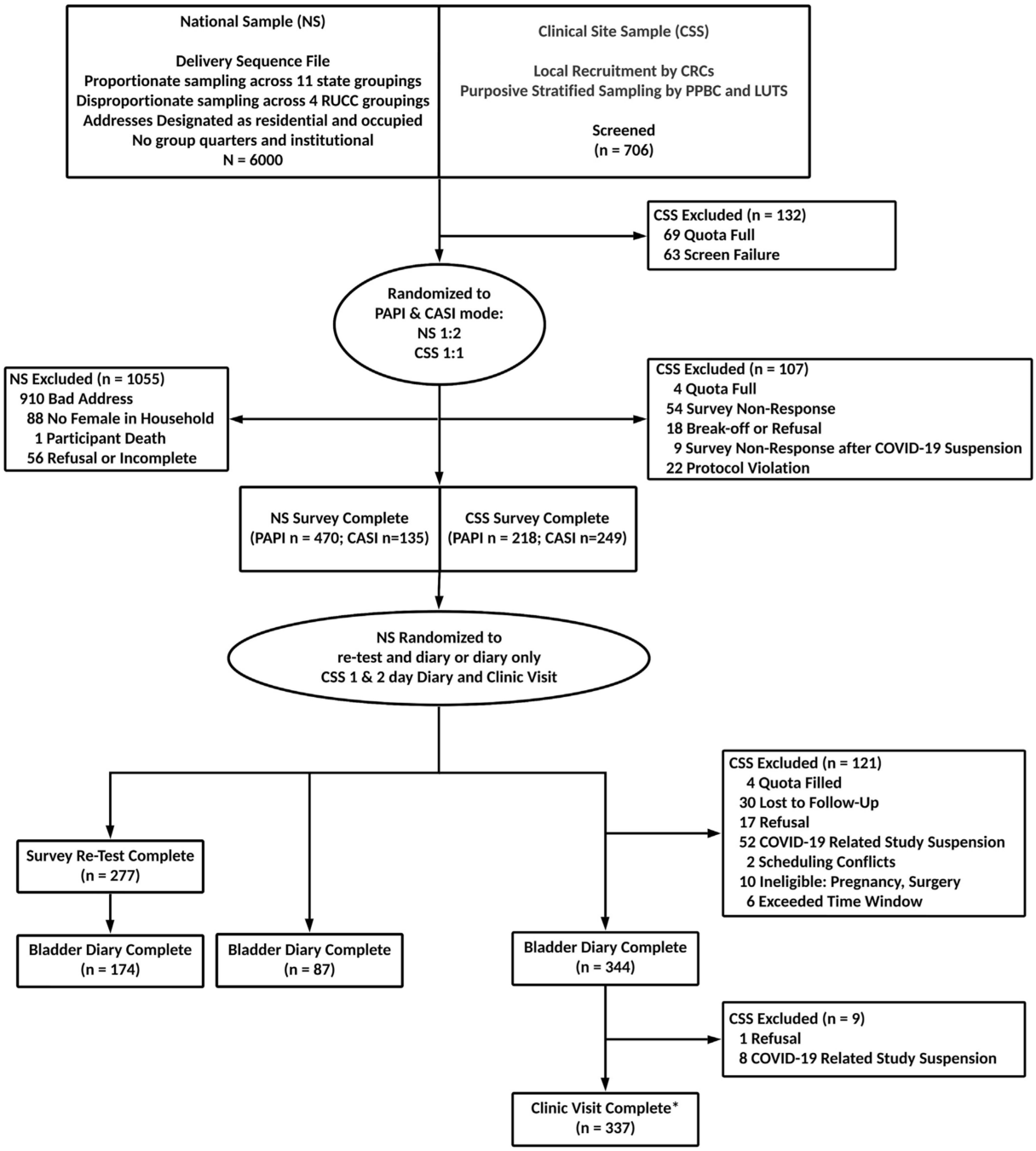

FIGURE 1. Study sampling and disposition

Asterisk denotes 2 did not complete diaries.

CASI, computer-assisted self-interview; *CRC*, clinical research coordinator; *CSS*, clinical research site sample; *LUTS*, lower urinary tract symptoms; *NS*, national sample; *PAPI*, paper-and-pencil interview; *PPBC*, Patient Perception of Bladder Condition; *RUCC*, Rural-Urban Continuum Codes.

FIGURE 2. Validation framework

MTMM validation framework of external construct measures from different data sources and different data collection methods. The (*gray arrows*) indicate measures a priori excluded as valid external constructs.

