🏆 Conservative Management Award

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A MULTI-SITE PROSPECTIVE RANDOMIZED CONTROLLED TRIAL OF GROUP-ADMINISTERED BEHAVIORAL TREATMENT IN REDUCING URINARY INCONTINENCE IN OLDER ADULT WOMEN

Hypothesis / aims of study

This innovative clinical trial enrolled adult women, ≥ 55 years from diverse backgrounds who reported stress, urgency, or mixed urinary incontinence (UI) and who had never been treated for UI. The study aim was to compare the effectiveness of a novel group-administered behavioral treatment class, the Group Behavioral Treatment (GBT), to no treatment.

Study design, materials and methods

A multi-site, prospective randomized, controlled trial to assess the efficacy of a face-to-face 2-hour GBT compared to a no care control. A reactive mass mailing recruitment was used, with enriched sampling for representation to achieve oversampling in urban and African American communities through zip code indicators for each study site. Mailings were sent to community-dwelling adult women 55 years and older. Responders were screened centrally for incontinence frequency and severity and to insure that potential participants were naïve to UI treatment. Potentially eligible women were referred to their local clinical sites for screening and random assigned to one of two treatment arms: 1) Group Behavioral Treatment or 2) No treatment. Inclusion/exclusion criteria included women 55 years and older, International Consultation on Incontinence Questionnaire (ICIQ UI-SF), score of at least 3 (1 for frequency, 2 for severity), report of UI for at least 3-months duration, no prior UI treatment, no symptomatic prolapse, and no previous bladder surgery or pelvic cancer. Primary outcome: ICIQ UI-SF. Secondary outcomes: 3-day voiding diary, paper towel test, 24-hr pad weight, Brink test, Incontinence Quality of Life Questionnaire (I-QOL) and Patient Global Impression of Improvement (PGI-I). GBT group received a one-time 2-hour bladder health class whereas the control group received no treatment. Both received a behavioral education brochure, were monitored every 3 months for 12-months with clinic visits at 3 & 12 months and mailed questionnaires at 6 & 9 months.

Results

This study was able to recruit 463 women with a mean age of 64+/-7.3 years, age range 55 to 91 years, mean BMI ≥30 in 52%, 46% African American; 1% Hispanic; 13% high school education or less, 30% employed full time. 232 subjects were randomized to GBT and 231 to no treatment control; 34 withdrew (GBT=22 & Control =12). Demographics were not significantly different between groups. Outcomes at 3, 6, 9 & 12 months showed significant differences in favor of GBT over control including ICIQ-UI SF ($p<0.0001$) (Table 1), average number of voids/day ($p=<0.0002$) and average number of leaks/day ($p=0.0002$) on a voiding diary (Table 2), paper towel test ($p=0.0008$), 24-hr pad weights ($p=0.0007$), Medical, Epidemiologic & Social aspects of Aging questionnaire (MESA) ($p<0.0001$), Incontinence Quality of Life (IQOL) ($p<0.0001$) & PGI-I ($p<0.0001$) but not the Brink test for pelvic floor strength ($p=0.09$). No significant adverse events or serious events were encountered in either group.

Interpretation of results

This novel group learning intervention safely and effectively reduced incontinence frequency, severity, and bother, while improving incontinence-related quality of life as measured by multiple validated instruments. Improvement was maintained for 12 months after the 2-hour, one time intervention. Behavioral interventions are recommended in most treatment guidelines as first line therapy for UI. The study recruitment methodology of mailed letters with a toll-free response telephone number was able to yield a group of treatment-naïve older adult women who were very accepting of a group behavioral intervention. The potential of using a group learning intervention as an initial treatment strategy for adult women with urinary incontinence may be less-costly for this very burdensome condition that affects 1 in 3 older women.

Concluding message

This bladder health education program delivered in a group setting was safe and effective in reducing UI frequency, severity and bother and improving quality of life for community-dwelling older adult women with UI. This easily scaled intervention increases opportunity to reach larger populations beyond medical practices and into community settings.

Table 1 – ICIQ-UI SF Scores at each Time Point

ICIQ score Median (25^{th}, 75^{th}) Min to Max	**Total all Subjects N=463**	**GBT Group N=232**	**Control Group N=231**	**p-value**
Baseline/Screening Median (25^{th}, 75^{th}) Min to max	N=462 8 (6, 11) 3 to 21	N=231 8 (6, 11) 3 to 21	N=231 8 (6, 11) 3 to 21	0.78
3 Months Median (25^{th}, 75^{th}) Min to max	N=424 7 (5, 10) 0 to 19	N=211 6 (4, 9) 0 to 19	N=213 7 (5, 10) 0 to 17	0.003
6 Months Median (25^{th}, 75^{th}) Min to max	N=397 6 (4, 10) 0 to 20	N=192 5 (4, 9) 0 to 20	N=205 7 (5, 10) 0 to 19	<0.0001
9 Months Median (25^{th}, 75^{th}) Min to max	N=385 6 (4, 9) 0 to 20	N=184 5 (4, 8) 0 to 18	N=201 7 (5,10) 0 to 20	<0.0001
12 Months Median (25^{th}, 75^{th}) Min to max	N=399 6 (4, 8) 0 to 20	N=196 5 (3, 7) 0 to 20	N=203 6 (4, 9) 0 to 19	<0.0001

Table 2 - Average Number of Daily Incontinence Episodes from Voiding Diaries

Average # Incontinence Episodes/Day	**Total all Sites N=463**	**GBT Group N=232**	**Control Group N=231**	**P-value**
Baseline/ Screen Median (25^{th}, 75^{th}) Min to max	N=462 1.3 (0.7, 2.3) 0 to 21	N=232 1.3 (0.7, 2.7) 0 to 21	N=230 1.3 (0.3, 2.0) 0 to 11	0.12
3 Months Median (25^{th}, 75^{th}) Min to max	N=420 0.7 (0.3, 2.0) 0 to 11	N=209 0.7 (0, 1.3) 0 to 10	N=211 1.0 (0.3, 2.0) 0 to 11	0.010
6 Months Median (25^{th}, 75^{th}) Min to max	N=395 0.7 (0.3, 1.7) 0 to 12	N=190 0.3 (0, 1.3) 0 to 7.3	N=205 1.0 (0.3, 2.0) 0 to 12	<0.0001
9 Months Median (25^{th}, 75^{th}) Min to max	N=383 0.7 (0, 1.3) 0 to 14	N=182 0.3 (0, 1.0) 0 to 8.7	N=201 1.0 (0.3, 2.0) 0 to 14	<0.0001
12 Months Median (25^{th}, 75^{th}) Min to max	N=397 0.7 (0, 1.7) 0 to 12	N=195 0.3 (0, 1.3) 0 to 11.7	N=202 0.8 (0.3, 2.0) 0 to 9.7	0.0002

Disclosures

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