ORIGINAL CONTRIBUTION

Biofeedback for Fecal Incontinence: A Randomized Study Comparing Exercise Regimens

Lynne Bartlett, M.P.H.[1] • Kathryn Sloots, R.N., B.Sc.(Hons.)[2]
Madeleine Nowak, B.Sc., Ph.D.[1] • Yik-Hong Ho, B.S.(Hons.), M.D., F.R.A.C.S.[3]

1 School of Public Health, Tropical Medicine & Rehabilitation Science, North Queensland Centre for Cancer Research, James Cook University, Townsville, Australia
2 Clinical Measurements Unit, The Townsville Hospital, Townsville, Australia
3 School of Medicine and the Australian Institute of Tropical Medicine, North Queensland Centre for Cancer Research, James Cook University, Townsville, Australia

BACKGROUND: Fecal incontinence affects up to 11% of Australian community-dwelling adults and 72% of nursing home residents. Biofeedback is a recommended conservative therapy when medication and pelvic floor exercises have failed to improve patient outcomes.

OBJECTIVE: This study aimed to investigate the impact of a new exercise regimen on the severity of fecal incontinence and the quality of life of participants.

DESIGN: This was a randomized clinical study.

SETTINGS: This study was conducted at the Anorectal Physiology Clinic, Townsville Hospital, Queensland, Australia.

PATIENTS: Seventy-two participants (19 male), with a mean age of 62.1 years, attended 5 clinic sessions: 4 weekly sessions followed by 4 weeks of home practice and a follow-up assessment session. A postal survey was conducted 2 years later.

INTERVENTION: Thirty-seven patients (12 male) were randomly assigned to the standard clinical protocol (sustained submaximal anal and pelvic floor exercises) and 35 patients (7 male) were randomly assigned to the alternative group (rapid squeeze plus sustained submaximal exercises).

MAIN OUTCOME MEASURES: The main outcomes were measured by use of the Cleveland Clinic Florida Fecal Incontinence score and the Fecal Incontinence Quality of Life Scale survey tool.

RESULTS: No significant differences were found between the 2 exercise groups at the beginning or at the end of the study or as a result of treatment in objective, quality-of-life, or fecal incontinence severity measures. Sixty-nine participants completed treatment. The severity of fecal incontinence decreased significantly (11.5/20 to 5.0/20, $P < .001$). Eighty-six percent (59/69) of participants reported improved continence. Quality of life significantly improved for all participants ($P < .001$). Results were sustained 2 years later. Patients who practiced at least the prescribed number of exercises had better outcomes than those who practiced fewer exercises.

LIMITATIONS: This study was limited because it involved a heterogeneous sample, it was based on subjective reporting of exercise performance, and loss to follow-up occurred because of the highly mobile population.

CONCLUSIONS: Patients attending this biofeedback program attained significant improvement in the severity of their fecal incontinence and in their quality of life. Although introduction of rapid muscle squeezes had little impact on fecal incontinence severity or patient quality of life, patient exercise compliance at prescribed or greater levels did.

KEY WORDS: Biofeedback; Fecal incontinence; Quality of life; Pelvic floor exercises; Exercise compliance; Randomized clinical study.

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Correspondence: Lynne Bartlett, M.P.H., Fecal Incontinence Research Group, School of Public Health, Tropical Medicine & Rehabilitation Sciences, James Cook University, Townsville, QLD 4811, Australia. E-mail: lynne.bartlett@my.jcu.edu.au

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Fecal incontinence (FI), the involuntary loss of liquid or solid stool with or without the patient's awareness, may negatively affect quality of life (QOL) resulting in embarrassment, loss of confidence and self-respect, psychiatric disorders, social isolation, and lost economic productivity.[1] Australian studies estimate the community prevalence of FI to be between 8% and 11%.[2–4] North Queensland clinical studies found more than 20% of colorectal and urogynecological outpatients had FI.[1,5] Up to 72% of Australian nursing home residents have FI.[6]

One safe, conservative first-line treatment is biofeedback-assisted exercise.[7] The Townsville Hospital, a publicly funded regional hospital with a large rural catchment, operates a holistic biofeedback clinic for FI, constipation, and chronic pelvic pain.[8,9]

Pelvic floor muscles support the abdominal contents helping maintain urinary and fecal continence. Pelvic floor muscle training increases the strength and endurance of the muscles, stimulates the nerves supplying the muscles, improves blood flow to the rectum or reservoir, anal region, and pelvic floor, and increases anatomical awareness to assist in reducing incontinent episodes. Muscle-building principles imply that the quality of contractions/squeezes is more important than the quantity.[10] Sustained (submaximal) anal sphincter and pelvic floor muscle exercises were routinely included in the Townsville Hospital biofeedback program to improve bowel continence, decrease urgency, moderate rectal or pouch sensitivity, encourage effective evacuation, and increase patient confidence.

A Cochrane review suggested the need for randomized clinical trials comparing exercises.[11] A standard exercise program incorporating rapid squeezes (to improve muscle bulk and reaction time[12]) and sustained contractions (to improve strength and endurance) was recommended.[13] This randomized clinical study was designed to compare a regimen of sustained plus rapid exercises with the standard exercise regimen of sustained exercises and those elements which could provide insight into the success of biofeedback therapy.