LUTS, lower urinary tract symptoms; *MOS*, Medical Outcomes Study; *MTMM*, multitrait-multimethod; *PFDI*, Pelvic Floor Distress Inventory; *QOL*, quality of life.

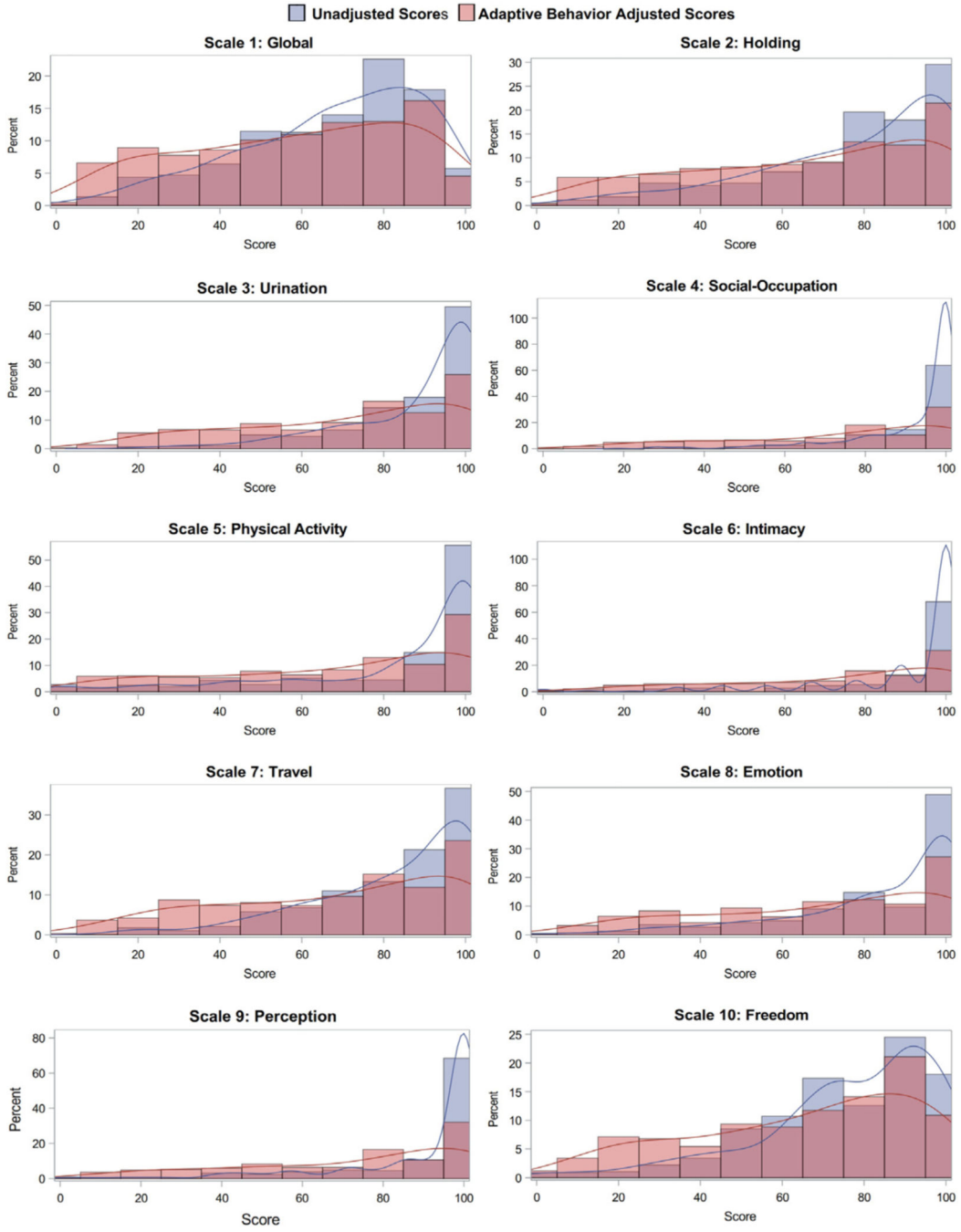

FIGURE 3. Adaptive behavior–adjusted and unadjusted BHS distributions for the NS

The distribution of individual BHS scores with and without adaptive behavior adjustment applied. All scores run from 0 (absence of bladder health) to 100 (maximum bladder health). Vertical axis depicts percentage of response frequency to scale levels, with the maximum response frequency varying by scale.

BHS, bladder health scale; *NS*, national sample.

