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A Controlled Trial of An Intervention to Improve Urinary/Fecal Incontinence and Constipation

John F. Schnelle, PhD[1,2], **Felix W. Leung, MD, FACG**[4,6], **Satish SC Rao, MD, PhD, FRCP (LON)**[7], **Linda Beuscher, PhD, GNP**[3], **Emmett Keeler, PhD**[5,6], **Jack W. Clift, MPP**[5], and **Sandra Simmons, PhD**[1,2]

[1]Vanderbilt University, School of Medicine, Division of General Internal Medicine and Public Health, Center for Quality Aging, Nashville, TN

[2]Geriatric Research, Education, and Clinical Center, VA Medical Center, Nashville, TN

[3]Vanderbilt University School of Nursing, Nashville, TN

[4]Sepulveda Ambulatory Care Center, Veterans Affairs Greater Los Angeles Healthcare System, North Hills, CA

[5]RAND Corporation, Pardee Graduate School

[6]David Geffen School of Medicine at UCLA, Los Angeles, CA

[7]Department of Internal Medicine, University of Iowa Carver College of Medicine Iowa City, IA, USA

Abstract

Objectives—Evaluate effects of a multi component intervention on fecal (FI) and urinary incontinence (UI) outcomes

Design—Randomized controlled trial

Setting—Six nursing homes

Participants—One hundred and twelve Nursing Home (NH) residents

Intervention—Intervention subjects offered toileting assistance, exercise, and choice of food / fluid snacks every 2 hours for 8 hours per day over 3 months.

Measurements—Frequency of UI and FI and rate of appropriate toileting as determined by direct checks from research staff. Anorectal assessments were completed on subset of 29 residents.

Results—Intervention significantly increased physical activity, frequency of toileting and food/ fluid intake Urinary incontinence improved ($p<.05$) as did frequency of bowel movements ($p<.01$) and percent of bowel movements ($p<.01$) in toilet. The frequency of fecal incontinence did not

Corresponding Author: John F. Schnelle, PhD, Professor of Medicine, Vanderbilt University Medical Center, Director, Center for Quality Aging, 1161 21st Ave. South, S-1121 Medical Center North, VUMC, Nashville, TN 37232-2400.
Alternate corresponding author: Sandra Simmons, PhD, sandra.simmons@vanderbilt.edu

Conflict of Interest:
Dr. Felix W. Leung: Oceanic therapeutics and produces constipation medication.

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change. Most subjects (89%) who underwent anorectal testing showed a dyssynergic voiding pattern which could explain the lack of efficacy of this intervention program alone on fecal incontinence.

Conclusion—The multi-component intervention significantly changed multiple risk factors associated with fecal incontinence and increased bowel movements without decreasing fecal incontinence. The dyssynergic voiding pattern and rectal hyposensitivity suggest that future interventions may have to be supplemented with bulking agents (fiber) and/or biofeedback therapy to improve bowel function.

Keywords

urinary incontinence; fecal incontinence; constipation

INTRODUCTION

Fecal incontinence (FI), immobility and dementia are highly prevalent conditions among nursing home (NH) residents, and many of these residents experience problems with controlling stool discharge and evacuation.(1–4) The underlying mechanism(s) of FI and other problems related to stool discharge and evacuation are poorly understood, and management of these conditions remains problematic. Typically a plethora of medications are advised which include laxatives,(5;6) laxative/stool softener preparation,(7) sorbitol,(8) lactulose,(9;10) a senna-fiber combination,(9) bulk fibers,(11–14) herbal supplement,(15) or an intestinal secretagogue.(16) There is little evidence, however, to support the efficacy of any of these medication treatments. Prompted-voiding toileting interventions, which increase the frequency of toileting, are also recommended and help compensate for the risk factors of immobility and dementia common to both urinary and fecal incontinence.