METHODS

Participants

More than 250 patients with FI were referred to a Townsville colorectal surgeon between 2004 and 2008; treatments included anal implants, medication, surgery, and biofeedback.[14] Of those referred for biofeedback before October 2006, 101 were assessed for eligibility for this study. Twenty-nine were excluded: 26 had relocated without a forwarding address, 2 did not meet selection criteria, and one refused to participate (Fig. 1). After anorectal manometric assessment and endoanal ultrasound, 72 eligible participants (19 male), with a mean age of 62.1 years (range, 32–82), consented to participate between January 2005 and October 2006 (Table 1). Females were younger than males (mean age/range = 60.5/32–82 vs 66.7/51–81; $P = .052$). They were at least 18 years old, were not pregnant, and had no terminal illness, mental illness, or gastrointestinal stoma. No participant had sacral nerve stimulation before or during this study. Their FI had failed to respond to conservative treatment prescribed by their general practitioner over a 6- to 12-month period.

Randomization

A total of 37 patients were randomly assigned to the standard clinical protocol of sustained submaximal anal sphincter and pelvic floor muscle exercises (SE group), and 35 were randomly assigned (in parallel) to the alternative group of rapid squeeze exercises and standard submaximal sustained anal sphincter and pelvic floor muscle exercises (RSE group; Fig. 1, Table 1). Independent unrestricted randomization was performed before study commencement using a computer-generated sequence. The study arm was placed in a sealed opaque envelope with the participant identification number on the front and given to the therapist immediately before session 3. Participants were blinded. Researcher (L.B.) received the randomization sequence immediately before analysis.

Ethics

The Townsville Hospital (47/04) and James Cook University (H1950) gave ethical approval. The Australian New Zealand Clinical Trials Registry number is ACTRN12610000258055.

Study Procedure

The biofeedback nurse therapist (K.S.) telephoned patients, explained the study, and invited them to participate. Treatment included 5 outpatient sessions, over 8 weeks. The first 4 sessions were weekly; participants then practiced techniques for 4 weeks before returning for their final session.

At their first attendance patients met with the researcher (L.B.), completed consent forms, a self-administered FI questionnaire,[1] the 29-question Fecal Incontinence Quality of Life Scale (FIQL) survey tool,[15,16] and the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI).[17]

Biofeedback session 1 included a review of relevant medical, surgical, obstetric, and medication history. Usual bowel habits and associated problems, diet, fiber, and fluid intake were discussed as were the aim of therapy and goal establishment. The therapist presented coping strategies and dietary advice.[8] Participants were given charts to facilitate recording daily bowel accidents and toileted movements, food intake, and medication used. Assessment of anorectal function included mean anal resting sphincter pressure, mean maximal voluntary contraction squeeze

