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Symptom Improvement in Women after Fecal Incontinence Treatments: A Multicenter Cohort Study of the Pelvic Floor Disorders Network

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Abstract

Objective—The study aims were to characterize women with fecal incontinence (FI) and measure changes in FI severity and quality of life (QoL) 3- and 12-months after treatment.

Methods—This study is a secondary analysis of a multicenter study measuring adaptive behaviors among women with FI. Women included had a primary complaint of at least monthly FI over 3 consecutive months and planned FI treatment. Demographic and medical history data were obtained at baseline. Data were collected at baseline, 3- and 12-months after clinically selected, non-standardized treatment. Validated questionnaires were: Fecal Incontinence Severity Index (FISI), Modified Manchester Health Questionnaire (MMHQ), Pelvic Floor Disorders Inventory's Colorectal and Anal Distress Inventory (CRADI), Pelvic Floor Impact Questionnaire's Colorectal and Anal Impact Questionnaire (CRAIQ), and Medical Outcomes Study Short-Form (SF-12).

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Questionnaire score changes from baseline were compared using paired t-tests at 3- and 12-months following treatment.

Results—Of the 133 women enrolled, 90 women had treatment data at 3-months and 77 at 12-months. Non-surgical therapies were the most common (78%) with anal sphincter repair in 22%. FISI scores and MMHQ scores significantly improved 3-months post non-surgical and surgical treatments (-8.8 ± 12.0 and -12.6 ± 19.2 , respectively, $p < 0.001$), as did CRADI and CRAIQ scores (-52.7 ± 70.0 and -60.6 ± 70.0 , respectively, $p < 0.001$), and SF-12 mental health scores (4.2 ± 9.4 , $p = 0.001$). Improvement persisted 12 months post treatment.

Conclusions—In women seeking care for FI, symptom severity and condition-specific QoL significantly improve within the first 3-months after FI treatment and are maintained up to 12-months.

Introduction

The International Consultation on Incontinence defines fecal incontinence (FI) as the involuntary loss of solid or liquid stool that is a social or hygienic problem, whereas consistency of stool and frequency of occurrence are also important components of defining FI.^{1,2} FI is relatively common, with a prevalence of 11-15% among community-dwelling adults.³⁻⁶ The prevalence of FI may indeed be underestimated with up to 50% of patients often not discussing the problem with their physicians.⁴ FI affects individuals of all ages but is more common in older women.⁵ Other risk factors include diarrhea, the presence of multiple chronic illnesses, and coexisting urinary incontinence.⁶

Various modalities are available for the treatment of FI. These include behavioral modifications, dietary changes, medications, anal sphincter muscle exercises with biofeedback, injectable agents, and surgical procedures, such as sacral neuromodulation and sphincteroplasty. The Cochrane Collaboration review of surgical treatment for FI noted small numbers of relevant trials, small sample sizes and methodological weaknesses as limitations to this literature.⁷ A recent Cochrane Collaboration review update on biofeedback and sphincter muscle exercises for FI concluded that adding biofeedback to anal sphincter muscle exercises and electrical stimulation was better at reducing FI than either exercises or electrical stimulation alone.^{8,9} Furthermore, little is known of the long term success of treatments for FI and their effect on quality of life.

This study was conducted by the Pelvic Floor Disorders Network as a secondary analysis of a larger study examining adaptive behaviors among women with bowel incontinence (ABBI). Utilizing a series of validated questionnaires, this study aimed to characterize a cohort of women with FI and prospectively measure improvements in symptoms and condition-specific quality of life 3 and 12 months after clinically selected, non-standardized treatments (usual care). As an exploratory analysis, we also compared prospective measured FI symptoms and impact on condition-specific quality of life at 3 and 12 months between women who had surgery and those with non-surgical treatments.

Methods

Population

This prospective, multi-center cohort study was designed to evaluate adaptive behaviors among women with bowel incontinence, the Adaptive Behaviors among women with Bowel Incontinence (ABBI) study (clinical trials identifier: NCT00729144). The ABBI study was conducted through the Pelvic Floor Disorders Network (PFDN), a clinical trials network that currently consists of eight clinical sites and a data coordinating center. As part of a larger study evaluating adaptive behaviors among women with pelvic floor disorders, an Adaptation Index has been developed and validated using the data from this cohort study.¹⁰ To develop and validate the Adaptation Index, women with fecal incontinence (FI) were recruited from referral-based specialty care clinics. Women met eligibility criteria if they had a primary complaint of FI consisting of liquid stool, solid stool, or mucous occurring at least monthly for 3 consecutive months and were planning treatment for FI. We excluded women with prior rectal or colon cancer, inflammatory bowel disease, pelvic irradiation, a current or prior rectal fistula(e), removal of any portion of the colon/rectum, rectal prolapse, or severe neurological conditions. Each clinical site and the data coordinating center received institutional review board approval, and all subjects provided written informed consent.