Prompted-voiding is highly effective with urinary incontinence (UI) but much less effective with FI.(17;18) Factors other than increased toileting frequency thought to be related to successful fecal voids but not urinary voids include increased physical activity, food and fluid intake. A previous study showed that the average daily caloric intake of incontinent NH residents was approximately 1100 calories per day (18) illustrating both food and fluid intake is inadequate for many NH residents (19–21). A previous intervention trial showed that an increase in toileting frequency and daily exercise alone did not improve fecal continence or the frequency of bowel movements among incontinent NH residents who otherwise showed improvement in UI and physical functioning outcome measures.(18) The low rate of bowel movements in this previous trial suggested that both low food and fluid intake and constipation contributed to the lack of intervention effects on fecal outcomes.

In the current study the effects of a multi-component intervention for FI that combined prompted-voiding, exercise, and increased food and fluid intake was implemented by research staff. This type of study is consistent with recommendations made in a recent NIH consensus conference on preventing urinary and fecal incontinence.(22) To address the low expected rates of fecal voids, the period of measurement to assess the frequency of fecal voids was extended from two days in previous studies to 10 days in the current study. In addition, anorectal testing was completed for a sub-sample of participants to identify physiological mechanisms that may impact the effectiveness of increased toileting assistance on FI outcomes. There were no published reports on anorectal manometry measurement in NH residents at the time of this study. We thus assessed anal resting and squeeze sphincter tone pressure changes in the anal canal and rectum during attempted defecation maneuvers and assessed rectal sensation. Our objectives were to characterize the bowel dysfunction in

this group **of** residents and to determine if steps to treat abnormalities should be integrated into interventions in future studies. The following research questions were addressed:

1. What is the effect of an intervention that combines toileting assistance, exercise and improved food and fluid intake on UI, FI, and constipation outcome measures?
2. What are the anorectal physiological changes associated with bowel dysfunction in NH residents as detected by anorectal manometry and rectal sensation assessment?

METHODS

Subjects and Setting

All fecal incontinent subjects who were not comatose as identified in the medical record and who were not short term stay residents as defined by Medicare coverage were eligible. Figure 1 illustrates the flow of eligible subjects through the trial. Of the total resident population in six participating NHs, 495 (65% of resident population) were identified as eligible and 153 (31%) of the residents or their proxies provided informed, written consent. Most residents could not provide self consent (over 95%) and consent was thus obtained from a proxy designated in the chart. Consent procedures were approved by the University-affiliated Institutional Review Board. Medical record data documenting FI was independently verified by interviews with NH staff. Twenty-eight residents were lost either prior to or during the five-week baseline phase, primarily due to consent withdrawal (e.g., bothered by frequent incontinence checks and requests to exercise). The remaining 125 participants were randomized by research staff using a table of random numbers into intervention (n=65) or control (n=60) groups, and 112 (58 intervention and 54 control) completed the 12-week intervention. Of those who completed intervention, 29 consented to the anorectal exam. Medical records were reviewed for demographic characteristics and each participant's cognitive status was assessed with the Folstein Mini Mental Status Exam. (23) Research staff collected all primary outcome data and implemented all three components of the intervention.

Baseline Incontinence Checks—Primary outcome measures included frequency measures of incontinent and continent urinary and fecal voids. Trained research staff performed physical checks of each participant every two hours between 7am and 3pm for 10 week days during two consecutive weeks to collect these data (4 checks per day × 10 days = 40 total possible checks per person). The resident was changed in the morning to assure dry undergarments and, during each subsequent check research staff thoroughly checked the participant's clothes for evidence of incontinence (e.g., wetness or fecal matter). Research staff provided incontinence care (changing of soiled garments), when needed, but only provided toileting assistance when the participant requested it during this 10-day period. The percentage of checks in which a participant had UI or FI was calculated for each participant based on this 10-day assessment.