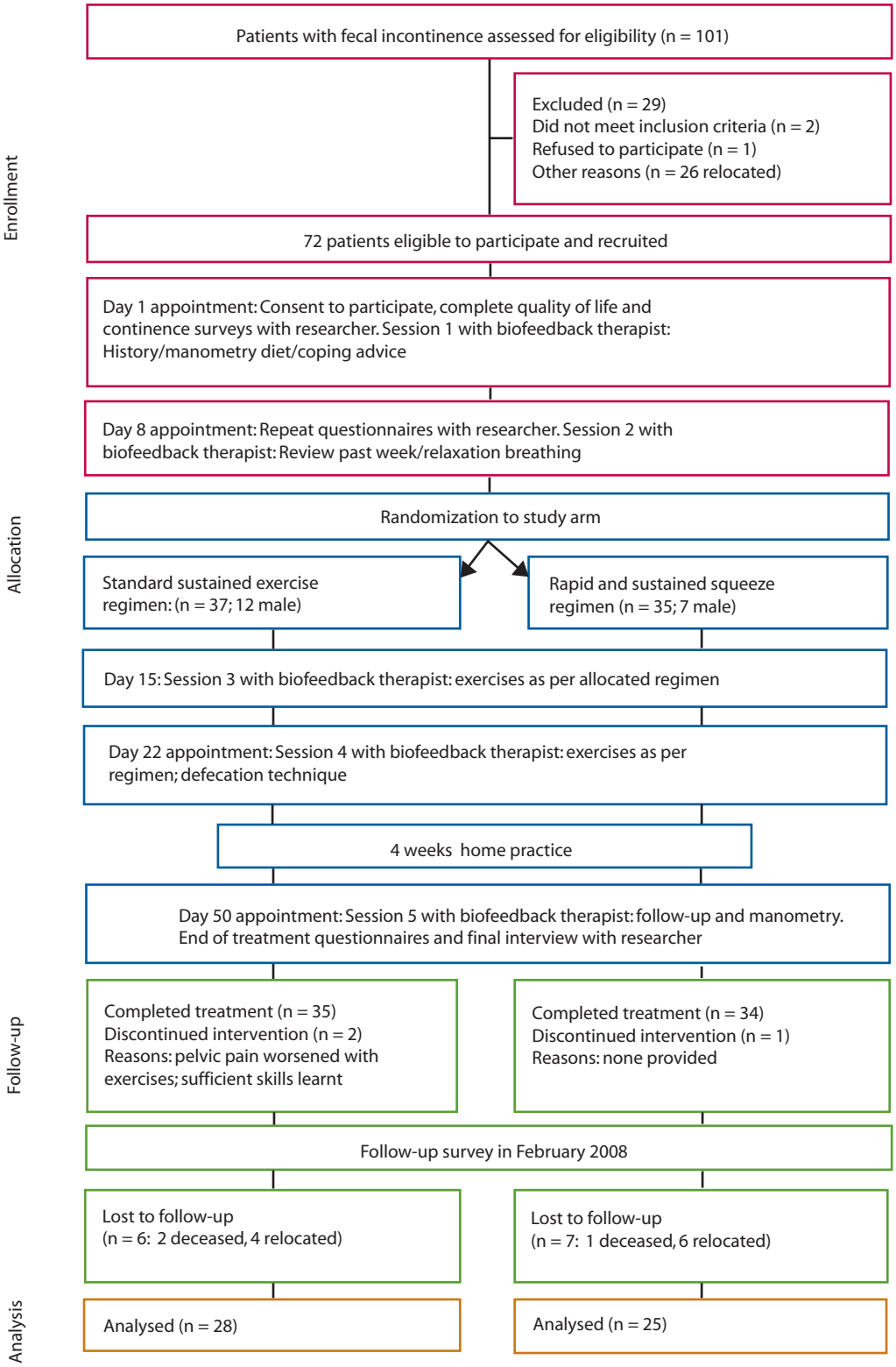

FIGURE 1. Progress of participants through study (Consort diagram).

TABLE 1. Patient demographic data

Variable	*All Participants*	*Sustained exercise group (control) (n = 37)*	*Rapid and sustained exercise group (intervention) (n = 35)*	*P*
Age, mean (range)	62.1 (32–82)	62.0 (32–82)	62.2 (38–82)	.952
Duration of fecal incontinence (months, median/IQR)	24 (18–48)	24 (16.5–42)	24 (18–60)	.417
Sex M/F	19/53	12/25	7/28	.232
Diabetes	8	5	3	.387
Rectal prolapse	9	5	4	.536
Chronic constipation	9	6	3	.268
Rectal emptying problems (male)	8 (4)	4	4	1.000
Psychiatric problems–depression	8	4	4	.613
Colon disease	23	15	8	.108
Spinal cord disease	2	1	1	.739
Neurological disease	2	2	0	.261
Urinary incontinence	26	14	12	.754
Hemorrhoidectomy	33	15	18	.354
Bowel surgery (for cancer)	20 (12)	14	6	**.050**
Injury to anus	5	2	3	.473
Radiation therapy	9	5	4	.536
Vaginal repair surgery[a]	17	8	7	.572
Difficult delivery[a]	36	17	19	.991
External anal sphincter defects (repaired)[a]	38 (13)	18	20	.866

IQR = interquartile range.
[a]Female participants only.

pressures, anal canal length, the rectosphincteric inhibitory reflex, and the volumes required to produce initial sensation, the first urge to evacuate, and maximum tolerated volume.[18,19]

In session 2 the therapist reviewed the previous week with the patient, including the completed bowel chart and the impact of any dietary changes or coping strategies. Each patient was instructed in relaxation (diaphragmatic) breathing[9] and encouraged to practice this technique for 7 to 10 minutes at least twice per day and to complete a bowel chart daily.

In session 3, following review of the previous week, participants were instructed in anal sphincter and pelvic floor muscle exercises according to their randomized exercise regimen (Fig. 2). Patients were prepared for biofeedback with an anal catheter and a rectal balloon, inflated to sensory threshold (stimulate anatomical awareness). Participants were coached to link pressure changes seen on the computer monitor with the exercises performed and sensations felt. They were instructed to use the exercises and techniques to reduce urgency and frequency, and to improve sensitivity, anorectal coordination, and continence.[9] Individualized instruction sheets were provided to enhance home performance of prescribed exercises.

Treatment components previously taught were reviewed in session 4; the exercises were adjusted and

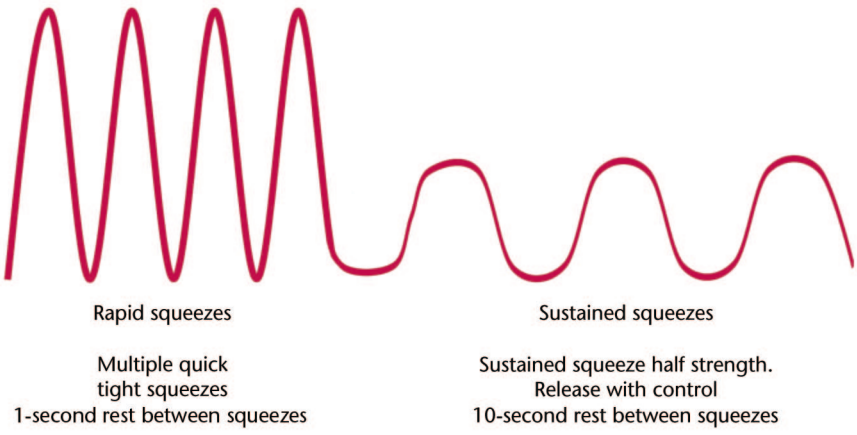

FIGURE 2. Daily exercises (anal sphincter and pelvic floor muscle).