Women received non-surgical and surgical treatments for FI per usual care. Non-surgical treatments included behavioral therapy, pelvic floor muscle exercises with and without instrumented biofeedback, medications (including supplementary fiber), or a combination of these treatments. Surgical treatment for FI could be combined with other pelvic floor surgeries and/or non-surgical interventions. Surgical intervention included anal sphincter repair but did not include sacral neuromodulation for FI, as the study occurred prior to FDA approval of neuromodulation for FI.

Measures

Subjects completed validated questionnaires by either telephone (by a central interviewing center) or in-person prior to treatment, 3 months following treatment per usual care, and again at 12 months after treatment. Validated questionnaires assessed bowel symptoms, impact on health related quality of life (HR-QoL) and general QoL, as well as other pelvic floor symptoms. Questionnaires included the Fecal Incontinence Severity Index (FISI)¹¹ and the Modified Manchester Health Questionnaire (MMHQ).¹² The FISI has 4 questions on incontinence of gas, mucus, liquid stool, and solid stool.¹¹ The frequency of incontinence symptoms range from: 2 or more times a day, once a day, 2 or more times a week, once a week, 1 to 3 times per month, or never. Responses are weighted on a 1 to 20-severity scale and a total FISI score is calculated (range 0-61). The patient-weighted scores were used in this analysis with a higher score indicating a greater impact or greater severity of symptoms. FISI scores of “0” indicated continence. The MMHQ is a validated questionnaire that reflects the overall impact of FI on QoL and consists of a total score and 8 domain scores (31 questions).¹² Specific items are measured on a 5-point scale as 1 = “never” to 5 = “always.” Total scores and domain scores both range from 0-100. The FISI is incorporated in the American-English version of the MMHQ.¹² The minimal important clinical difference

values based on anchor-based methodology for the FISFI -4 and -3, respectively, from this same study.¹³

Additional pelvic floor disorder symptoms were assessed with two separate composite questionnaires: The Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ).¹⁴ Each questionnaire has three scales (urinary, colorectal and pelvic organ prolapse) with the individual scales having psychometric data for validity, reliability, and responsiveness to change.¹⁵ The 46-item PFDI assesses symptom distress in women with pelvic floor disorders and has three scales: the Urinary Distress Inventory (UDI; range 0-300), the Pelvic Organ Prolapse Distress Inventory (POPDI; range 0-300), and the Colorectal-Anal Distress Inventory (CRADI; range 0-400).¹⁴ Similarly, the PFIQ measuring the impact of bladder, bowel, and vaginal symptoms on a woman's daily activities, relationships and emotions is composed of 3 scales of 31 questions each: the Urinary Impact Questionnaire (UIQ; range 0-400), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ; range 0-400), and the Colorectal-Anal Impact Questionnaire (CRAIQ; range 0-400).¹⁴ In all measures, a higher score indicates worse symptom bother or greater impact of symptoms on daily functioning. The minimal important difference values based on anchor-based methodology were -11 for the CRADI and -18 for the CRAIQ.¹⁵

Participants completed the SF-12, a shortened validated version of the SF-36, to measure the impact on general QoL.¹⁶ The SF-12 has two scales, the mental and physical component summary scales (range 0-100), where a higher score indicates better health-related quality of life. The Patient Global Impression of Improvement (PGI-I) scale is a self-rated assessment of change after treatment and has 7 response levels ranging from "very much worse," "no change" to "very much better."¹⁷ For this analysis, we dichotomized the data to compare those who were better (better, much better, and very much better) to those who were not improved (no change, worse, much worse, and very much worse).