Appropriate toileting percentage was calculated by dividing the number of voids in the toilet by the total number of voids. Thus, if a resident was found wet 4 times and urinated in the toilet once the appropriate toileting percentage for UI would be 20%. All statistics were calculated separately for urinary and fecal voids yielding four separate statistics (percent checks UI, percent checks FI, percent appropriate toileting urination and percent appropriate toileting bowel). In addition, given the potential importance of constipation as a factor limiting the effectiveness of toileting assistance, the total number of bowel movements (incontinent + continent) was calculated per participant per day.

Physical Activity and Mobility Endurance—In addition to incontinence care and prompted voiding, a second intervention component was designed to increase physical activity, which was measured with a movement device that residents wore on their thighs for eight hours on two separate days. The device provides a continuous record of physical movement in both lateral and vertical directions and has been validated in previous work.(24) Physical activity was defined as any sustained movement over six minutes. For mobility endurance, the distance a resident could walk, or wheel their chair if non-ambulatory, within a 10-minute limit was averaged over two assessment trials. The number of sit-to-stands a resident could complete in 30 seconds was averaged over two assessment trials as a measure of lower body strength. Residents were allowed to use their arms to push or pull themselves to a standing position because very few residents could stand without using their arms. The two assessment trials for walking endurance and sit-to-stands were conducted by trained research staff on two separate days using a standardized protocol.(25)

Food and Fluid Intake—A third intervention component was designed to increase daily food and fluid intake. Offering NH residents a choice of snacks and fluids several times per day between meals is an effective method to accomplish this goal.(19) To estimate the degree to which the intervention improved intake, baseline observations were conducted during and between all three regularly-scheduled meals to document food and fluid intake. Meal and between meal observations were conducted on two separate days for a total of six meal and six between-meal periods per participant. The standardized observation protocols and a two-day assessment period have been shown to be reliable and valid for estimating food and fluid intake among NH residents.(20) Calories from additional foods and fluids between meals were estimated based on type of item given, caloric value of item (retrieved from the kitchen or printed on item itself) and amount consumed (proportion of food items, ounces of fluids).

Intervention and Post Intervention—Following all baseline measures, participants were randomized to either the intervention or control group. The intervention was implemented by trained research staff five week days per week between 7am and 3:30pm for 12 consecutive weeks. Each research staff member was assigned to three or four participants in the intervention group. Attempts were made to implement the intervention every two hours for a total of four possible intervention opportunities per resident per day. During each intervention episode, the resident was checked for incontinence and prompted to use the toilet (intervention component 1) They were offered a choice of food and fluid snack items (intervention component 3) and prompted to exercise (repeat sit-to-stands and walking or wheelchair propulsion for up to five minutes per care episode (intervention component 2) although exercise often was not provided during the first round of the day if the resident was still in bed. The control group continued to receive usual care as provided by indigenous NH staff.

During the 12-week intervention physical activity, food and fluid intake were monitored for two days each month for both intervention and control subjects using the same baseline assessment procedures. In addition, between meal food and fluid intake was documented daily for intervention subjects. It was hypothesized that physical activity and between-meal food and fluid intake would increase for the intervention subjects. The checks for incontinence and measures of appropriate toileting and constipation symptoms described in the baseline phase were collected each day of intervention for the intervention subjects and repeated for 10 days post intervention for the control subjects. The control subjects were not prompted by research staff to use the toilet during either the baseline or post assessments, but research staff provided toileting assistance when it was requested by the resident during both phases. The standardized assessments to measure mobility endurance were repeated for two days for both intervention and control subjects at the end of the 12-week intervention.