TABLE 2. Continence, quality-of-life, and anorectal physiology changes compared by exercise regime

		Pretherapy		*Posttherapy*			*2-year follow-up*		
	Exercise regime	*Median (IQR)*	*(n)*	*Median (IQR)*	*(n)*	*P*	*Median (IQR)*	*(n)*	*P*
FIQL subscales[a]									
Lifestyle	SE	3.5 (2.4–3.9)	(37)	3.8 (3.1–4.0)	(35)	.787[b]	3.9 (3.2–4.0)	(28)	.907[c]
	RSE	3.3 (2.8–3.7)	(35)	3.7 (3.4–3.9)	(34)		3.8 (3.4–4.0)	(25)	
	All	3.4 (2.7–3.8)	(72)	3.8 (3.4–4.0)	(69)	**<.001[d]**	3.8 (3.3–4.0)	(53)	.880[e]
Coping	SE	2.1 (1.3–3.1)	(37)	2.9 (2.3–3.5)	(35)	.517[b]	3.2 (2.3–4.0)	(28)	.277[c]
	RSE	2.3 (1.6–2.7)	(35)	3.3 (2.5–3.7)	(34)		3.2 (2.7–3.8)	(25)	
	All	2.3 (1.4–2.8)	(72)	3.1 (2.4–3.6)	(69)	**<.001[d]**	3.2 (2.5–4.0)	(53)	.754[e]
Depression	SE	3.0 (2.2–3.6)	(37)	3.5 (3.0–3.8)	(35)	.843[b]	3.4 (2.8–3.9)	(28)	.063[c]
	RSE	2.7 (2.3–3.4)	(35)	3.3 (3.1–3.5)	(34)		3.6 (2.9–3.8)	(25)	
	All	2.8 (2.3–3.4)	(72)	3.4 (3.0–3.6)	(69)	**<.001[d]**	3.6 (2.9–3.8)	(53)	.845[e]
Embarrassment	SE	2.3 (1.7–3.0)	(37)	3.5 (2.7–4.0)	(35)	.762[b]	3.7 (2.2–4.0)	(28)	.229[c]
	RSE	2.0 (1.7–2.7)	(35)	3.3 (2.6–3.7)	(34)		3.7 (2.5–4.0)	(25)	
	All	2.2 (1.7–3.0)	(72)	3.3 (2.7–3.8)	(69)	**<.001[d]**	3.7 (2.5–4.0)	(53)	.281[e]
Continence grading scale[f]									
Total score (max 20)	SE	12.0 (9.0–15)	(37)	5.0 (3.0–8.0)	(35)	.312[b]	4.0 (1.0–8.0)	(27)	.825[c]
	RSE	11.0 (8.0–15)	(35)	4.5 (2.8–7.3)	(34)		4.0 (1.0–8.0)	(25)	
	All	11.5 (8.3–15)	(72)	5.0 (3.0–8.0)	(69)	**<.001[d]**	4.0 (1.0–8.0)	(52)	.820[e]
Solid + liquid FI score (max 8)	SE	4.0 (3.0–6.0)	(37)	2.0 (1.0–3.0)	(35)	.123[b]	1.0 (0.0–2.0)	(27)	.896[c]
	RSE	4.0 (3.0–6.0)	(35)	2.0 (0.8–3.0)	(34)		1.0 (0.0–3.3)	(25)	
	All	4.0 (3.0–6.0)	(72)	2.0 (1.0–3.0)	(69)	**<.001[d]**	1.0 (0.0–3.0)	(52)	.707[e]
Anorectal physiology									
Mean maximal resting pressure (mmHg)	SE	34.6 (21–50)	(37)	32.4 (19–53)	(35)	.806[b]			
	RSE	30.1 (22–49)	(35)	31.6 (23–53)	(33)				
	All	34.6 (22–49)	(72)	32.0 (21–53)	(68)	.071[d]			
Maximum squeeze pressure (mmHg)	SE	61.0 (37–99)	(37)	68.4 (51–113)	(35)	.663[b]			
	RSE	58.8 (38–90)	(35)	57.4 (43–113)	(33)				
	All	59.2 (38–90)	(72)	67.3 (46–111)	(68)	**<.001[d]**			
Volume of initial sensation (mL)	SE	28 (18–43)	(37)	20 (16–30)	(34)	.628[b]			
	RSE	25 (18–38)	(35)	21 (15–35)	(30)				
	All	28 (18–40)	(72)	20 (15–30)	(64)	**.027[d]**			
Volume at first urge (mL)	SE	75 (53–113)	(37)	75 (50–98)	(33)	.973[b]			
	RSE	70 (55–95)	(35)	60 (49–85)	(30)				
	All	73.5 (55–100)	(72)	60 (50–85)	(63)	.058[d]			
Maximum tolerable volume (mL)	SE	160 (115–200)	(37)	125 (104–173)	(34)	.454[b]			
	RSE	148 (104–163)	(35)	125 (90–161)	(30)				
	All	150 (110–180)	(72)	125 (96–165)	(64)	**.023[d]**			

n = number of patients; FI = fecal incontinence; FIQL = Fecal Incontinence Quality of Life Scale; IQR = interquartile range; SE = sustained exercise group (control); RSE = rapid and sustained exercise (intervention).

[a]FIQL, Rockwood et al[15]; scales calculated as per Rockwood 2008.[16]

[b]*P* value comparing changes pre- and posttherapy was measured using the Wilcoxon unpaired test.

