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Small-Group, Community-Member Intervention for Urinary and Bowel Incontinence:

A Randomized Controlled Trial

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Abstract

OBJECTIVE: To evaluate the effects of Mind Over Matter: Healthy Bowels, Healthy Bladder, a small-group intervention, on urinary and bowel incontinence symptoms among older women with incontinence.

METHODS: In this individually randomized group treatment trial, women aged 50 years and older with urinary, bowel incontinence, or both, were randomly allocated at baseline to participate in Mind Over Matter: Healthy Bowels, Healthy Bladder immediately (treatment group) or after final data collection (waitlist control group). The primary outcome was urinary incontinence (UI) improvement on the Patient Global Impression of Improvement at 4 months. Validated instruments assessed incontinence, self-efficacy, depression, and barriers to care-seeking. Intent-to-treat analyses compared differences between groups. Target sample size, based on an anticipated improvement rate of 45% in treated women vs 11% in the control group, 90% power, type I error of 0.05, with anticipated attrition of 25%, was 110.

RESULTS: Among 121 women randomized (62 treatment group; 59 control group), 116 (95%) completed the 4-month assessment. Most participants were non-Hispanic white (97%), with a mean age of 75 years (SD 9.2, range 51–98); 66% had attended some college. There were no significant between-group differences at baseline. At 4 months, 71% of treated women vs 23% of women in the control group reported improved UI on Patient Global Impression of Improvement ($P<.001$); 39% vs 5% were much improved ($P<.001$). Regarding bowel incontinence, 55% of treated women vs 27% of women in the control group improved on Patient Global Impression of Improvement ($P<.005$), with 35% vs 11% reporting much improvement ($P<.005$). Treated women

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improved significantly more than women in the control group on all validated instruments of incontinence severity, quality of life, and self-efficacy. Care-seeking rates were similar between groups.

CONCLUSION: Participation in a small-group intervention improves symptoms of both urinary and bowel incontinence in older women. Mind Over Matter is a feasible model with potential to bring effective behavioral solutions to the community.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, .

More than 60% of older U.S. women suffer from urinary incontinence, bowel incontinence, or both, the annual cost of which exceeds $30 billion.[1,2] In addition to significant negative effect on quality of life and depression,[2] incontinence increases risk for institutionalization.[3,4] Incontinence can be improved through behavioral modifications including pelvic floor muscle exercises, bladder training, and dietary adjustments.[5,6] However, more than half of women with urinary incontinence and 70% of women with bowel incontinence do not seek care.[7]

Videos, mobile applications, and in-person classes that help women adopt behaviors to mitigate urinary incontinence have demonstrated a modest effect.[8–12] None address bowel incontinence, which affects 30% of women with urinary incontinence, has similar self-management strategies, and is associated with lower care-seeking and worse quality of life.[13,14]

“Dare to Age Well” is an in-person health promotion program that improved urinary incontinence in older women in the United Kingdom.[8] With permission from its developer, our team worked with our community to adapt this program for bladder and bowel incontinence. To enhance potential for scalability, we modified the program to be led by a trained community member rather than a clinical or research professional, partnering with a state dissemination agency to develop a train-the-trainer model.

Termed “Mind Over Matter; Healthy Bowels, Healthy Bladder” (Mind Over Matter), our adapted intervention includes education and skill-building to perform evidence-based self-management strategies for urinary and bowel incontinence. The objective of this trial was to evaluate the effect of Mind Over Matter on bladder and bowel incontinence symptoms and care-seeking among community-dwelling older women.

METHODS

We conducted an individually randomized group treatment trial with a waitlist control group (ratio 1:1) examining the effectiveness of a group intervention, Mind Over Matter, for women aged 50 years or older, to reduce symptoms of urinary incontinence, bowel incontinence, or both. Figure 1 provides a graphic representation of the study design and data collection points. Written informed consent was collected from all participants. The University of Wisconsin Health Sciences—Minimal Risk Institutional Review Board approved this study, registered at www.clinicaltrials.gov (). There were no important changes to methods after trial commencement.

Mind Over Matter was adapted from the urinary continence promotion portion of Tannenbaum and colleagues' Dare to Age Well intervention tested in the Continence Across Continents to Upend Stigma and Dependency trial.[8,15] Mind Over Matter combines education with personalized goal setting and action planning to empower women to make and sustain behavior changes to improve symptoms. The optimal group size is 8–12 women who have or want to prevent bladder or bowel symptoms. Mind Over Matter differs from Dare to Age Well in three key ways: 1) additional information about fiber supplementation, bowel incontinence, and defecatory positioning is incorporated; 2) Mind Over Matter consists of three sessions each lasting 2 hours, whereas Dare to Age Well is a single session lasting 90 minutes; and 3) Mind Over Matter is facilitated by a community member who has attended an extensive 2-day training, rather than a health care or research professional.