Anorectal Testing Protocol—All subjects were given the option of consenting for the entire study which included the intervention and anorectal assessments or the intervention study alone. Subjects who consented for the entire study completed anorectal exams prior to randomization. A team lead by two Geriatric Nurse Practitioners who were trained by a co investigator conducted the assessments. Each of the 29 consented participants received a phosphate enema prior to the anorectal assessment to induce evacuation of fecal content, and a research nurse performed a digital rectal examination to verify that the rectal vault was empty. Foods and fluids were not withheld on the morning of the assessment. With the subject lying in the left lateral position, a flexible probe (Konigsberg, Pasadena, CA) with three solid state pressure transducers and a 4 cm long latex balloon (Trojan, Church & Dwight Co, Inc, Princeton, NJ) was placed in the anorectum. Two of the sensors separated by 1 cm were positioned in the anal high pressure zone about 1 to 2 cm above the anal verge. The third transducer, covered by the latex balloon, was located at 6 cm above the nearest anal transducer and measured the intrarectal pressure. The catheter was connected to a digital data recorder (Gaeltec Nanologger™, Gaeltec, Ltd, Dunvegan, Isle of Skye, Scotland), and data were analyzed by Gaeltec software. The anal high pressure zone was located by the station pull through method. The catheter was then secured to the back of the subject using tape or held in location manually during the duration of the testing. After a seven-minute rest period, the subject was asked to squeeze the anal sphincter as if to prevent fecal leakage and to do so with as much force and sustained effort as possible. The baseline sphincter pressure immediately before the onset of squeeze and the peak sphincter pressure during squeeze were recorded. The duration of squeeze was defined as the interval during squeeze when the subject was able to maintain the sphincter pressure at least 10 mm Hg above baseline.(26;27) Next the subject was asked to push and bear down as if to have a bowel movement. Baseline and residual sphincter pressures during strain were recorded.(28) Defecation index (DI) was calculated from the following equation: DI = rectal pressure when straining/anal residual pressure when straining.(29–31) Rectal sensory thresholds were assessed by balloon distensions.(32) These include the threshold balloon volume for first sensation, urge to defecate, and maximum tolerable sensation. The presence or absence of rectoanal inhibitory reflex and the smallest balloon volume that triggered the reflex were recorded.

Measurement Reliability—Prior to baseline assessments, all research staff received training in study assessment protocols to reach a level of agreement at or above 90% using kappa agreement statistics for each of the primary outcome measures (UI and FI status, appropriate toileting episodes). Reliability checks were repeated by two observers intermittently during the intervention trial for urinary and fecal outcome measures. Process reliability checks also were conducted intermittently during the intervention trial to assure staff adherence to the intervention protocol elements (checking incontinence status, prompting for toileting assistance, exercise, food and fluid offers). Reliability for the exercise, food and fluid intake measures were collected by two observers for a sub-set of assessments during each assessment period (baseline, monthly, post).

Statistical Analysis

Data analyses were conducted for the 112 participants completing the study with transformation of some variables. Participants who either were physically unable or refused to sit-to-stand, walk or wheel were assigned a value of zero. Baseline values for distance walked or wheeled, food and fluid intake from snacks, and length of NH stay were top-coded at 98% to reduce the impact of outliers.

Even though randomization ensures balance between intervention and control groups on average, some predictive variables differed between the intervention and control groups, and

better precision in the estimate of treatment effects was obtained by controlling for these variables and other important predictors. To measure intervention effects, the final values of the primary outcome measures were regressed linearly on the baseline values, an indicator variable for group assignment (intervention versus control), two variables that remained unbalanced after randomization (sit-to-stands and total MMSE score), and other independent variables that significantly affected the outcomes. Forward stepwise linear regression was used to inform selection of the other independent variables after forcing in baseline values, treatment, and number of sit-to-stands and MMSE total score. We tested for interactions between treatment assignment and the most significant predictive variables and used Cook's Distance, DFFITS and DFBETAS to find influential observations. These influential observations were left in after investigation to ensure validity. For the processes promoted by the intervention (fluid intake, calories from snacks, physical activity) and the secondary outcomes (body weight, sit-to-stands, distance walked or wheeled) the differences in the changes over time were calculated between control and intervention groups.

Fecal incontinence was difficult to analyze statistically because 45% of the participants had no bowel movements at all in either the baseline or post 10-day assessment periods and so could not be incontinent. To clarify the effects of the intervention, we analyzed the effects on frequency of bowel movements and performed sensitivity analysis restricting the sample in several ways: to those who had bowel movements in the baseline period, to those who had bowel movements in the post period, and to those who had bowel movements in both periods.