[c]*P* value comparing difference between final session and 2-year follow-up was measured using the Wilcoxon unpaired test.

[d]*P* value comparing pre- and posttherapy using Wilcoxon paired signed rank test.

[e]*P* value comparing final session and 2-year follow-up was measured using Wilcoxon paired signed rank test.

[f]Cleveland Clinic Florida Fecal Incontinence Score.

practiced again with use of the computer monitor according to the individual's progress. The final treatment component involved a combination of toileting position, relaxation breathing, and evacuation technique to improve evacuation and decrease stool fragmentation.[9] Participants received updated written and verbal instructions for use during the 4 weeks of home practice.

At the final session, anorectal function, exercise regimens, bowel charts, and the 4-week home practice period were assessed with suggestions for future improvements. Patients were encouraged to continue practicing the exercises and techniques and were advised that, once satisfactory results were achieved, they could reduce the number of daily exercises to a maintenance level. An additional appointment was offered if required. Symptom severity and the effect of FI on QOL were reassessed, patient satisfaction with progress was recorded, and a short, semistructured interview was conducted.

The February 2008 follow-up survey included the CCF-FI and FIQL and questions about continued performance of prescribed exercises, type[20] and number of bowel movements per day, any postbiofeedback FI treatments and dietary or medication changes that may have affected FI.

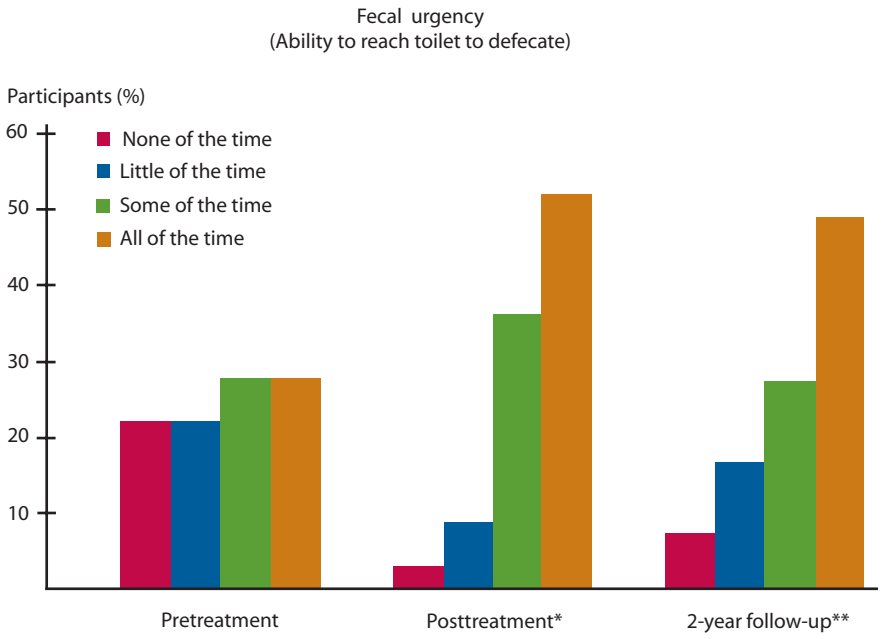

FIGURE 3. Improvement in fecal urgency, *$P < .001$, pretreatment vs posttreatment (Wilcoxon signed rank test); **$P = .336$, 2-year follow-up vs posttreatment (Wilcoxon signed rank test).

Statistical Analysis

The sample size of 34 participants per exercise group (5% α, 80% power) was calculated from data of FI patients previously treated (CCF-FI improvement, mean 2.9/SD 2.989). We hypothesized a CCF-FI improvement of 5.0 for the RSE group. Because 5% of patients had previously not completed biofeedback, we enrolled 72 participants.

Patients who did not complete the program were treated as missing. Numerical data are presented as mean and range or median and interquartile range, depending on the distribution. Comparisons between characteristics were calculated using χ^2 tests and χ^2 tests for trend, nonparametric Wilcoxon tests, and t tests. Exercise dose–response effects and initial FI severity were evaluated to test for trends in global FIQL and CCF-FI improvement with use of the Spearman rank correlation coefficient (r_s). Statistical analyses were conducted using SPSS for Windows version 17 (SPSS Inc, Chicago, IL). A significance level of .05 was adopted a priori.

RESULTS

Enrolled patients reported having FI for 24 (interquartile range, 18–48) months. Although more participants in the SE group had undergone bowel surgery ($P = .05$), no other significant differences in baseline demographic or clinical characteristics between the 2 groups were reported (Table 1). Sixty-nine participants (35 SE) completed all 5 treatment sessions (median duration, 8 weeks).

There were no significant differences between the 2 exercise groups at the beginning and at the end or as a result of treatment in the objective manometric measurements, FIQL subscales, or CCF-FI (Table 2). Nor were there any differences between the exercise groups in rating individual treatment components, satisfaction with results of the treatment program, or improvement in subjective bowel function. Thus, their data were pooled. There were no adverse events.