TABLE 1

Demographics of the national and clinical-site samples

Demographics	National sample (N=605)	Clinical-site sample (N=467)
N PAPI/N CASI	470/135	218/249
Age in y, mean (SD)	56.0 (16.4)	44.8 (18.7)
Age by category	N (%)	N (%)
18–25	20 (3.5)	107 (23.9)
26–44	127 (22.0)	119 (26.6)
45–64	229 (39.7)	134 (29.9)
≥65	201 (34.8)	88 (19.6)
Missing	28 (4.6)	19 (4.1)
Gender identity	N (%)	N (%)
Female/woman	582 (99.8)	456 (98.5)
Trans male/trans man	0 (0)	2 (0.4)
Genderqueer/gender nonconforming	0 (0)	3 (0.6)
Identify in a different way	1 (0.2)	2 (0.4)
Missing	22 (3.6)	4 (0.9)
Highest education completed		
High school or less	101 (17.4)	70 (15.1)
Some college or associate degree	190 (32.7)	146 (31.5)
Bachelor’s degree	119 (20.5)	146 (31.5)
Graduate degree	171 (29.4)	101 (21.8)
Missing	24 (4.0)	4 (0.9)
Latina, Hispanic, or Spanish origin		
Not of Latino, Hispanic, or Spanish origin	513 (95.4)	402 (91.0)
Mexican or Mexican American	10 (1.9)	22 (5.0)
Puerto Rican	2 (0.4)	5 (1.1)
Cuban	2 (0.4)	1 (0.2)
Another Latino, Hispanic or Spanish origin	11 (2.0)	12 (2.7)
Missing	67 (11.1)	25 (5.4)

Demographics	National sample (N=605)	Clinical-site sample (N=467)
Race[a]		
American Indian or Alaska Native	3 (0.5)	0(0)
Another race, ethnicity, or origin	5 (0.9)	12 (2.6)
Asian	7 (1.2)	23 (5.0)
Black or African-American	32 (5.6)	120 (26.3)
Middle Eastern or North African	0(0)	1 (0.2)
Multiracial	34 (6.0)	34 (7.4)
Native Hawaiian or other Pacific Islander	1 (0.0)	0 (0)
White	486 (85.6)	267 (58.4)
Missing	37 (6.1)	10 (2.1)
English as primary language	570 (97.4)	446 (96.5)
Sought care for bladder	136 (23.2)	213 (46.2)
Parous	449 (74.2)	254 (54.4)
History of any pelvic surgery	163 (26.9)	99 (21.2)
Hysterectomy	137 (22.6)	69 (14.8)
BMI, mean (SD)	28.7 (7.2)	29.4 (7.5)
Healthy weight N (%)	190 (33.5)	141 (30.9)
Obese N (%)	212 (37.3)	186 (40.8)
Overweight N (%)	157 (27.6)	124 (27.2)
Underweight N (%)	9 (1.6)	5 (1.1)
Missing N (%)	37 (6.1)	11 (2.4)
Comorbidity count[b]		
0	302 (49.9)	217 (46.5)
1–2	250 (41.3)	210 (45.0)
≥3	53 (8.8)	40 (8.6)

BMI, body mass index; *CASI*, computer-assisted self-administered instrument; *PAPI*, paper and pencil instrument; *SD*, standard deviation.

[a]Multiple responses allowed; thus, does not sum to 100%. Supplemental Table 3 contains the complete breakdown of race and ethnicity

[b]Total comorbidities include the following: sleep apnea, diabetes mellitus, high blood pressure, depression, asthma/chronic lung disease, and neurologic disease. Neurologic disease is y/n if having any of the following: cerebral palsy, Parkinson's disease, multiple sclerosis, spinal cord injury, stroke, spina bifida.

TABLE 2

Final domain-specific item factor loadings, 2-way mixed intraclass correlation with 95% confidence interval for domains, and Cronbach alpha (standardized) for each of the 4 domains