RESULTS

Reliability

There were 2,348 occasions across all phases of the study in which two observers recorded incontinence status during checks with Kappa values of .96 and .94 for FI and UI, respectively (P<.001). Pearson correlations between two observers for distance walked or wheeled, number of sit to stands, percent food or fluid consumed ranged from .90 to .98 (P<.001). The Pearson correlation between two observers for frequency of activities based on accelerometer graphs was .67 (p<.01).

Intervention and Control Group Comparisons

Table 1 compares subjects randomized to intervention and control groups. The two groups were comparable at baseline on most measures and similar to incontinent NH residents in previous studies.(17;18) Intervention subjects scored significantly higher than control subjects at baseline on MMSE total score ($t = -2.09$, $p < .04$) and number of sit-to-stands ($t = -2.91$ $p < .01$). The only difference between subjects who dropped-out after baseline (n=13) and those who completed the trial (n=112) was that drop-outs had a lower baseline bowel frequency (.10 per day versus .26 per day, $t = 2.21$, $p<.03$).

Process Differences between Intervention and Control—There were significant differences between intervention and control subjects during the three months of intervention on measures reflecting change in fluid intake, calories from snacks, and activities in minutes per day and number of activities per day. The intervention group significantly increased from baseline on the following measures (per person per day) relative to the control group: fluid intake by a mean and standard deviation of 13.5 ± 6.3 ounces versus 1.86 ± 4.0 for controls, p<.001; calories from snacks between meals by 173 ± 153 versus 67 ± 135 for controls, p<.001; number of activities by 1.7 ± 2.3 versus −0.5 ± 2.6 for controls, p<.001; and number of minutes in activities by 10.6 ± 26.4 versus −10.9 ± − 21.9 for controls, p<.001. There were no reductions in percent of food eaten during meals for

either group so the increase in between meal food and fluid consumption for the intervention subjects reflected a net gain in total daily intake. There were non-significant trends in the two groups for changes in weight (2.1 pound ± 6.5 change for intervention subjects versus 0.7 ± 8.9 for controls) and for one endurance measure (1.2 ± 49.9 meters improvement in distance walked or wheeled for intervention subjects versus −5.1 ± 48.4 for controls).

Urinary Differences between Intervention and Control—The intervention had a significant effect on UI frequency and percentage of appropriate toileting even when adjusting for other variables (treatment coefficient for UI = −0 .07, t = −1.95, p <. 05; appropriate toileting percentage coefficient = .53, t = 10.8, p<.000). Variables in the final regression equation were baseline rates of UI, between-meal fluid intake, laxatives, sit-to-stands and MMSE total score. Higher fluid intake, MMSE score, laxative use, and baseline frequency of UI were associated with higher UI rates during intervention. Higher strength (number of sit-to-stands) was associated with less UI. There was also a significant interaction between MMSE and treatment with subjects showing higher MMSE scores, or less cognitive impairment, responding less well in treatment (coefficient −.01, t = −2.09, p <.05)

Fecal Differences between Intervention and Control—Table 2 illustrates intervention effects on FI frequency, appropriate fecal voiding percentage and total number of bowel movements (**continent +incontinent**). There were no significant effects of treatment on FI frequency when all subjects were considered as illustrated by the first column in Table 2. This outcome did not change when outliers were excluded or when subjects without baseline or post intervention recorded bowel movements were excluded from the analysis. However, the remaining columns in Table 2 illustrate large treatment effects on percentage of appropriate fecal toileting and total number of bowel movements (continent +incontinent). There was a 52% appropriate toileting difference between intervention and control subjects even when other factors were considered, and intervention subjects increased continent + incontinent bowel movements by .23 per day versus a −.11 reduction for controls. Similar to the results for UI, there was a significant interaction between MMSE total score and treatment with subjects showing lower MMSE scores, or more cognitive impairment, responding better to treatment (Table 2. column3).