The biofeedback treatment was efficacious with substantially improved continence and QOL over the treatment period and at 2008 follow-up ($P < .001$, Friedman nonparametric repeated measurements test). Between the initial and final treatment sessions there were significant reductions in incontinent episodes (4 (range, 1–11.5) to 1 (range, 0–2.3) per week, $P < .001$) and stool frequency (13 (range, 8–28) to 12 (range, 8–20) bowel movements per week, $P = .007$) recorded in the bowel diaries. Fecal urgency improved significantly ($P < .001$; Fig. 3) and FI severity reduced significantly (Table 2; $P < .001$). At the final session, 86% (59/69) of participants had improved continence, and 20% (14/69) reported no fecal leakage in the preceding month. Patients' QOL was improved, with an increase in all 4 FIQL subscales ($P < .001$; Table 2). Improvement in QOL was correlated with the initial FI severity (CCF-FI less the lifestyle aspect, $r_s = 0.274$, $P = .023$; Fig. 4). There was significant improvement in the patients' subjective rating of bowel control over the treatment period (0 = worst, 10 = best), from 3 (range, 1.8–4) to 7.5 (range, 6.3–8.6), $P < .001$. Objective anorectal manometric and proctometrographic measurements, recorded at the first and final biofeedback sessions (Table 2) were significantly

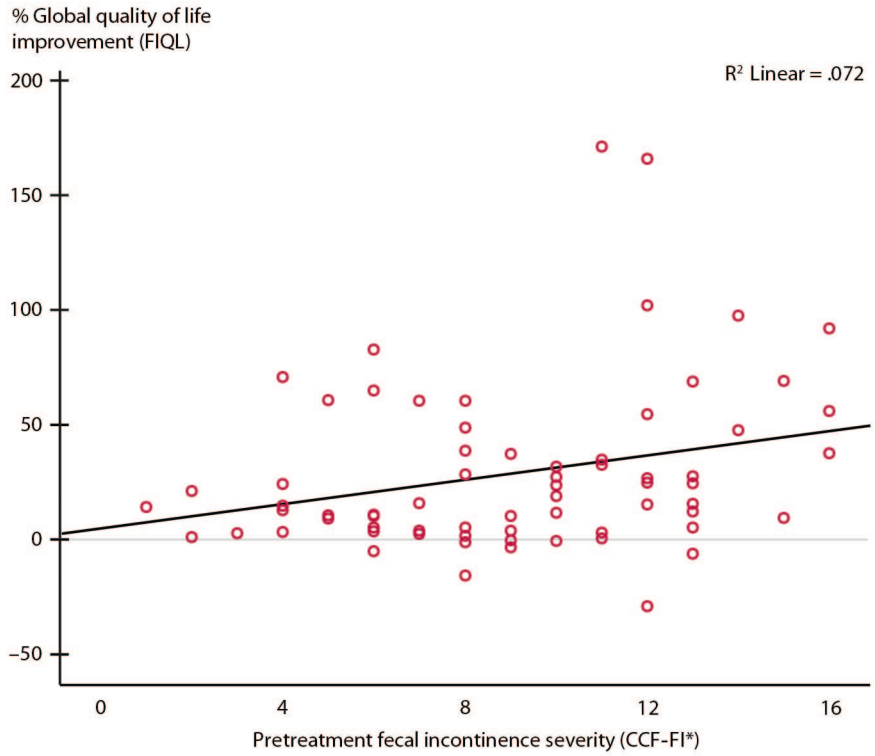

FIGURE 4. Relationship between quality-of-life improvement and initial fecal incontinence severity; n = 69, median improvement (interquartile range) 15.7% (3.8%–43.0%), $r_s = 0.274$, $P = .023$. CCF-FI = Cleveland Clinic Florida Fecal Incontinence Score; FIQL = Fecal Incontinence Quality of Life Scale. *Lifestyle component omitted.

improved for maximum squeeze pressure ($P < .001$) and volume of initial sensation ($P = .027$), marginally different for mean resting pressures and volume at first urge, and the maximum volume tolerated decreased ($P = .023$).

At 2 years, 13 participants were lost to follow-up (3 were deceased, 10 could not be contacted). FIQL and CCF-FI results continued to improve, although not significantly, among the 53 participants who provided this information (Table 2); 38% (20/53) reported no fecal leakage. Initial FI severity and QOL improvement at the 2 years follow-up was poorly correlated ($r_s = 0.116$, $P = .407$; Fig. 5).

Performance of Exercises

Prescribed squeeze-seconds per day for week 4 and the home practice period are reported in Table 3, as are those performed and the proportion of participants who complied with the exercise prescription. From the patient diaries 22 (12 SE) participants performed at least the prescribed number of exercise seconds in week 4, and the week 8 diaries showed that the SE group performed 195 (range, 94–343) seconds per day and the RSE group performed 264 (range, 54–357) seconds per day (Table 3). Participants who completed at least 100% of prescribed exercises, on average, exercised 50% more than prescribed at week 4 and 18% more at week 8. There was no significant difference for exercise prescription or compliance between the SE and RSE groups. Before treatment, compliant participants (n = 26, 12 SE/14 RSE; mean compliance, 118%) had significantly poorer continence scores ($P = .014$) and FIQL scores (lifestyle, $P = .018$; coping, $P = .004$; depression, $P = .003$; embarrassment, $P = .04$), than noncompliers (n = 34, 17 SE/17 RSE; mean compliance, 52%). Improvement in FIQL scores for compliers, over the duration of treatment, was significantly greater than for noncompliers (lifestyle, $P = .046$; coping, $P = .015$; depression, $P = .002$; embarrassment, $P = .011$), as was their reduction in incontinent episodes ($P = .045$). An improvement in QOL (global FIQL) and FI severity (CCF-FI) was directly related to exercise performance ($r_s = 0.357$, $P = .005$ and $r_s = 0.136$, $P = .301$).

