CLINICAL INVESTIGATION

Translating Clinical Research into Practice: A Randomized Controlled Trial of Exercise and Incontinence Care with Nursing Home Residents

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OBJECTIVES: To examine clinical outcomes and describe the staffing requirements of an incontinence and exercise intervention.

DESIGN: Randomized controlled trial with blinded assessments of outcomes at three points over 8 months.

SETTING: Four nursing homes.

PARTICIPANTS: Two hundred fifty-six incontinent residents.

INTERVENTION: Research staff provided the intervention, which integrated incontinence care and exercise every 2 hours from 8:00 a.m. to 4:00 p.m. 5 days a week.

MEASUREMENTS: Average and maximum distance walked or wheeled, level of assistance required to stand, maximum pounds lifted by arms, fecal and urinary incontinence frequency, and time required to implement intervention.

RESULTS: Intervention residents maintained or improved performance whereas the control group's performance declined on 14 of 15 outcome measures. Repeated measures analysis of variance group-by-time significance levels ranged from $P < .0001$ to .05. The mean time required to implement the intervention each time care was provided was 20.7 ± 7.2 minutes. We estimate that a work assignment of approximately five residents to one aide would be necessary to provide this intervention.

CONCLUSIONS: The incontinence care and exercise intervention resulted in significant improvement for most residents, and most who could be reliably interviewed expressed a preference for such care. Fundamental changes in the staffing of most nursing homes will be necessary to translate efficacious clinical interventions into everyday practice. **J Am Geriatr Soc 50:1476–1483, 2002.**

Key words: practice guidelines; dissemination barriers; labor requirements

Approximately two million older Americans live in one of more than 16,000 United States nursing homes (NHs).[1] Over the next few decades, the frail older population will more than double, and the chance that an older individual will spend some time in a NH will approach 50%.[2] The quality of care provided to vulnerable older residents in this country's NHs continues to undergo close scrutiny. Lawsuits alleging poor quality of care are increasing.[3] Public concern about quality has led to at least one state considering using videotaping to monitor the process and quality of care. The Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) now posts selected quality indicators derived from the Minimum Data Set on their public Website.[4] The causes of poor quality of care are many, but one cause is receiving increasing attention: lack of adequate staffing. Although there is consensus among consumer, union, and nursing home industry groups that current NH staffing levels are inadequate,[5] there is "uncertainty" about what staffing levels are adequate, because there is little scientific evidence that identifies the specific staffing requirements necessary to provide better NH care. The Institute of Medicine recently recommended that research be conducted "to examine the actual time and staff mix required to provide adequate processes and outcomes of care consistent with the needs of consumers."[6]

A variety of clinical practice guidelines included in the Center for Medicare and Medicaid Services Resident As-

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sessment Instrument and guidelines developed by professional organizations are recommended for implementation in NHs to improve the quality of care.[7–14] Although some clinical research has documented that exercise and incontinence interventions can improve outcomes in NH residents, most of these practice guidelines are based on expert opinion.[15–18] Unfortunately, there is little information about the labor requirements necessary to implement these guidelines and clinical interventions, because clinical trials and practice guidelines are generally not designed to assess these requirements. Nevertheless, these data are critical to the translation of effective interventions into everyday practice in NHs.[19] The number of residents who need a care process and the amount of time required per episode of care determined the staff time required to implement that process. Most clinical trials are designed and described in a manner that precludes accurate estimates of these critical staffing issues.

In this paper, we present data relevant to determining the staffing requirements of implementing a clinical intervention protocol that improved multiple outcomes in nursing home residents. This intervention targets the more than 50% of residents who are incontinent of urine and who have been documented to be physically inactive and at high risk for hospitalization.[20,21] The intervention, Functional Incidental Training (FIT), includes care processes that are designed to increase activity and functional ability and are integrated with incontinence care. The integration of these care processes is meant to address time efficiency and safety concerns. FIT has been shown to improve mobility endurance when delivered 5 days a week for 2 months.[22] We replicated the FIT protocol in a randomized trial of 8 months duration. We designed the trial to document intervention outcomes and determine the staffing resources necessary to produce these outcomes. In this paper, we address three specific questions: (1) What are the functional benefits for residents maintained on the FIT protocol for 8 months? (2) What percentage of residents are good candidates for the intervention, based on their preferences for and individual responsiveness to the intervention? (3) How much time is needed to implement the intervention per episode of care, and what are the implications of this time requirement for translating this intervention into NH practice?