Domain				
General perception of BH	**Scale 1: Global**			
Rate the function of your bladder	0. 904[a]			
Bladder is…(bothersome)	0.898[a]			
How you feel about your bladder	0.864[a]			
Bladder controls me	0.855[a]			
Compared with others of your age…	0.782[a]			
Last time you thought about your bladder	0.708[a]			
ICC =0.94 (0.93–0.94)[a]; alpha=0.9128				
General day-to-day life impact	**Scale 2: Holding**	**Scale 3: Efficacy**		
Worry about your bladder	0.879[a]	0.216		
Easy or difficult to hold it	0.847[a]	0.040		
Fear of embarrassment restricts activities	0.771[a]	0.163		
ICC=0.75 (0.71–0.78)[a]; alpha=0.8064				
Easy or difficult to start urinating	−0.046	0.875[a]		
Easy or difficult to completely empty bladder	0.191	0.825[a]		
Perceived efficacy of void	0.390	0.702[a]		
ICC=0.62 (0.57–0.66)[a]; alpha=0.7601				
Activity-specific impact	**Scale 4: Social-Occupation**	**Scale 5: Physical Activity**	**Scale 6: Intimacy**	**Scale 7: Travel**
Spending time with friends	0.864[a]	0.150	0.249	0.255
Friends or family arriving to home for dinner	0.866[a]	0.178	0.169	0.161
Going to home of friends or family for dinner	0.783[a]	0.1555	0.355	0.252
Ability to meet daily obligations	0.704[a]	0.264	0.309	0.330

Domain				
General perception of BH	**Scale 1: Global**			
Ability to focus responsibilities	0.662[a]	0.252	0.320	0.200
Participating in meetings or other group activities	0.639[a]	0.250	0.393	0.289
ICC=0.55 (0.52–0.58)[a]; alpha=0.9388				
Moderate physical activities	0.198	0.932[a]	0.122	0.161
Vigorous physical activities	0.200	0.865[a]	0.189	0.215
Light physical activities	0.206	0.886[a]	0.054	0.065
ICC=0.63 (0.58–0.67)[a]; alpha=0.9300				
Physical intimacy other than sex	0.320	0.1448	0.839[a]	0.229
Sexual intimacy	0.156	0.152	0.793[a]	0.339
Emotional intimacy	0.338	0.168	0.777[a]	0.080
ICC=0.56 (0.51–0.61)[a]; alpha=0.8811				
Using public transportation around town	0.322	0.093	0.222	0.846[a]
Long-distance traveling	0.283	0.152	0.192	0.833[a]
Activity-specific impact	**Scale 4: Social-Occupation**	**Scale 5: Physical Activity**	**Scale 6: Intimacy**	**Scale 7: Travel**
Getting around town using own car	0.394	0.131	0.215	0.766[a]
ICC=0.63 (0.58–0.67)[a]; alpha=0.8977[a]				
Emotional-perceptual impact	**Scale 8: Emotion**	**Scale 9: Perception**		**Scale 10: Freedom**
Feel different from other people	0.853[a]	0.280		0.135
Enjoy life less	0.818[a]	.0343		0.133
Lack confidence	0.782[a]	0.282		0.278
Bladder always on mind	0.744[a]	0.224		0.180
Frustration	0.726[a]	0.252		0.192
ICC=0.89 (0.88–0.91)[a]; alpha=0.9141[a]				
Feelings about life in general	0.304	0.894[a]		0.160

Domain			
General perception of BH	**Scale 1: Global**		
Feelings about yourself as a person	0.277	0.893[a]	0.187
Feelings about your overall health	0.365	0.809[a]	0.185
ICC=0.55 (0.50–0.60)[a]; alpha=0.9326[a]			
Leak when laugh, cough, or sneeze	0.247	0.130	0.868[a]
Fear of odor restricts activities	0.507	0.139	0.688[a]
Way you dress	0.413	0.910	0.630[a]
ICC=0.82 (0.80–0.85)[a]; alpha=0.7427[a]			

Item factor loadings used orthogonal with varimax rotation.

BH, bladder health; *ICC*, intraclass correlation.

[a]Domain-specific primary factor loadings.

TABLE 3

Correlations of bladder health scales with external construct measures, by multitrait-multimethod data source and data collection method

Source/Method	Domains and scales									
	General perception	**General day-to-day**		**Activity-specific**				**Emotional-perceptual**		
External construct	Global	Holding	Efficacy	Social-occupation	Physical activity	Intimacy	Travel	Emotion	Perception	Freedom
Same source/same method—Self-administered questionnaire										
MOS Role				0.44						
MOS Physical					0.52					
MOS Interfere				0.47						
MOS Mental								−0.19	−0.25	−0.16
KHQ Part I[a]	−0.77	−0.68								
KHQ Part II[a]	−0.74			−0.83	−0.58	−0.76	−0.71	−0.81	−0.70	−0.68
KHQ SS[a]	−0.68	−0.69	−0.37	−0.69	−0.46	−0.62	−0.61	−0.66	−0.56	−0.59
UDI[a]	−0.64	−0.7	−0.47	−0.61	−0.48	−0.54	−0.55	−0.62	−0.48	−0.67
BFLUTS-V[a]			−0.69							
Same source/different method—diary										
Day frequency	0.26	0.18		0.21	0.15					0.11
Leak[a]	−0.19	−0.24		−0.23	−0.13	−0.22	−0.17	−0.19	−0.14	−0.27
Urgency[a]		−0.32					−0.32			
Emptying[a]			−0.30							
Dribble[a]			−0.24							