At 2 years, 84.9% of participants (45) reported remembering how to perform their exercises; 21 of 30 (70%) of the SE group and 20 of 28 (71%) of the RSE group still practiced their exercises but less frequently than recommended (Table 3). Although improvement in FI increased over the 2 years, continence scores and FIQL scores were not significantly different between the participants who continued to perform their exercises and those who did not.

DISCUSSION

The major finding of this study was that there were no significant differences in objective or subjective measures

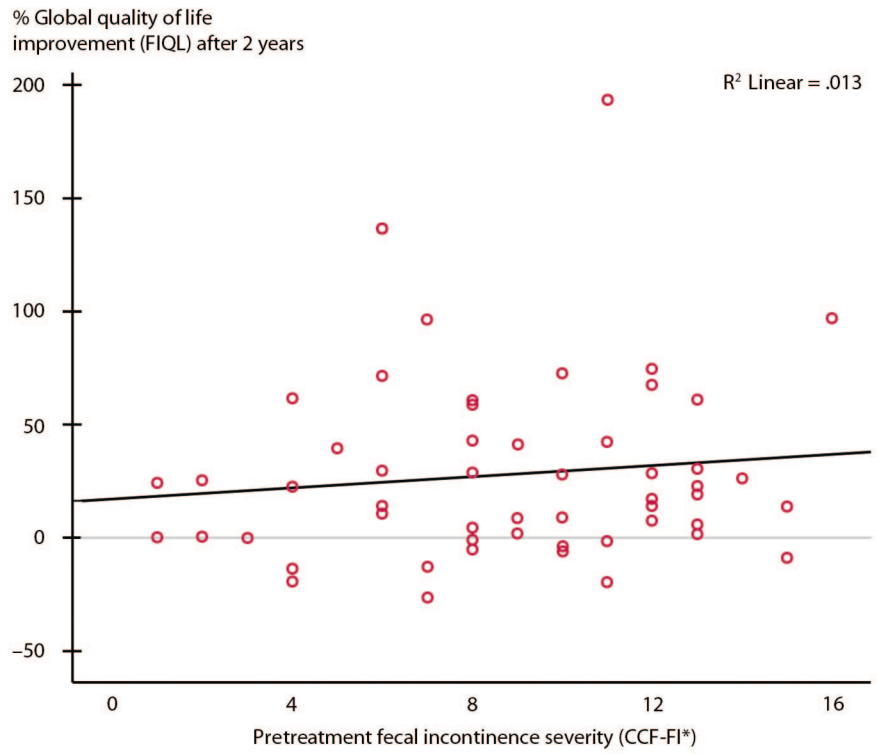

FIGURE 5. Relationship between quality-of-life improvement after 2 years and initial fecal incontinence severity; n = 53, median improvement (interquartile range) = 19.0% (0.2%–42.7%), r_s = .116, P = .407. CCF-FI = Cleveland Clinic Florida Fecal Incontinence Score; FIQL = Fecal Incontinence Quality of Life Scale. *Lifestyle component omitted.

between the 2 exercise regimens. However, 86% of participants had improved continence with 20% achieving complete fecal continence by the end of treatment and 38% reporting no fecal leakage 2 years later. Ninety percent of

TABLE 3. Number and duration of prescribed and performed exercises per day

	Exercise regime							
	Week 4				*Week 8*			
	SE (n = 37)		*RSE (n = 35)*		*SE (n = 35)*		*RSE (n = 34)*	
	n	*Duration*[a]	*n*	*Duration*[a]	*n*	*Duration*[a]	*n*	*Duration*[a]
Prescribed exercises (median)								
Pelvic floor, rapid	0	1.0	3	1.0	0	1.0	4	1.0
Anal sphincter, rapid	0	1.0	3	1.0	0	1.0	4	1.0
Pelvic floor, sustained	3	5.5	3	5.5	3	5.5	3	6.0
Anal sphincter, sustained	3	5.5	3	5.5	3	5.5	3	6.0
Repetition sets per day		6.5		6.5		6.5		6.0
Total prescribed per day (sec)		214.5		300.0		220.0		300.0
Performed exercises (median)								
Exercise performed per day (sec)		172.9		180.4		195.0		264.0
% Individual compliance with prescribed		80.6%		84.8%		85.7%		85.7%
Performed ≥ prescribed, n (%)		12 (32%)		10 (29%)		12 (34%)		14 (41%)
Performed < prescribed, n (%)		19 (51%)		20 (57%)		17 (49%)		17 (50%)
Data missing, n (%)		6 (16%)		5 (14%)		6 (17%)		3 (9%)
2-year follow-up		SE				RSE		
Participants reporting exercise performance		21/30 (70%)				20/28 (71%)		
Exercise performed per days (sec) (SE: n = 19; RSE: n = 17)		102.9[a]				44.3[a]		

SE = sustained exercise group; RSE = rapid and sustained exercise group.
[a]Duration in seconds.

participants were very satisfied with their treatment outcomes. Both continence and QOL scores improved significantly during treatment with the improvements maintained 2 years later.