METHODS

Setting and Participants

Residents were recruited from three proprietary NHs and one nonprofit NH that were staffed according to typical industry standards of seven to 10 residents per aide on the 7:00 a.m. to 3:00 p.m. shift and 10 to 12 residents per aide on the 3:00 p.m. to 11:00 p.m. shift. Residents met the inclusion criteria if they were not on post–acute skilled care units or terminally ill and were incontinent of urine, free of a catheter, and able to follow a one-step instruction (e.g., move your hand). The University of California, Los Angeles, Human Subjects Protection Committee approved the protocol. Research staff obtained consent directly from those residents who could pass a brief test documenting their understanding of the consent form and, for all other eligible residents, from their legally designated representatives (proxies). In all cases, assent was obtained from the residents for their participation in the trial.

To describe the participants, research staff extracted medical and demographic data from medical records and performed a Mini-Mental State Examination.[23] Medical comorbidity was determined at baseline in two ways. First, research staff obtained a simple count of diagnoses from the resident's medical record. Second, a study physician used baseline information from the medical record and a brief physical examination of the resident to rate comorbidity using the Cumulative Illness Rating Scale for Geriatrics (CIRS-G).[24] The CIRS-G is a clinician-rated scale of severity of disease (ranging from 0 = no problem to 4 = extremely severe) in each of 14 organ systems. To assess reliability of the CIRS-G, two study physicians independently completed the scale for 47 residents. The agreement between the two physicians for total CIRS score ratings was $r = .71$ ($P < .001$). The CIRS-G has been validated in institutionalized older people, in whom a higher number of organ systems with moderate or severe impairment has been associated with higher 2-year mortality and acute hospitalizations.[25]

We also attempted to assess residents' preferences for key components of the intervention. The protocol used to elicit responses has been described previously.[26] All residents were given the opportunity to answer four preference questions, with repeat interviews conducted within 24 hours to assess stability of responses. The four questions were: "How many times during the day would you like someone to help you to use the toilet? Change your adult pad? Walk? Wheel your chair?" We used these resident preference data to estimate the labor requirements of implementing the intervention, because the number of residents who are candidates for the intervention is one of two key variables that influence labor requirements. The other variable is the amount of time required per episode of care. Preference data, along with information about how many residents actually respond to the intervention, can also be used to derive an estimate of how many residents potentially should receive the intervention.

Overview of the Study Design and Intervention

Residents were randomized into intervention and control groups using a computerized randomization program completed after baseline assessments. The intervention group received the intervention for 32 weeks. Postintervention assessments were completed at 8 weeks (Post-1) and 32 weeks (Post-2) in both groups. The intervention was implemented every 2 hours, 5 days a week, from approximately 8:00 a.m. to 4:30 p.m., for a possible total of four care episodes per day. During each episode of care provided by research staff, residents were prompted to toilet and were changed if they were wet. No effort was made to influence the incontinence care practices of NH staff during hours when the resident was not being provided care by research staff. Before or after this incontinence care, staff encouraged residents to walk or, if nonambulatory, to wheel their chairs and to repeat sit-to-stands up to eight times using the minimum level of human assistance possible. During one episode per day, each resident, usually while in bed, was given upper body resistance training (arm curls or arm raises). Before and after each care episode, residents were offered fluids. Based on prior work,

this twice-per-session fluid prompting is necessary to significantly increase fluid intake in this population.[27] Initial exercise goals were set at 75% of the residents' maximum distance walked or wheeled during the baseline assessment or 75% of the highest weight lifted in one baseline trial. If residents achieved these goals on 90% of their weekly care episodes, goals were increased by approximately 1 minute for mobility exercise and two stands per trial or one pound per resistance training session. The maximum goal established for any resident was 10 minutes for walking or wheeling and eight stands per trial. There was no maximum for resistance training.