Table 3 shows the intervention effects on constipation as defined by a frequency of bowel frequency criterion. The accepted definition of constipation is fewer than three bowel movements in a seven-day period (less than .43 per day) even though straining and stool consistency are other criteria. (33) There were no differences between groups at baseline on the proportion of intervention and control subjects who met this constipation criterion but highly significant differences during intervention, with fewer intervention subjects meeting this constipation criterion. It is interesting to note that all subjects who had a laxative or a stool softener order received these treatments during the 10 day baseline and post follow up period. However, laxatives did not emerge as a significant variable in any of the regression analyses including total bowel frequency (continent + incontinent).

Table 4 shows the results for the subjects who completed anorectal testing. The lowest volume that triggered the recto anal inhibitory reflex and caused distension-induced sphincter relaxation (15.9 ± 1.7ml) was significantly lower than the abnormally elevated volume of threshold (first) sensation (65.0 ± 8.6ml, p<.05). Two subjects could not follow instructions to strain and two were not tested for strain-induced responses. The remaining 25 showed a dyssynergic pattern of defecation (Type I, n=6, and Type II, n=19) with an increase of anal sphincter pressure when asked to strain. There were no differences between the 29 subjects who completed anorectal testing and the remaining subjects who did not on any measured variables. Due to the low number of subjects completing anorectal testing and

the absence of variability on important anorectal measures (almost all showed dyssnergic pattern) the relationship of clinical outcomes to these results could not be determined in the analysis.

DISCUSSION

The results of this randomized controlled trial showed that the multi-component intervention improved several measures thought to be related to quality of care and life for NH residents. We also found significant improvement in the frequency of UI and urinary appropriate toileting which replicates previous findings. A result not previously reported was the fact that subjects with more cognitive impairment were most responsive to prompted voiding. This finding is important since NHS often exclude residents from toileting programs due to dementia or other vague cognitive impairment criteria. We have argued that such exclusions are not valid and the findings from this paper support this conclusion. Moreover, we have reported in another study that cognitively impaired residents responded more positively than the more cognitively intact to a fluid intake intervention that relied on prompting and physical assistance. We suspect the problems of the cognitively impaired are more influenced by their inability to self initiate behaviors (drinking /toileting requests) than with other residents. Prompting protocols compensates for these self initiation problems and leads to a higher degree of responsiveness than with other residents whose incontinence may have more complex causes. With regards to FI, although we found that the appropriateness and frequency of continent bowel movements increased significantly in the intervention as compared to the control group, the number of FI episodes did not change.

These findings may in part be explained by the anorectal physiological data. In a sub-sample of participants who underwent these evaluations we found they had impaired resting basal pressure and reduced effective squeeze pressure, indicating weakness of both the internal and external anal sphincter function, but preserved rectoanal inhibitory reflex. They also had impaired thresholds for rectal sensation. As the rectum fills up with fecal matter, the higher threshold for first sensation prevents the resident from being alerted to the arrival of fecal matter in the rectal vault. Consequently, the resident is unaware of the need to contract the external sphincter voluntarily to stop the expulsion of fecal matter through the anal canal. Furthermore, the minimum rectal volume (15.9 ± 1.7 ml) required to trigger the rectoanal inhibitory reflex is significantly smaller than that which evokes the first sensation (65.0 ± 8.6 ml). Therefore, the arrival of stool has already distended the rectum and has induced reflex relaxation of the internal anal sphincter, with consequent descent of stool through the anal canal. The lack of voluntary external anal sphincter contraction could result in leakage of fecal matter between toileting attempts.

