

QUALITY CONTROL IN THE DESIGN AND IMPLEMENTATION OF A MULTI-SITE, PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL OF GROUP BEHAVIORAL TREATMENT FOR URINARY INCONTINENCE IN OLDER WOMEN

Hypothesis / Aims of Study

A multi-site, prospective, randomized, controlled trial of group behavioral treatment (GBT) versus no treatment was conducted to determine feasibility and clinical efficacy for treatment of urinary incontinence (UI). Design and implementation of the study required strict attention to detail regarding training of the GBT session instructors who would be working directly with enrolled subjects, and subsequent targeting of the conceptual components of GBT during sessions. The need for a high degree of uniformity of training for instructors and also during study implementation across all clinical sites was recognized as key component for project success. This study focuses on quality control measures used in the study, design and implementation of the 'train the trainer' model, and outcomes of trainer certification fidelity and script concordance.

Study Design / Materials and Methods

Older adult women with UI were recruited using a mass mailing method targeted to community-dwelling women 55 year and older. Centralized screening was used to identify the frequency and severity of UI, and to verify that women were naïve to UI treatment. Eligible subjects participated at one of three clinical sites closest to their place of residence. Participants randomized to the GBT group received a one-time 2-hour bladder health class which included instruction in the anatomy and physiology of voiding and UI, bladder training, pelvic floor muscle exercises and other behavioral techniques, and methods of self-reward to enhance and reinforce ongoing compliance. Participants in both groups received a Behavioral Treatment Brochure for UI, but those randomized to the control group received no group training sessions. Validated measures were assessed at baseline, and at 3, 6, 9, and 12 months in both groups. The primary outcome of the clinical study itself was the International Consultation on Incontinence Questionnaire (ICIQ-SF) score.

The quality control portion of the study involved creation of a standardized training set including an instructional slide deck and a standardized narrative script used by GBT instructors at all three clinical sites. The script was organized into specific conceptual topics including: welcome and introductions; purpose of the sessions; anatomy, physiology and voiding patterns; an engaged discussion of behavioral management; bladder training; urge suppression; pelvic floor muscle therapy (PFMT) and strategies for muscle contraction to prevent urine leakage. Subjects were taught to incorporate all of these techniques into daily lifestyle, and were provided suggested motivating factors and methods of personal reward as well as a session summary. A 30-item trainer fidelity and script concordance assessment tool was created which identified major teaching points to be included in all sessions. Of these, 10 items were considered critical and were mandatory in each session (Table). A 'train the trainer' model was used. The lead investigators initially taught the GBT content to the site instructors using the slide deck and conceptual script. Each site instructor then individually taught the content back to the entire investigator group using the same methods. They were allowed to present the materials in their own personal style, but were required to follow the conceptual structure and script outline of the GBT sessions.

Site instructors were scored for training fidelity using the 30-item assessment checklist and other feedback methods in order to be certified to begin conducting actual GBT sessions with enrolled subjects. All sessions were digitally audio recorded and uploaded into a secured cloud based data repository. Sessions were analyzed by one of the lead investigators who was not a clinical site investigator and who was not directly involved in GBT sessions with participants. This investigator compared the content of the audio recordings against the conceptual narrative to determine script concordance. A goal to review 5% of total recordings was established *a priori* during study design. The primary outcomes of the quality control part of the trial were the degree of trainer fidelity and script concordance.

Results

A total of 463 women (mean age 64 ± 7.3 years, range 55 – 91) were enrolled. Of these, 232 were randomized to the GBT arm, and 231 were randomized to the no treatment control group. Demographics were statistically similar between groups. Overall primary outcomes at 3, 6, 9, and 12 months showed significant improvement in the ICIQ score of those in the GBT group ($p < 0.0001$).

Regarding GBT site instructor training, 3 individual trainers were provided feedback using a 360-degree method by the lead investigators. Narrative script modifications were finalized and refinements in technique were offered to all trainers. Each individual GBT site instructor's performance was evaluated using the 30-item trainer fidelity and script concordance assessment tool, and all achieved 100% scores and were certified. All specifically included each of the 10 critical / mandatory conceptual items (Table). A total of 52 GBT sessions were taught across the 3 clinical sites. Of these, 6 sessions (2 for each site) were randomly analyzed by the quality control investigator to determine overall script concordance. This represented 11.5% of all

sessions. Each of the 6 sessions analyzed met 100% of the 30-item checklist, and 100% of the 10 critical / mandatory conceptual items.

Interpretation of results

A very high level of quality control was achieved in a multi-site, prospective, randomized behavioral research clinical trial. The 'train the trainer' model with 360° feedback and standardized certification checklist yielded high trainer fidelity. Randomized assessment of actual GBT sessions with enrolled participants demonstrated very strong script concordance. GBT utilizing a standardized 2-hour bladder health class helped older adult women achieve significantly better continence outcomes compared to a no treatment control.

Concluding Message

These quality control design techniques are a model for standardized instructor training and program implementation for GBT. They may provide both a method to disseminate a more generalizable behavioral intervention for UI and prove useful in other future behavioral research.

Table

10 Critical / Mandatory Components of GBT Conceptual Narrative Script

- Anatomy and physiology of the continence mechanism
- Anatomy and physiology of pelvic floor muscles and pelvic organ support structures
- Normal voiding patterns and voiding habits
- Discussion of options GBT participants have personally used to manage urinary leakage including advantages and disadvantages of these methods
- Instruction on technique for PFMT and inclusion of a practice session
- The value of a routine approach to PFMT
- Use of the pelvic floor muscles to do the 'squeeze trick'
- Emphasize the goal of a 3-4 hour voiding interval
- Discuss urge suppression strategies
- Describe the value of identifying and using personal rewards and motivation methods

Disclosures

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Subjects: HUMAN **Ethics Committee:** William Beaumont Medical Center **Helsinki:** Yes **Informed Consent:** Yes