Subject Characteristics

Demographic and medical history variables were collected at baseline including age, race, education, type of medical insurance, and smoking status. Body mass index was obtained from self-reported values and recorded in kg/m². Self-reported medical history included parity, diabetes, connective tissue disease, and prior FI treatments, including prior physical therapy, biofeedback, and surgery. The Bristol Stool Form Scale was assessed at baseline to characterize the most common type of stool consistency.¹⁸ Rome III Clinical criteria were used to define irritable bowel syndrome (IBS).¹⁹

Analysis

The analytic sample included women who received treatment per usual care (within 6 weeks $\pm$ 2 weeks after consent) and had at least one of the four questionnaires complete at 3-months and 12-months. Demographic and medical history variables were compared among women who were included in the analytic sample versus those who dropped out, withdrew, or did not receive treatment for various reasons. We evaluated the change of questionnaire scores from baseline at 3- and 12-months following treatment using one-sample paired t-test for the overall study cohort. We also evaluated differences within surgical treatment group

and the non-surgical treatment group using one-sample t-test. A between group comparison was also performed at 3 and 12 months to explore any group differences using Wilcoxon two-sample test. P values of 0.05 or less were considered statistically significant. Analyses were performed in SAS 9.2 for Windows (SAS Inc., Cary, NC).

Results

Figure 1 displays the flow of study subjects. Among the 133 women who were recruited in the study, 43 were considered lost to follow-up at 3 months. Over one-third (15/43, 35%) of the women lost to follow-up did not receive treatment within 6 weeks $\pm$ 2 weeks. An additional 13 women were lost to follow up at 12 months. Among the 90 women who were observed at 3 months, 7 women did not complete any of the questionnaires, while among the 77 women who were observed at 12 months, 6 women did not complete any of the questionnaires.

There were no significant differences for any demographic variables, medical history, or previous treatments for FI (all $p > 0.05$, data not shown) comparing women who received treatment per usual care approaches and completed at least one of the questionnaires at 3 months ($n=83$) to those that did not ($n=50$). Women who completed at least one of the 12 month questionnaires ($n=71$) were slightly older (60 ± 13 years versus 55 ± 15 years, $p=0.05$) than women who did not receive treatment or did not complete questionnaires ($n=62$).

Participants' demographics, medical history, and prior treatment for FI are outlined in Table 1. The study cohort had an average age of 57.4 ± 14.1 years, a median parity of 2 (range 0 to 9), an average BMI 28.9 ± 6.8 kg/m², and 11.3% were African-American. Thirty-one percent of the women had a clinical diagnosis of IBS, with more women having diarrhea predominant IBS or mixed (constipation and diarrhea) predominant IBS. Stool consistency types varied, with the most common stool consistency reported as a Bristol Stool Form Scale, Type 4 (stool like a sausage or snake, smooth and soft).

Clinically determined and applied FI treatments are shown in Table 2. Although most women received more than one treatment type, the most common treatments recorded at 3-months were fiber supplementation (41%) and pelvic floor muscle exercises (43%). Twenty women (22%) received surgical treatment for FI.

FI severity and impact on QoL significantly improved and met criteria for a minimal important difference after treatment ($p < 0.001$) (Table 3). Other colorectal symptoms and the impact of these symptoms on QoL also significantly improved after FI treatment ($p < 0.001$). The impact of FI on general mental health improved 3-months after FI treatment ($p = 0.001$); although no significant change was noted for improvements in general physical health ($p = 0.80$). No significant worsening or improvements in questionnaire scores were noted between 3-months and 12-months following FI treatment, with the exception of the improvement of general physical health scores ($p = 0.03$). All questionnaire scores at 12-months compared to baseline scores were significantly improved ($p < 0.05$), except for the SF-12 general physical health component summary score ($p = 0.07$).

As an exploratory analysis, changes in outcome measure scores were compared in women who received surgical and non-surgical treatments (medication, pelvic floor muscle exercises, biofeedback, or other types of treatment) after 3 and 12-months in Table 4. Overall, the 20 women who had surgical FI treatment and the 63 women who received non-surgical treatments had significant improvements in questionnaire scores at 3-months and 12-months after treatment compared to baseline scores. Women who had surgical treatments had greater improvements in FI severity (FISI scores), colorectal symptoms (CRADI scores) and impact on QoL (CRAIQ and MMHQ scores) at 3 months than women receiving non-surgical treatments ($p < 0.05$, data not shown). The improvements in scores among women receiving surgical FI treatments persisted at 12 months ($p < 0.05$), with the exception of FI severity ($p = 0.32$, data not shown). Both groups had improvements in the FISI, CRADI, CRAIQ, and MMHQ scores that met thresholds of minimal important differences. Within the overall cohort, 14% (12/83) women had complete resolution of FI at 3 months, and only 7% (5/71) of these women remained continent at 12 months. Overall, 17% (12/71) women were continent of bowel and gas at 12 months regardless of treatment type.