The behavior change model underpinning Mind Over Matter is Schwarzer's[16] Health Action Process Approach, which posits that self-efficacy, action planning, and coping planning help individuals move along the continuum from preintention, to intention, to action and maintenance of health behavior change. Behavior changes include pelvic floor muscle exercises (relaxation, contraction, endurance, and coordination components), dietary changes for optimization of stool consistency with gradual fiber supplementation, fluid adjustment to avoid bladder irritants and optimize fluid intake, and bladder training techniques. Each Mind Over Matter session is separated from the subsequent session by 2 weeks, so that participants have an opportunity to set goals, work towards them, and evaluate their progress at the next session. All Mind Over Matter facilitators participated in a 2-day, hands-on, in-person certification training and passed a competency evaluation before administering Mind Over Matter as part of this trial. Additional details about program content are available in Appendix 1, available online at http://links.lww.com/AOG/B483; additional details about facilitator recruitment and training are available in Appendix 2, available online at http://links.lww.com/AOG/B483.

Participants allocated to the treatment group received the intervention in the spring of 2017; those allocated to the control group received the identical intervention in the fall of 2017 (after final data collection). Trained observers used a fidelity checklist to assess facilitator adherence to the script and alignment with Mind Over Matter's conceptual underpinnings for each treatment and control workshop session. Fidelity to the intervention protocol was considered adequate if there were fidelity lapses (diversion from intervention script or key elements) in fewer than 20% of sessions.

Women were eligible to participate in this trial if they: 1) were aged 50 years or older and lived independently, defined as "living on your own or with someone else, but not needing assistance with daily activities"; 2) could speak and read English; and 3) had experienced urinary incontinence at least weekly or bowel incontinence at least monthly in the previous 4 weeks. Exclusion criteria included: 1) acute illness,2) dementia, 3) inability to attend all three workshop sessions, and 4) plan to initiate other new treatments for urinary or bowel incontinence during the study time period. Because this was an effectiveness trial in a real-world setting, women were allowed to continue preexisting treatments during the study without changes. No specific data were collected about these preexisting treatments.

Participants were recruited via flyers, newsletters, newspapers, mailings and e-mailings, and community outreach between May 4, 2017, and June 30, 2017. Computer generated randomization was performed within each community 1 week before the spring Mind Over Matter workshop and participants were informed of their allocation (spring or fall) at that time. A computer-based pseudo-random number generator that generates random numbers using a complex algorithm seeded by the computer's clock (Research Randomizer, www.randomizer.org), was used to generate a series of random numbers from 1 to 50 for the number of participants consented in each community the week before its spring workshop. Participant identification numbers for the community were listed in chronologic order in an excel document, and the list of random numbers in its randomly generated order was pasted next to participant identification numbers in chronologic order. Those participants whose random number was odd were allocated to the spring session (treatment group); those whose random number was even were allocated to the fall (control group). Allocations were pasted into the document linking participant identification numbers with contact information, and participants were contacted by study staff and informed of their allocation status. Participants were not blinded to their allocation; all data analyses were performed with a de-identified dataset.

Participants completed self-administered written questionnaires at baseline, 1 month (immediately after the treatment workshop for their community), and 4 months (Fig. 1). Participants who completed both the baseline and final questionnaires received $50; those who completed only one or the other received $25. No compensation was provided for completing the 1-month questionnaire.

Our primary effectiveness outcome was improvement in urinary incontinence symptoms as assessed by the Patient Global Impression of Improvement[17] at the 4-month timepoint. In its original validation, the Patient Global Impression of Improvement text was, "Check the one number that best describes how your urinary tract condition is now, compared with how it was before you began taking medication in this study," with response options on a 7-point Likert scale of: "1) Very much better; 2) Much better; 3) A little better; 4) No change; 5) A little worse; 6) Much worse;7) Very much worse." For this study, the lead-in text read: "Check the box that best describes how your accidental urine leakage is now, compared to how it was 3 months ago," with identical response options to the original instrument. Our target sample size was based on an estimate that 45% of treatment participants would report that their urinary incontinence was better (options 1–3 on the Patient Global Impression of Improvement) compared with 11% in women in the control group. Our estimate for improvement in the treatment group of 45% was based on preliminary feasibility testing of Mind Over Matter, during which 45% of participants reported improvement in urinary incontinence symptoms 3 months after the workshop (unpublished data from our research group); our estimate for improvement in the control group of 11% was based on that found in Tannenbaum et al's[8] prior work. Using these assumptions, a sample size of 82 was needed to obtain 90% power with a type I error of 0.05; we assumed an attrition rate of 25% and our target was, thus, 110 participants.