Biofeedback enables patients to see the effect of squeezing, releasing, and resting the correct muscle on a computer screen, thereby producing high-quality contractions. Patients in this biofeedback program are advised to follow an exercise regimen of few and often until they are able to perform stronger and longer exercises less frequently (Table 3).[9] Although pelvic floor muscle training (PFMT) has been used to prevent and treat incontinence since the 1940s,[21] and biofeedback has been a prescribed FI treatment since 1974,[22] few studies have assessed the efficacy of PFMT alone for FI.[23] One recent randomized study showed manometric biofeedback with pelvic floor exercises was a more effective treatment for FI than pelvic floor exercises alone,[24] whereas another showed no difference between biofeedback and standard treatment.[25]

In this study, 86% of participants achieved improved continence within the treatment period, thus confirming the effectiveness of this holistic biofeedback program for FI. In a review of 46 studies of biofeedback treatment for FI, Norton[7] reported that 38 studies provided improvement rates, with only 7 showing better improvement than this study. The improved continence scores in this study also compare favorably with more recent studies.[26–29] It is difficult to compare QOL in FI studies that use different measurement tools; among the few biofeedback studies that have used the FIQL measurement tool, the scores and improvements are similar.[27,30] It is particularly difficult to compare this study with a Sri Lankan study where only 31 of 50 participants completed the survey and their QOL on each FIQL scale before treatment was very poor.[31]

The percentage of those cured, ie, no FI (38%, at the 2-year follow-up) compared less favorably with 19 of 46 biofeedback studies reviewed[7] which reported a higher cure rate than the present study, although only 26 provided cure rate data. Furthermore, the cure-rate in this study may have been lower than in earlier studies because of symptom tolerance, ie, choosing a personal cost–benefit ratio that substantially improved QOL with fewer exercises, rather than a complete cure with more exercises.

Rapid pelvic floor and anal squeeze exercises aim to improve muscle reaction time and increase muscle bulk, and submaximal sustained muscle squeezes aim to increase muscle strength and endurance.[9,12] Introducing rapid squeezes in this study population did not significantly affect patients' continence or QOL scores, either during the treatment period or at the 2-year follow-up. Objective manometry scores were not significantly changed during treatment and were not measured at the 2-year follow-up. Possible reasons for this lack of change are the short (5 weeks) duration of exercise practice, the fact that the rapid squeezes did not appear to be sufficiently different from the standard regimen to result in a significant difference in QOL or FI severity, and the patients in the pilot study that was used for sample size calculations were not representative of the heterogeneity of the study population. It may have been more appropriate to measure the impact of rapid squeezes by evaluating the time taken to reach baseline resting pressure between a set of rapid squeezes or the mean fatigue rate index.[32,33] However, the combination of both rapid and sustained exercises serves to increase patient awareness and control of these muscles.[21,34]

Patients who performed at least the prescribed number of exercises during the treatment period had significantly greater improvement in QOL and fewer incontinent episodes than those who performed fewer exercises than prescribed. However, at the 2-year follow-up, the QOL and continence scores of former compliers and noncompliers were similar, suggesting that the improvement in continence may be due to increased awareness and control, improved sensitivity, and decreased urgency achieved during treatment and maintained 2 years later. Although it requires several months of PFMT to improve the physiological condition of the musculature,[9,35] 2 years after treatment, many participants would be on a maintenance exercise program, performing fewer exercises daily. At the final treatment session patients were advised to increase the number of exercises to the previously prescribed level if they experienced a decline in continence on the maintenance program. Despite the lower number of maintenance exercises reported, there was continued improvement in FIQL and continence scores. The exercise/dose responses provide some evidence refuting the conclusion that biofeedback or exercises do not enhance the outcomes of treatment over standard care.[11]

QOL improvement was poorly correlated with FI severity, despite a significant trend, demonstrating that the biofeedback program was effective regardless of the initial level of severity. Poorer initial continence and FIQL scores were associated with better exercise compliance and greater improvement in QOL. Although this improvement may be due to regression to the mean, it could suggest that higher motivation encourages treatment compliance and thus a more successful outcome. The lifestyle component of the CCF-FI for this analysis was deducted to account for "regression to the mean" aspect,[36] ie, where QOL at the beginning was compared with QOL after treatment. At the 2-year follow-up, correlation between initial FI severity and QOL improvement was even less correlated, adding further evidence to the success of the program for all levels of FI severity.

A major limitation of this study was the heterogeneity of the population, which may have diluted the ability to

find significant differences, and the small sample size rendered it susceptible to a type 2 error. Better resourced programs may be able to study more homogenous groups. In addition, the results relied on patients reporting information about exercises performed. A subsequent study using home perinometers to objectively record exercise performance is underway. Moreover, this holistic program includes both anal and PFMT exercises that could reduce patient focus, whereas other studies test anal squeezes only. Finally, the highly mobile North Queensland population presents problems with enrollment and follow-up; it would be advantageous for future studies to collect more contact information to ensure better long-term follow-up.

CONCLUSIONS

More than 80% of patients attending this holistic biofeedback program achieved improvement in FI severity and QOL regardless of their initial continence score, with more than one third obtaining complete symptom relief. Compliance with the exercise program significantly improved patient outcomes. Adding rapid squeezes to the exercise regimen had little impact on FI severity or patient QOL.

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