Discussion

This study has demonstrated that FI severity, colorectal symptoms, and condition-specific QoL significantly improves within the first 3-months after usual care treatments and is maintained up to 12-months. This study adds important information to the few studies investigating long term efficacy and durability of non-surgical and surgical FI treatments. The data presented in this study could also contribute to estimates of effect size for future clinical trials involving treatment of FI.

In 2003, Norton et al reported a randomized trial comparing 171 patients with FI who were randomized to 1 of 4 groups: (1) standard care (advice); (2) advice plus instruction on sphincter exercises; (3) hospital-based computer-assisted sphincter pressure biofeedback; and (4) hospital biofeedback plus the use of a home electromyogram biofeedback device.²⁰ Biofeedback was no different than standard care with advice (53% improved in group 3 vs. 54% in group 1) and there were no differences among the groups on episodes of incontinence, continence score or quality of life. Although there were no differences among groups, efficacy was maintained at one year for all subjects. In another randomized controlled trial comparing biofeedback to pelvic floor muscle exercises, FI severity improved in the biofeedback group (FISI scores 33 at baseline improved to 23 at 3 months) compared to the group receiving pelvic floor muscle exercise advice (FISI scores 35 at baseline to 32 at 3-months).²¹ A few additional uncontrolled studies reported similar outcomes with significant improvement in FISI scores (7 points) after multi-component behavioral therapy along with medications, 63% of patients continent at one year in another study using biofeedback, and another reported that most responders are still improved at 5 years following biofeedback therapy for FI.^{22,23,24} Although this current study is not a randomized controlled trial, this cohort study adds information on clinical changes in symptoms following usual care for FI among seven specialty referral clinical sites in the US.

In much of medicine, and in studies investigating FI in particular, “best current therapy” has not yet been identified and many “standard” practices have not been validated in clinical

trials. Moreover, no studies have been identified to explore how to select patients for conservative or surgical treatment therefore patient selection remains empirical.¹ The most recent consensus from the International Consultation on Incontinence 4th ed. stated, “expert consensus in this committee and the world literature is unanimous in recommending conservative interventions, singly or in combination, for the majority of patients with FI as first-line treatment.”¹ Without good pathophysiologic or clinical evidence for superiority of one practice over another, usual care studies, such as this one, allow us to encompass a wide variety of practice styles that are difficult to explain.²⁵ This type of study may also be considered preliminary to trials of experimental conservative therapies, new drugs or devices, or for treatment strategies that are not part of usual-care practices. Pragmatic effectiveness trials where the research question *per se* is to determine if a treatment approach is superior to usual care should obviously have de facto usual care as the control group and this study provides some preliminary guidance to future studies in this area.

Although this analysis was not powered to detect statistically significant changes between the two subgroups, nor was this study a randomized trial, differences were noted in an exploratory analysis between the surgical and non-surgical treatment groups. First, women who had surgery had greater improvements in FI severity at 3-months than the non-surgical group. However, improvements in FI severity were not different at 12-months in either group. Second, women receiving surgical anal sphincter repair had a larger magnitude of improvement in the condition-specific QoL scores at 3- and at 12-months in comparison to women receiving non-surgical treatments. Continence rates were not compared between the two groups given the small numbers of women who achieved continence (n=12) at 3 and 12 months. Women with sphincter tears undergoing anal sphincter surgery may have also had baseline differences in other characteristics, such complicated deliveries, that were not collected for this analysis. Ultrasound evidence of anal sphincter tears was not collected. Further, it is not known what type of pre- and peri-operative education was given regarding diet and pelvic floor muscles exercises for the women having surgical FI treatment. More data are needed on the 5-year durability following surgical and non-surgical treatments for FI.