The baseline questionnaire collected demographic and health information and included an assessment of cognitive status, the Cognitive Function Screening Instrument.[18] Figure 1

provides a graphic depiction of the study time line and questionnaires administered at each timepoint. Urinary incontinence severity and quality-of-life effect were assessed at all three timepoints using the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form[19] and the modified Patient Global Impression of Improvement[17] as described above at the 4-month timepoint. Bowel incontinence severity and quality-of-life effect were assessed at all three timepoints using the St. Mark's Incontinence Score[20]; a similarly modified Patient Global Impression of Improvement, "Check the box that best describes how your accidental bowel leakage is now, compared to how it was 3 months ago," was asked at the 4-month timepoint. The Pelvic Floor Distress Inventory Short Form 20[21] assessed prolapse, bowel, and uri-nary symptoms at baseline and 4 months.

To ascertain prior care-seeking, participants were asked, "Have you ever talked to a health care provider (like a doctor or nurse practitioner) about accidental urinary leakage?" and "Have you ever talked to a health care provider (like a doctor or nurse practitioner) about accidental bowel leakage?" on their baseline questionnaire. To understand care-seeking during the study period and intention moving forward, the 4 months questionnaire asked, "Have you talked to a health care provider (like a doctor or nurse practitioner) about accidental urine leakage in the last 4 months?" and "Do you plan to talk to a health care provider about accidental urine leakage in the next 6 months?" with similar language for bowel leakage. Participants completed the Barriers to Care seeking for Accidental Bowel Leakage Questionnaire[22] and the Barriers to Incontinence Care seeking Questionnaire[23] on the baseline and 4 months questionnaires. The Geriatric Self-Efficacy for Urinary Incontinence[24] assessed self-efficacy to control urinary symptoms and the Patient Health Questionnaire assessed depression[25] at baseline and 4 months. Key symptoms and behaviors over the previous 4 weeks were assessed at all three timepoints (Appendix 3, available online at http://links.lww.com/AOG/B483).

To evaluate our primary outcome, any improvement in urinary incontinence as assessed by the Patient Global Impression of Improvement at 4 months in the treatment and control groups, we used x^2 testing to compare differences in proportions reporting improvement and calculated 95% CIs around these differences in proportions. The 7-point response options from the Patient Global Impression of Improvement were recoded to create a dichotomous variable with responses 1–3 considered "any improvement," and responses 4–7 considered not improvement. A similar planned secondary analysis evaluated any improvement in bowel incontinence as assessed by the Patient Global Impression of Improvement at 4 months in the treatment and control groups in the same way. We also planned secondary analyses to compare rates of "much or very much improvement" as assessed by the Patient Global Impression of Improvement at 4 months in the treatment and control groups for 1) urinary incontinence and 2) bowel incontinence. For these analyses, the 7-point response options from the Patient Global Impression of Improvement were recoded to create dichotomous variables with responses 1–2 considered "much or very much improvement" and responses 3–7 considered not very much improvement. We also planned a secondary analysis using logistic regression to identify the odds of 1) any and 2) very much improvement in a) urinary incontinence and b) bowel incontinence, also controlling for community, given that the individual intervention was delivered to an entire group at once.

The threshold for statistical significance for these analyses was $P<.013$ based on a Bonferroni adjustment (.05/4).

Additional planned secondary analyses included comparison of treatment and control groups at baseline and 4 months on validated measures of condition severity, care-seeking, self-efficacy to control urinary incontinence, and depression. Comparison of treatment and control groups regarding key behaviors such as routine performance of pelvic floor muscle exercises, specific fluid intake estimates, and achievement of desirable stool consistency (type 3–4 on the Bristol Stool Form Scale[26]) were planned at all three timepoints. Based on review of this manuscript, additional analyses were recommended and performed to compare 1) any improvement and 2) much or very much improvement in urinary incontinence among the subset of women who had isolated urinary incontinence or dual incontinence, and rates of any and much improvement in bowel incontinence among the subset of women who had isolated bowel incontinence or dual incontinence, excluding the women who did not have the outcome of interest at baseline. Chi-square testing was used to compare these groups.

Demographic and clinical characteristics in the treatment and control groups were compared using χ^2 tests for categorical variables and t-tests for continuous variables. Women were defined as having urinary incontinence if they reported urinary leakage on both items 1 and 2 of the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form, and bowel incontinence if they reported leakage of either solid or liquid stool with a frequency of rarely or more in the previous 4 weeks on the St. Mark's Incontinence score. For the primary outcome, rates of symptom improvement in the treatment and control groups at 4 months were compared using χ^2 testing and logistic regression to control for community. *t*-tests were used to compare means on scored instruments and difference in differences between groups. Care-seeking intention and history in the treatment and control groups were compared as dichotomous variables using χ^2 testing. All analyses conducted were intention-to-treat; tests with a type I error rate less than 0.05 were considered statistically significant. Statistical analyses were conducted using IBM SPSS 24.0 and SAS 9.4.