These data may provide a plausible explanation for the potential usefulness of treatment protocols designed to increase non liquid stool volume in NH residents, e.g. fiber supplement.(13;14) The increased volume and firmness of stool due to fiber enhances the likelihood that the threshold for first sensation can be reached in a timely fashion and may also decrease the likelihood of leakage. Fiber supplement in NH residents has led to reduced constipation and decreased use of laxatives and the data reported in this study suggest it may be helpful with FI.(12–14)

The other major physiological finding relates to dyssynergia, which is characterized by incomplete evacuation of fecal material from the rectum or difficulty with defecation due to either paradoxical contraction or failure to relax the pelvic floor muscles when straining to defecate. It is one of the most common forms of functional constipation both in children and adults. (32);(34) The finding that almost all of the residents who participated had dyssynergic pattern of defecation during straining is a novel observation potentially related

to FI outcomes. More specifically, even when the resident demonstrated appropriate intervention related fecal voids, the functional obstructive defecation pattern will impede the flow of fecal matter when the resident attempts to defecate. Incomplete emptying may increase the probability of future incontinence episode between toileting attempts. The stool retention or symptoms of constipation brought on by the dyssynergia may also prompt doctors to prescribe prophylactic laxatives or stool softeners, exacerbating leakage.

In summary, a significant proportion of NH residents demonstrate dyssynergic defecation and rectal hyposensitivity that predisposes them to constipation and fecal retention and many receive laxatives (69%- see table 1) that can additionally lead to fecal leakage. These physiological and pharmacological mechanisms probably act to limit the effectiveness of behavioral programs such as prompted voiding that do increase the number of appropriate fecal voids but do not lead to significant reductions in FI. The efficacy of a combined program of fiber supplement, prompted voiding, and verbal reminder to refrain from straining to minimize dyssynergic defecation should be evaluated in future studies. The current multi-component intervention had significant positive effects on all urinary and fecal frequency outcomes with the exception of FI frequency and there is evidence from other studies that if the intervention was extended to six months positive effects on hydration, body weight and mobility outcomes also would occur.(32);(35)

The most notable limitation to this study is that FI was not measured over the 24-hour period or over weekends although the assessment period was 10 days. One would not expect intervention effects over the 24-hours but one might expect that frequency of all fecal voiding **(continent+ incontinent)** would be higher than that reported in this study. The consent rate was lower for this study (31%) than that reported in our previous studies (50% or higher) and impacted our power to detect intervention effects. If we had a more typical consent rate we would have had about 100 people per group and could have detected a drop from 6% to 3% in FI. However, given the observed effect size of 1% even a much larger sample size would not have affected our primary conclusions. We suspect that the description of the anorectal assessment procedures which were included in all consent documents may have impacted our consent rate. The small number of residents who consented to the anorectal procedure also limits the study findings. However, the high prevalence of bowel pathology (87%) demonstrated in the sub-sample suggests that dyssynergia may be a significant underlying problem. for many residents with fecal incontinence. These data indicate the need for specific intervention measures in addition to those implemented in this study (e.g. fiber supplement and biofeedback)in order to improve FI in NH residents.

Finally, based on the time required to implement the intervention by research staff it is almost certain that most NHS do not have the staff to translate the protocol into practice. Targeting the intervention to only the most responsive residents as well as other time efficient strategies will need to be considered. These translational issues will be the focus of another paper.

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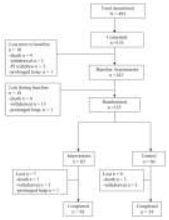