Regardless of the type of treatment received, both groups improved in FI severity and condition-specific QoL at 3- and 12-months after treatment. Overall, women in the surgical and non-surgical groups met the thresholds for achieving a minimal important difference (MID) in the FISFI (MID -4 points), MMHQ (MID -3 points), CRADI (MID -11 points), and CRAIQ (MID -18 points).¹³ Based on a conservative method of estimating the minimally important difference as the change from baseline to 3 months in scale scores that correspond to an effect size of 0.5 (1/2 SD), all condition-specific measures in this study demonstrate clinically meaningful changes to patients which are maintained at 12 months.^{13,26-29} More data regarding patient-reported outcome measures and validated tools to measure a clinically meaningful change in scores after treatment are needed for FI intervention studies.

The strengths of this study are its multi-center, prospective design that includes multiple providers of usual care treatments for FI and the assessment of outcomes using validated and reliable questionnaires over a one year period. Additionally, these data allow for comparison

of different types of treatment and their durability over a 12-month period of time. The main limitations are also inherent in the usual care, prospective cohort design. Participation bias could be present as subjects were asked to participate in the study. A selection bias may exist among the types of treatments chosen by the participants and providers. Migration of usual care over time has important implications in future trial design since there is no way to guarantee that usual care during this study will reflect usual care during conduct of future trials. Other limitations are that individual treatment components cannot be individually studied (dietary advice, medications, exercises instruction given together, type of surgery performed), women who initially received surgical care may have had concomitant non-surgical treatments, the lack of documented data on sphincter muscle injuries by ultrasound, and there was a significant drop-out rate after consent was obtained. This may reflect the usual care treatment strategies of the study as well as recruitment from referral-based practices or lack of treatment efficacy. Although we were unable to detect important differences between subjects who did and did not follow up, this should raise awareness in recruitment and retention for trials investigating FI in the future.

Conclusion

Women seeking treatment for FI have significant and clinically meaningful improvements in FI severity and QoL during the first year following both surgical and non-surgical treatments. The largest gain after FI treatments occurs during the first 3-months and persists to 12-months. Data provided on the clinically meaningful change in questionnaire scores after treatment may inform future FI intervention studies on relevant patient-reported outcomes.

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Figure.

Study Flow Diagram for Adaptive Behaviors Among Women with Bowel Incontinence (ABBI) Participants

Table 1

Characteristics among women providing baseline data for the Adaptive Behaviors among Women with Bowel Incontinence (ABBI) cohort

Characteristic	Total N	Mean (SD) or n (%)
Age in yrs: mean (SD)	133	57.4 (14.1)
Parity: median (range)	115	2.0 (9.0)
BMI in kg/m ² : mean (SD)	118	28.9 (6.8)
Race	133	
White/Caucasian		114 (85.7%)
Black/African American		15 (11.3%)
Asian		2 (1.5%)
Other		2 (1.5%)
Hispanic ethnicity (%)	133	10 (7.5%)
Highest Education (%)	114	
Less than high school		9 (7.9%)
High school		31 (27.2%)
Some college		37 (32.5%)
College graduate		20 (17.5%)
Graduate or professional degree		17 (14.9%)
Health insurance (%)	133	
Private insurance (employment based or self-purchased)		51 (38.3%)
HMO		12 (9.0%)
Medicaid		5 (3.8%)
Medicare		32 (24.1%)
Self pay (without insurance)		3 (2.3%)
Other		29 (21.8%)
Don't know/Refused		1 (0.8%)
Tobacco use	118	
Current smoker		12 (10.2%)
Diabetes	117	15 (12.8%)
Connective Tissue Disease	115	3 (2.6%)
Bristol Stool Form Scale (Types 1 – 7)	119	
Type 1 - Separate, hard lumps like nuts		13 (10.9%)
Type 2 - Sausage shaped but lumpy		10 (8.4%)
Type 3 - Like a sausage or snake but with cracks on surface		16 (13.4%)
Type 4 - Like a sausage or snake, smooth and soft		39 (32.8%)
Type 5 - Soft blobs with clear cut edges		15 (12.6%)
Type 6 - Fluffy pieces with ragged edges, a mushy stool		17 (14.3%)
Type 7 - Watery, no solid pieces		9 (7.6%)
Rome III IBS Clinical Diagnosis (symptoms >1 day/month)	119	37 (31.1%)