RESULTS

Of 166 women screened, 122 consented and 121 were randomized (62 treatment group; 59 control group); 116 (95%) completed the 4-month assessment (Fig. 2). All six community partners offered both treatment and control workshops according to study timeline and protocol. There were no major fidelity lapses during treatment or control workshop sessions in any community.

Participants were predominantly non-Hispanic white (97%), retired, and overweight, with a mean age of 7569 years (range 51–98); 66% had attended some college. There were no significant between-group differences at baseline (Table 1). The majority of participants (n=73, 60%) had both urinary and bowel incontinence; 44 (36%) had isolated urinary incontinence; 1 (1%) had isolated bowel incontinence; data were missing on either urinary or bowel incontinence at baseline for three participants (3%).

Regarding the primary outcome, 71% (42/59) of treated women compared with 23% (13/57) of women in the control group reported any improvement in urinary leakage on the Patient Global Impression of Improvement at 4-month follow-up ($P<.001$), with a difference in proportions of 48% (95% CI 32–65%, $P<.001$). Table 2 displays responses to the Patient Global Impression of Improvement for any and very much improvement in urinary leakage and bowel leakage at 4-month follow-up, using intent-to-treat analyses. Regarding bowel leakage, 55% of treated women compared with 27% of women in the control group improved, with 35% compared with 11% reporting that they were very much or much improved ($P=.009$). Importantly, women in the treatment group were less likely than women in the control group to report that their incontinence symptoms were worse at 4-month follow-up (5% vs 19% for urinary incontinence; 3% vs 20% for bowel incontinence); no one in the treatment group reported that urinary or bowel incontinence symptoms were much worse, compared with 5% for urinary and 4% for bowel incontinence in the control group.

The treatment and control groups did not differ in baseline scores on validated instruments assessing pelvic floor symptom severity and effect, self-efficacy, and depression. Treated women improved more than women in the control group on all validated instruments of urinary and bowel incontinence severity, quality of life, and self-efficacy at 4-month follow-up; depression scores did not change significantly in either group (Table 3). The urinary subscale of the Pelvic Floor Distress Inventory Short Form-20 changed most significantly between the treatment and control groups (mean reduction11.90±18.79 vs 4.96±12.49 points, respectively, $P=.02$), with the differences in the colorectal subscale approaching statistical significance (mean reduction 6.12±15.72 vs 0.92±14.33 points, $P=.07$). The differences in the prolapse subscale of the Pelvic Floor Distress Inventory Short Form 20 were not different between groups (reduction in 4.79±16.09 points in the treatment group vs 3.74±15.61 points in the control group, $P=.72$).

Significantly more women in the treatment compared with the control group had sought care for urinary incontinence at baseline, but rates of prior care-seeking for bowel incontinence were similar in both groups (Table 4). Between-group differences in rates of care-seeking during the study or in plans to seek care at the end of the study did not differ. Scores on the Barriers to Incontinence Care seeking Questionnaire and Barriers to Care seeking for Accidental Bowel Leakage questionnaire were comparable in the treatment and control groups at baseline and were not statistically significantly different at 4 months (Table 3).

There were no significant differences between groups at baseline in number of voids per day, number of overnight voids, number of pads used per day, and amount of money spent on pads per week, and there were no significant differences between groups over time in any of these measures (data not shown). At baseline, the proportion of participants performing pelvic floor muscle exercises (Kegels) often or always was similar in the treatment (16%) and control (9%) groups ($P=.23$, Fig. 3). In the treatment group, this number increased to 93% at 1 month and remained 63% at 4 months; the control group remained steady at 8% and 9%, respectively ($P<.001$ at both the 1- and 4-month timepoints). There were no differences at baseline in mean servings per day of coffee, tea, diet soda, alcohol, or water, nor were there any differences between groups at 1 or 4 months (data not shown). The proportion of participants with desirable type 3 or 4 stool (optimal stool consistency) on the

Bristol Stool Form Scale was similar at baseline: 57% (33/58) in the treatment group and 61% (35/57) in the control group (P=.62). At 1 month, 71% (34/48) of the treatment group compared with 41% (18/44) of the control group had type 3 or 4 stools (P=.004) but this difference did not maintain statistical significance at 4 months (72% vs 56%, P=.10) (Fig. 3).

DISCUSSION

Mind Over Matter improved urinary incontinence in 71% and bowel incontinence in 55% of participants. It did not affect rates of care-seeking, possibly owing high levels of care-seeking at baseline and the short follow-up period. Mind Over Matter improved self-efficacy to manage urinary incontinence and led to the uptake of regular pelvic floor muscle exercises in most participants.

This trial is novel because Mind Over Matter addresses both bowel and bladder symptoms and is delivered by a lay person from the community, rather than a health care or research professional. Community focused interventions that provide incontinence symptom relief at low cost are easily accessible and offer high value with potential for scale to low resource settings.