Source/Method	Domains and scales			
	General perception	General day-to-day	Activity-specific	Emotional-perceptual
Different source/different method—external subjective				
Expert rating	0.72	0.66	0.61	
Different source/different method—external objective				
PTT[a]	−0.26		−0.25	−0.34
PVR[a]		−0.26		
Uroflow Max		0.13		

Empty cells indicate no a priori expected or examined correlation.

BFLUTS-V, Bristol Female Lower Urinary Tract Symptoms, Voiding; *KHQ*, King's Health Questionnaire; *MOS*, Medical Outcomes Study; *PTT*, paper towel test; *PVR*, postvoid residual; *SS*, symptom scales; *UDI*, Urinary Distress Inventory.

[a]High score indicates greater dysfunction.

TABLE 4

Correlations of bladder function indices with external construct measures, by multitrait-multimethod data source and data collection method

External measure	Bladder function indices					
	UTI	**Frequency**	**Sensation**	**Continence**	**Comfort**	**Emptying**
KHQ-SS[a]	−0.64	−0.44	−0.55	−0.48	−0.49	
UDI[a]		−0.41	−0.49	−0.51	−0.45	−0.53
BFLUTS-V[a]						−0.50
Day frequency[a]		−0.12				
Leak[a]				−0.19		
Urgency[a]			−0.28			
Emptying[a]						−0.27
Dribble[a]				−0.17		−0.28
Expert rating	0. 41	0.42	0.47	0.40	0.30	0.49
PTT[a]				−0.36		

Empty cells indicate no a priori expected or examined correlation.

BFLUTS-V, Bristol Female Lower Urinary Tract Symptoms, Voiding; *KHQ*, King's Health Questionnaire; *PTT*, paper towel test; *SS*, symptom scales; *UDI*, Urinary Distress Inventory; *UTI*, urinary tract infection.

[a]High score indicates greater dysfunction.

TABLE 5

Known-group validity: bladder health scale scores with and without adaptive behavior adjustment and bladder function index scores for national and clinical-site samples

BH Scale	No adaptive behavior adjustment		Adaptive behavior adjusted	
	National	Clinical site	National	Clinical site
Global	67.4 (22.3)	49.9 (25.2)	58.59 (27.1)	42.5 (26.9)
Holding	77.5 (23.8)	62.2 (28.3)	66.3 (29.3)	51.8 (30.4)
Perceived efficacy	88.1 (17.0)	75.6 (24.2)	71.4 (26.7)	57.3 (29.5)
Social-occupation	91.7 (14.3)	78.4 (23.1)	73.8 (26.5)	59.1 (29.7)
Physical activity	82.6 (26.2)	74.3 (30.1)	68.5 (30.4)	56.9 (32.1)
Intimacy	89.9 (19.9)	74.6 (30.4)	73.8 (26.9)	58.6 (30.9)
Travel	82.9 (19.7)	66.3 (26.9)	68.6 (27.9)	52.7 (30.0)
Emotion	83.0 (21.9)	66.2 (29.3)	69.0 (28.4)	52.6 (30.7)
Perception	89.5 (19.3)	73.8 (28.2)	72.7 (28.0)	56.2 (31.3)
Freedom	76.4 (21.6)	69.7 (25.8)	65.3 (27.2)	55.5 (29.2)

	No adaptive behavior adjustment	
Bladder Function Index	National	Clinical site
UTI	90.3 (21.5)	73.8 (33.7)
Frequency	76.1 (26.8)	63.3 (31.6)
Sensation	73.8 (26.2)	60.9 (30.7)
Continence	66.5 (24.4)	61.1 (28.5)
Comfort	79.4 (23.8)	66.0 (30.0)

BH Scale	No adaptive behavior adjustment		Adaptive behavior adjusted	
	National	Clinical site	National	Clinical site
Emptying		71.9 (26.0)		57.2 (29.6)
Total		76.4 (18.2)		63.4 (22.3)

Values are presented as mean (standard deviation). The Welch *t*-test was used for all scale score comparisons between groups. All comparisons between samples with and without adjustment demonstrated a statistically significant difference ($P<.001$).

UTI, urinary tract infection.