Figure 1.
Study Flow Chart

Table 1

Baseline Comparisons between Intervention and Controls

		Control	Treatment	Difference	p-value
Age	Mean	86.15	85.84	−0.30	0.872
	SD	10.46	9.42		
Female % of Subjects	Mean	0.81	0.84	0.03	0.676
	SD	0.39	0.37		
Months in Facility	Mean	39.04	30.55	−8.48	0.072
	SD	26.18	23.33		
MMSE Score	Mean	9.63	12.95	3.32	0.039
	SD	8.39	8.37		
Prescribed Laxatives % of Subjects	Mean	0.69	0.69	0.00	0.960
	SD	0.47	0.47		
Weight	Mean	148.98	147.06	−1.91	0.800
	SD	40.20	39.26		
Calories from Snacks per day	Mean	32.91	39.67	6.75	0.614
	SD	62.72	76.58		
Fluid from Snacks/oz. per day	Mean	0.72	0.66	0.06	0.920
	SD	0.18	0.22		
Sit-to-Stands	Mean	2.09	3.56	1.47	0.004
	SD	2.03	3.15		
Walk/Wheel Distance (Meters)	Mean	54.20	58.66	4.45	0.658
	SD	55.85	50.34		
Number of Bowel Movements per day	Mean	0.24	0.28	0.04	0.418
	SD	0.26	0.26		
Urinary Incontinence % of checks	Mean	0.33	0.33	−0.01	0.87
	SD	0.19	0.20		
% of Appropriate Urinary Toileting	Mean	0.20	0.19	−0.01	0.88
	SD	0.27	0.24		
Fecal Incontinence % of checks	Mean	0.05	0.06	0.01	0.57
	SD	0.08	0.07		
% of Appropriate Fecal Toileting	Mean	0.41	0.36	0.06	0.52

		Control	Treatment	Difference	p-value
	SD	0.42	0.39		
	N	54	58		

Table 2

Intervention Effects on Fecal Outcomes

	F1 Frequency			F1 Appropriate Toileting			F1 Appropriate Toileting			Total Bowel Movements		
Variable	**Coefficient**	**t-value**	**p-value**	**Coefficient**	**t-value**	**p-value**	**Coefficient**	**t-value**	**p-value**	**Coefficient**	**t-value**	**p-value**
Baseline	0.240	1.71	0.09	0.44	4.25	0.00	0.42	4.39	0.00	0.57	4.36	0.00
Sit-to-Stands	0.000	0.00	1.00	0.01	0.72	0.47	0.02	1.67	0.10	0.01	1.00	0.32
MMSE/10	−0.007	−0.86	0.39	0.00	0.07	0.94	0.18	2.44	0.02	−0.04	−0.98	0.33
Bowel Movements at Baseline	0.048	1.24	0.22	−0.38	−2.40	0.02	−0.29	−1.89	0.06			
Treatment	0.009	0.64	0.53	0.52	6.60	0.00	0.46	6.11	0.00	0.35	4.94	0.00
Treatment*MMSE/10							0.30	−3.12	0.00			
Constant	0.006	0.50	0.62	0.30	3.31	0.00	0.29	3.43	0.00	−0.04	−0.66	0.51
N	112			62			62			112		
R-sq	0.17			0.58			0.65			0.34		

Table 3

Constipation Before and After Intervention

	Constipation* at Baseline		
	Control	**Treatment**	**Total**
Constipation?			
No	10	13	23
Yes	44	45	89
Total	54	58	112
	Pearson chi2(1) = 0.260, Pr = 0.610		
	Constipation at End of Study		
	Control	Treatment	Total
Constipation?			
No	3	28	31
Yes	51	30	81
Total	54	58	112
	Pearson chi2(1) = 25.4954, Pr = 0.000		

Note: Constipation is defined here as fewer than 0.43 bowel movements per day over the 10 day assessment

Table 4

Anal rectal measurements

	n	Mean±SEM
Baseline intra-rectal pressure before squeeze	29	9.6±1.5
Peak intra-rectal pressure during squeeze		31.7±4.2*
Baseline sphincter pressure before squeeze [normal 40 – 70 mm Hg]		25.0±2.8
Peak sphincter pressure during squeeze [normal >100 mm Hg]		54.1±6.4*
Squeeze duration [normal >30 seconds]		8.2±1.2
Baseline intra-rectal pressure before strain	25	14.2±2.1
Peak intra-rectal pressure during strain [normal >50 mm Hg]		49.5±5.6*
Baseline sphincter pressure before strain		22.3±1.7
Residual sphincter pressure during strain [>baseline implies dyssynergia]		53.3±5.2*
Defecation Index [normal >1.4]		1.0±0.1

* vs. baseline before squeeze or strain, $p<0.05$, paired t test