Other group programs targeting urinary incontinence in older women have demonstrated comparable effect.[8,12] In the Dare to Age Well intervention from which Mind Over Matter was adapted, 66% of participants had any improvement in urinary incontinence, with 30% much improved, as compared with 71% and 39% in our study.[8] Similarly, in the Group Learning Achieves Decreased Incidents of Lower Uri-nary Symptoms study, participants in a group behavioral treatment intervention decreased mean International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form scores by 1.9 points at 3 months, in line with our decrease of 2.1 points.[12] Both these group interventions were administered by research or clinical staff in a single session (1–2 hours) and combined education about bladder health with self-management strategies and supplemental materials to support behavior changes. Mind Over Matter differs from these interventions because it is administered by a community member, targets bowel incontinence in addition to urinary incontinence, and has a total intervention time of 6 hours over three sessions.

The ease of recruiting participants for this trial, particularly in rural communities, suggests that bowel continence promotion is both feasible and effective when coupled with urinary continence promotion. Although we cannot draw conclusions about the effect of Mind Over Matter for women with isolated bowel incontinence, because there was only one participant with isolated bowel symptoms in our sample, 70% of women with bowel incontinence also have urinary incontinence.[27]

This study is limited by its homogenous sample, relatively brief follow-up, inherent limitations of self-reported data, and lack of objective measures of urinary incontinence and pelvic floor muscle strength. Although we did discuss with participants the importance of not sharing information from the workshop until the trial was over, there could have been communication between women in the treatment and control groups. Such cross-contamination would have made us less likely to see differences between groups; we were

reassured by the stable number of women doing Kegels in the control group (8%, 9%, 8% throughout the study), suggesting that the treatment group didn't share class materials. Natural changes in diet and exercise during the summer months may have contributed to improvement in both groups.

Whether Mind Over Matter's effect will be generalizable to more diverse populations remains unknown. All study participants were interested in completing a continence workshop, and thus represent a highly motivated sample, as is the case with other studies of similar continence promotion interventions. More women in the treatment group had previously sought care for urinary incontinence, which could suggest a higher level of motivation for improvement, though there were no differences between groups on any validated measures of incontinence severity at baseline. Future studies should study Mind Over Matter's effect over a longer time-frame in diverse populations.

One of the most important strengths of this trial is its nesting within a larger hybrid effectiveness-implementation trial.[28] This larger trial was a type 1 hybrid, meaning that the primary focus was effectiveness, evaluated in this randomized controlled trial, with a smaller focus on implementation outcomes, results of which will be presented in a separate manuscript. Mind Over Matter was adapted from Dare to Age Well with engagement of local communities and our state dissemination agency with the specific intent that it be feasible for communities without health professionals to implement and sustain. Although not a prespecified outcome in the hybrid trial, more than half the communities that offered Mind Over Matter in the trial continue to offer Mind Over Matter 2 years later. The average lag time between generation of scientific evidence and its implementation into practice is 17 years.[29] The Wisconsin Institute for Healthy Aging (www.wihealthyaging.org) piloted dissemination of Mind Over Matter across Wisconsin this spring—17 months after completion of its randomized trial. Although its long-term effectiveness and cost-effectiveness remain to be tested, Mind Over Matter has the potential to bring behavioral solutions to women with both bladder and bowel incontinence in communities that lack healthcare professionals trained specifically to treat pelvic floor disorders.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Authors' Data Sharing Statement

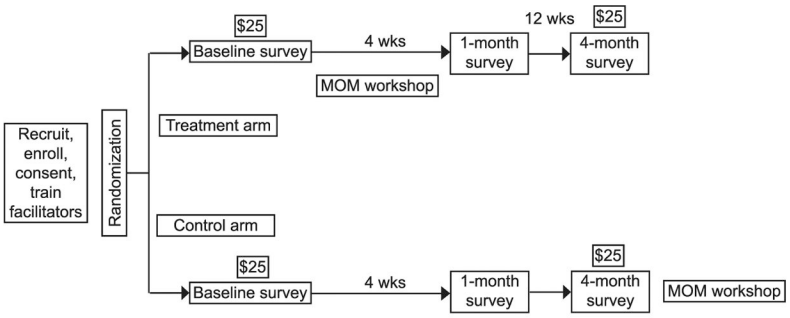
Will individual participant data be available (including data dictionaries)? Yes.

What data in particular will be shared? All self-reported data from participant questionnaires.

What other documents will be available? Additional related documents (study protocol, IRB application).

When will data be available (start and end dates)? Data will become available January 1, 2021, and will be available for 5 years.

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Data will be shared with academic researchers for secondary analyses only after approval from the principal investigator and using an IRB-approved mechanism.