Characteristic	Total N	Mean (SD) or n (%)
IBS – Constipation		8 (6.7%)
IBS – Diarrhea		13 (10.9%)
IBS – Mixed		15 (12.6%)
IBS - Unspecified		1 (0.8%)
Rome III IBS Clinical Trials (symptoms >1 day/week)	119	16 (13.4%)
Previous physical therapy or provider-taught pelvic floor muscle exercises for FI	119	12 (10.1%)
Previous biofeedback for FI	118	8 (6.8%)
Previous surgery for FI	118	5 (4.2%)
Previous surgery on rectal/anal area	118	16 (13.6%)

Table 2

Frequency of Fecal Incontinence Treatments at Baseline, 3-Months, and 12-Months

Treatments for Fecal Incontinence According to Type	Baseline (N=133)	3-months (N=90)	12 months (N=77)	Additional treatment from 3 to 12 months (N=77)
Medications (including Fiber supplementation)	N(%)	N(%)	N(%)	N(%)
Loperamide (Imodium®)	13 (9.8%)	7 (7.8%)	5 (6.5%)	1 (1.1%)
Diphenoxylate plus atropine (Lomotil®)	3 (2.3%)	1 (1.1%)	1 (1.3%)	0 (0.0%)
Fiber (Psyllium, Polycarbophil, Methylcellulose)	8 (6.0%)	37 (41.1%)	29 (37.7%)	1 (1.1%)
Lubiprostone (Amitiza®)	0 (0.0%)	1 (1.1%)	1 (1.3%)	0 (0.0%)
Docusate sodium (Colace®, Dulcolax®, stool softeners)	5 (3.8%)	2 (2.2%)	2 (2.6%)	0 (0.0%)
Other FI Meds (laxatives, stool bulking agent other than fiber, steroid)	5 (3.8%)	3 (3.3%)	3 (3.9%)	2 (2.2%)
Surgery	5 (3.8%)	20 (22.2%)	18 (23.4%)	0 (0.0%)
Pelvic Floor Muscle Exercises *	12 (9.0%)	39 (43.3%)	35 (45.5%)	0 (0.0%)
Biofeedback **	8 (6.0%)	10 (11.1%)	9 (11.7%)	0 (0.0%)
Other treatments ***	0 (0.0%)	6 (6.7%)	5 (6.5%)	0 (0.0%)
Any treatments ****	36 (27.1%)	90 (100.0%)	77 (100.0%)	5 (5.6%)

* at baseline it includes physical therapy (including pelvic floor muscle exercises) supervised by a therapist, nurse, or physician; at 3 months it is pelvic floor muscle rehabilitation/exercises

** at baseline it includes biofeedback supervised by a therapist, nurse, or physician; at 3 months it is biofeedback (home device or clinic/office-based treatment)

*** Data at 3 months includes electric stimulation or other/specify on form 12 (Follow up)

**** for both visits, it includes at least one FI treatment including medication, surgery, exercises, biofeedback, or other

Table 3

Changes in Questionnaire Scores 3- and 12- Months Post-Treatment for FI

	Score changes from baseline to 3-months post-treatment [*]			Score changes from 3-months to 12-months post-treatment [*]		
	N	Mean (SD)	p-value ^{**}	N	Mean (SD)	p-value ^{**}
FISI-patient weights, range 0-61[†]	83	-8.8 (12.0)	<0.001	71	1.4 (10.5)	0.26
CRADI, range 0-400[†]	83	-52.7 (70.0)	<0.001	69	-3.0 (71.9)	0.73
CRAIQ, range 0-400[†]	76	-60.6 (90.0)	<0.001	64	-3.4 (77.6)	0.73
MMHQ, range 0-100[†]	66	-12.6 (19.2)	<0.001	56	-1.4 (17.9)	0.56
SF-12 Mental, range 0-100 (lower scores represent greater impact of QoL)	78	4.2 (9.4)	0.001	70	-1.2 (10.0)	0.30
SF-12 Physical, range 0-100 (lower scores represent greater impact of QoL)	78	0.3 (8.7)	0.80	70	2.5 (9.2)	0.03

* At least one FI treatment: surgery, medication, pelvic floor muscle exercises, biofeedback, or other

** One-sample paired t-test

[†] Higher scores on questionnaires in table represent greater symptom severity or impact unless otherwise indicated

Table 4

* One sample paired t-test comparing within group changes from baseline to 3-months

One sample paired t-test comparing within group changes from baseline to 12-months

[†] Higher scores on questionnaires in table represent greater symptom severity or impact

^a Lower scores on questionnaires in table represent greater improvement in symptoms