Outcome	Instruments / Questions asked at multiple time points	Baseline	1 month	4 month
Urinary incontinence	International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-SF)[19]	X	X	X
	Patient Global Impression of Improvement (PGI-I)[17] regarding urinary leakage			X
Bowel incontinence	St. Mark's Incontinence Score/Vaizey[20]	X	X	X
	Patient Global Impression of Improvement (PGI-I)[17] regarding bowel leakage			X
Pelvic floor symptoms	Pelvic Floor Distress Inventory Short Form 20 (PFDI-20)[21]	X		X
Care seeking	Barriers to Incontinence Care Seeking Questionnaire (BICS-Q)[23]	X		X
	Barriers to Care seeking for Accidental Bowel Leakage (BCABL)[22]	X		X
Self-efficacy	Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI)[24]	X		X
Depression	Patient Health Questionnaire 9 (PHQ-9)[25]	X		X
Key behaviors and symptoms over the last 4 weeks	Number of daytime voids, nighttime voids, pads per 24 hours, cost per week on pads	X	X	X
	How often do you do Kegel squeezes, or pelvic floor muscle exercises (5 point Likert)	X	X	X
	Servings per day of coffee, tea, diet soda, alcohol, and water	X	X	X
	Bristol Stool Form Scale[26]	X	X	X

Fig. 1.

A graphic representation of the timeline for the study, including questionnaires administered at multiple timepoints, along with timeframe during which the treatment and control groups received the intervention. MOM, Mind Over Matter; Healthy Bowels, Healthy Bladder.

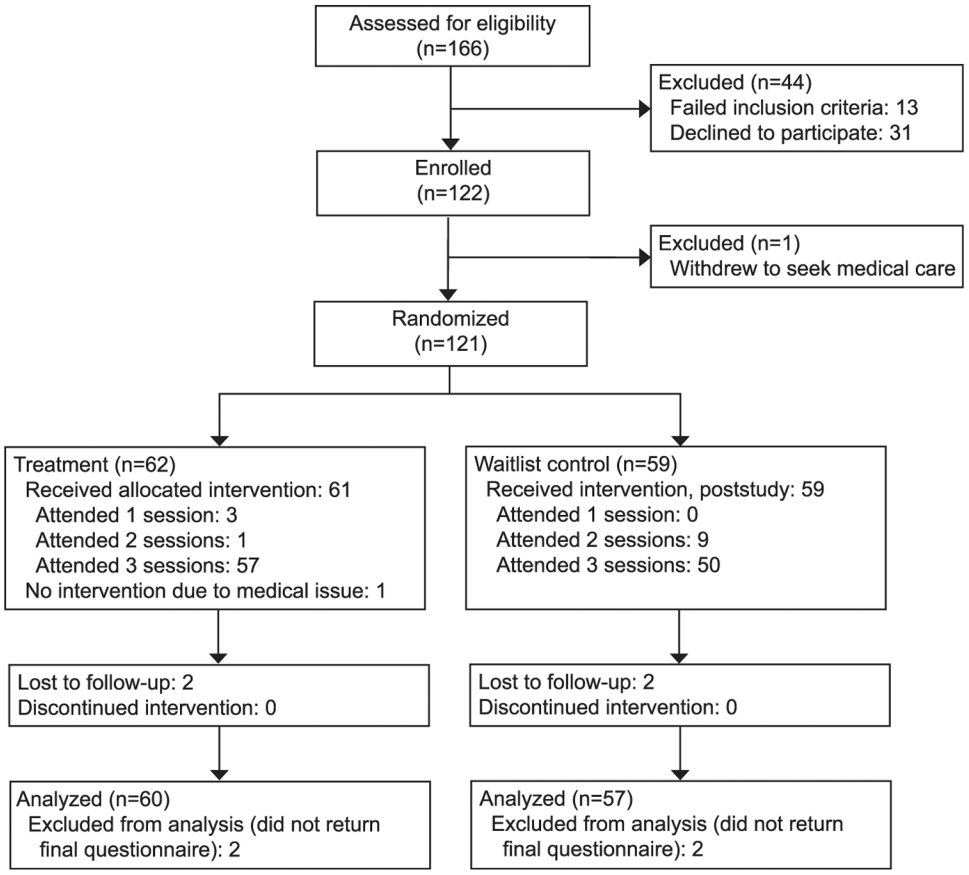


Fig. 2.

CONSORT (Consolidated Standards of Reporting Trials) diagram depicts recruitment, enrolment, allocation, and follow-up in the treatment and control groups.

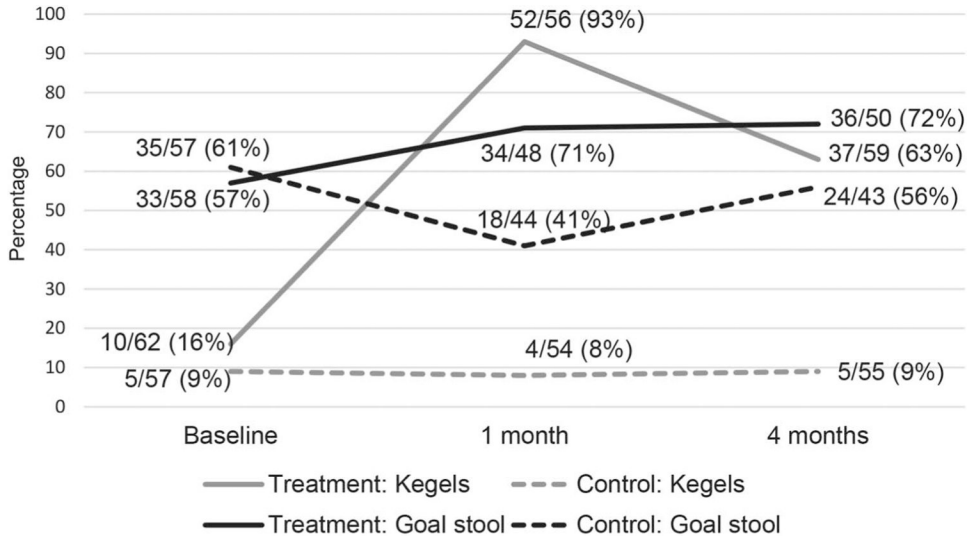


Fig. 3.

Depicts the proportion of participants who did pelvic floor muscle exercises often or always at baseline, 1 month, and 4 months in the treatment group (*solid gray line*) vs the control group (*dotted gray line*) and the percentage of participants who achieved goal stool consistency at the same timepoints in the treatment group (*solid black line*) vs the control group (*dotted black line*). At baseline, the proportion of participants performing pelvic floor muscle exercises (Kegels) often or always was similar in the treatment and control groups (P=.23) and was higher in the treatment than in the control group at both 1 month (P<.001) and 4 months (P<.001). The proportion of participants with desirable type 3 or 4 stool (optimal stool consistency) on the Bristol Stool Form Scale was similar at baseline in treatment and control groups (P=.62) and was higher in the treatment than in the control group at both 1 month (P=.004) and 4 months (P=.10).

Table 1.

Sample Description Stratified by Allocation Group*

Characteristic	Treatment Group (n=62)	Control Group (n=59)	*P*
Age (y)	74.5±8.1	74.9±10.4 (n=58)	.84
BMI (kg/m^2)	29.0±7.0 (n=61)	30.1±7.4 (n=58)	.24
Ethnicity Hispanic, Latina, or Spanish origin	0/59 (0)	1/53 (2)	.47
Race			.61
White	61/62 (98)	56/58 (97)	
Native American or Alaska Native	1/62 (2)	2/58 (3)	
Education			.31
High school or less	19/62 (31)	22/58 (38)	
Technical or Associate's degree	12/62 (19)	15/58 (26)	
Bachelor's or graduate degree	31/62 (50)	21/58 (36)	
Marital status			.45
Married or partnered	24/62 (39)	24/58 (41)	
Widowed	20/62 (32)	19/58 (33)	
Single	7/62 (11)	10/58 (17)	
Divorced	11/62 (18)	5/58 (9)	
Lives alone	33/62 (53)	33/58 (57)	.58
Employment			.52
Works full- or part-time	8/62 (13)	12/58 (21)	
Retired	49/62 (79)	42/58 (72)	
Volunteer only	5/62 (8)	4/58 (7)	
Health insurance			.51
Medicare	50/62 (82)	44/59 (75)	
Medicaid with or without Medicare	5/62 (8)	5/59 (9)	
Private or employer only	6/62 (10)	10/59 (17)	
Medical history			
Urinary incontinence	61/61 (100)	57/59 (97)	.15
Urge urinary incontinence	56 (92)	51 (90)	.66
Stress urinary incontinence	51 (84)	50 (86)	.69

Characteristic	Treatment Group (n=62)	Control Group (n=59)	*P*
Bowel incontinence	37/62 (60)	38/58 (66)	.51
Incontinence of well-formed stool	14 (23)	22 (40)	.07
Incontinence of loose stool	37 (60)	30 (53)	.44
Fecal urgency	36/62 (59)	41/58 (71)	.18
Incontinence of flatus	36/62 (60)	39/58 (70)	.28
Constipation	25/62 (40)	30/59 (52)	.21
Diabetes mellitus	10/62 (16)	12/59 (20)	.55
Hypertension	33/62 (53)	31/59 (53)	.94
Crohn's disease or ulcerative colitis	1/62 (2)	1/59 (2)	.97
Irritable bowel syndrome	8/62 (13)	8/59 (14)	.92
Depression	17/62 (27)	12/59 (20)	.36
Cancer	9/62 (15)	7/59 (12)	.67
Cognitive function	2.9±2.5 (n=61)	2.8±2.4 (n=57)	.80
Overall health excellent or very good	34/62 (55)	27/59 (46)	.32

BMI, body mass index.

Data are mean±SD or n/N (%) unless otherwise specified.

* Not all column percentages sum to 100 because of rounding.

Table 2.

Proportions, Differences, and Odds Ratios for Self-Reported Improvements in Incontinence at 4 Months in the Treatment Group Compared With the Control Group*

	Proportion Reporting Improvement			OR (95% CI)	Adjusted OR (95% CI)
	Treatment Group	Control Group	Difference (95% CI)		
Among entire study sample					
Urinary incontinence	n=59	n=57			
Better (primary outcome)	0.71	0.23	0.48 (0.32–0.65)†	8.4 (3.6–19.3)†	9.1 (3.7–22.3)†
Much better	0.39	0.05	0.34 (0.20–0.48)†	11.5 (3.2–41.2)†	12.1 (3.3–44.7)†
Bowel incontinence	n=60	n=55			
Better	0.55	0.27	0.28 (0.10–0.45)‡	3.3 (1.5–7.1)‡	3.7 (1.6–8.7)‡
Much better	0.35	0.11	0.24 (0.09–0.39)‡	4.4 (1.6–12.0)‡	5.3 (1.8–15.7)‡
Excluding participants with no reported urinary incontinence at baseline					
Urinary incontinence	n=59	n=54			
Better	0.71	0.22	0.49†	8.6 (3.7–20.3)†	8.5 (3.6–20.1)†
Much better	0.39	0.06	0.33†	10.9 (3.0–38.9)†	10.6 (3.1–38.2)†
Excluding participants with no reported bowel incontinence at baseline					
Bowel incontinence	n=36	n=37			
Better	0.81	0.27	0.54†	11.2 (3.7–33.6)†	11.1 (3.7–33.5)†
Much better	0.47	0.11	0.36‡	7.4 (2.2–25.2)‡	7.3 (2.1–25.1)‡

OR, odds ratio.

*All analyses are intention-to-treat. Adjusted ORs control for community. Participants who did not provide a response to the Patient Global Impression of Improvement at 4 months are excluded from these analyses.

†$P<.001$.

‡$P<.005$.

Table 3.

Differences in Validated Instrument Scores From Baseline to 4 Months in the Treatment Group Compared With the Control Group

	Treatment Group			Control Group			
Measure	**Baseline**	**4 mo**	**Delta**	**Baseline**	**4 mo**	**Delta**	***P**
PFDI-20	95±46	71±44	−23±38	100±49	91±46	−9±31	.031
ICIQ-SF	9.7±5.0	7.7±4.5	−2.1±3.1	8.6±3.7	9.0±3.7	0.3±2.7	<.001
SMIS	6.7±4.7	5.1±3.7	−1.7±3.7	7.1±4.6	7.2±4.5	−0.3±4.0	.049
GSE-UI	60±28	71±62	11±22	56±27	58±51	2±16	.015
PHQ-9	3.5±4.0	3.8±4.3	0.3±2.3	4.5±4.9	4.4±4.6	0±3.2	.57
BICS-Q	2.2±3.1	2.9±4.4	0.7±4.2	3.2±4.8	4.2±5.7	1.0±4.9	.73
BCABL	29.4±7.8	29.0±7.3	−0.4±6.4	32.6±8.2	32.9±8.3	0.3±7.9	.68

PFDI-20, Pelvic Floor Distress Inventory Short Form 20; ICIQ-SF, International Consultation on Incontinence Questionnaire Short Form; SMIS, St. Marks Incontinence Score; GSE-UI, Geriatric Self Efficacy for Urinary Incontinence; PHQ-9, Patient Health Questionnaire 9; BICS-Q, Barriers to Incontinence Care seeking Questionnaire; BCABL, Barriers to Care seeking for Accidental Bowel Leakage Questionnaire.

Data are mean±SD unless otherwise specified.

*P reflects comparison of delta over time for each scale in the treatment vs control groups.

Table 4.

Care-Seeking History and Plans Stratified by Treatment Group

Care-Seeking and Plans	Treatment Croup	Control Group	*P*
Care-seeking before study			
Urinary incontinence	42/62 (68)	27/59 (46)	.02
Bowel incontinence	15/62 (24)	12/59 (20)	.61
Care-seeking during the study period			
Urinary incontinence	13/58 (22)	10/57 (18)	.51
Bowel incontinence	5/59 (9)	9/56 (16)	.21
Plans care-seeking within 6 mo			
Urinary incontinence	24/52 (46)	25/55 (46)	.94
Bowel incontinence	12/51 (28)	19/43 (37)	.34

Data are n/N (%) unless otherwise specified.