The degree to which the intervention succeeded in increasing physical activity was assessed in two ways. First, behavioral observations were conducted every 15 minutes for 8 hours per day during a 2-day baseline period and on 2 days during the intervention period for intervention and control residents. For these observations, research staff located each resident every 15 minutes and noted the resident's physical activity, (e.g., walking, standing, lying, or sitting). During these same 2-day baseline and intervention assessments, all residents wore motion sensors (Caltracs, Hemo-Kinetics Inc., Madison, WI) that provided a continuous record of their movements. Data accuracy for all measures was assured by conducting interobserver agreement checks throughout all phases of the trial and blinding observers to group assignment whenever possible. For the major outcome measures (physical performance assessments), the agreement between a blinded observer and a second observer was documented on 100% of the observations. Blinding was accomplished by training people who had no responsibility for randomization or for the implementation of the trial on a daily basis to conduct the assessment.

Outcome Assessments

Incontinence

To assess incontinence, research staff directly checked residents for wetness every hour between 8:00 a.m. and 4:00 p.m. during 2 days at baseline, when all residents were receiving usual nursing home care, and again during week 32 of the intervention, when control residents were still receiving usual care. The procedure used to assess urinary and fecal incontinence frequency has been described elsewhere.[15] Data are reported as the percentage of checks wet and fecally incontinent and the appropriate toileting ratio. For example, if a resident was wet on four of eight daily checks and fecally incontinent on two, then the percentage wet would be 50% and the percentage fecally incontinent would be 25%. The appropriate toileting ratio is calculated by dividing the number of times a resident used a toilet or toilet substitute by the total number of voids. A higher ratio indicates more continence. For example, if a resident successfully toileted four times in a day and was wet on none of the hourly checks, then their appropriate toileting rate would be four divided by four, or 100%, which indicates total continence.

Endurance

Standing, walking, and wheelchair endurance were assessed for intervention and control residents using a standardized protocol on three separate occasions: at baseline and again at 8 and 32 weeks postbaseline. On each occasion, eight trials were conducted on 2 separate days between 8:00 a.m. and 4:30 p.m., with trials separated by approximately 2 hours. For each trial, residents were asked to stand using the minimum level of human assistance possible, although they were allowed to use their chair arms or wall rails if they could not otherwise stand without human assistance. This modification to the standing test was made because so few residents (2%) were capable of standing without using their arms during the baseline assessments. The amount of assistance provided to residents during these assessments was defined according to five levels: no physical assistance (Level 1); no physical assistance but instructions on how to stand (e.g., move to edge of chair, push up with arms) (Level 2); instruction plus manual guidance to start the movement but no physical lifting (Level 3); partial physical lift (Level 4); and complete physical lift (Level 5). Residents who could not stand at Levels 1 through 3 were allowed to wheel their chairs for the endurance tests. During these endurance tests, each resident was encouraged to walk or wheel for up to 10 minutes, with one 60-second rest stop allowed. For each 2-day assessment period, the number of trials that a resident actually attempted to walk or wheel and the average distance walked or wheeled over all eight trials were calculated. The difference between these two methods of calculation did not result in different conclusions, and we therefore report the distance values averaged over all eight trials and the maximum distance that a resident walked or wheeled on any one of the eight trials. During the second trial on each of the 2 days of assessment, the resident was asked to stand as many times as possible in 30 seconds. We report the average number of stands that a resident completed over these two trials and the maximum number of stands they completed on their best effort during the 2 days. These data are reported only for residents who could stand with a level of assistance of 3 or less (e.g., no physical lift).

Strength

Upper body strength assessments were completed for intervention and control residents on two separate trials on different days than the endurance assessments. A one-repetition maximum lift was used to evaluate strength and took place at baseline and at 8 and 32 weeks postbaseline. Residents were positioned at 45° in bed and asked to complete an arm raise or arm curl with each arm. The arm raise and arm curl exercises were conducted on separate days. To determine each resident's full range of motion, no weight was used initially. Residents were then asked to repeat this motion using a 1-pound hand-held weight. The weight was gradually increased by 1-pound increments until the resident could no longer complete the full range of motion. Residents attempted each exercise using alternating arms to allow for a rest between each lift.

Assessment of Labor Requirements to Implement the Intervention

Research staff who implemented the FIT protocol recorded the amount of time needed to provide care, noting the time to locate each resident and the time spent in toileting, exercise, and fluid administration. Travel time to

locate residents was assumed to be the time lapsed between when work with one resident ended and work with a second resident began. The average time needed per care episode, and variability between care episodes, was calculated to estimate the number of residents one NH staff member could treat with the FIT protocol.

Statistical Analysis

A repeated measures of analysis of variance program was used to analyze whether there were differences between intervention and control groups over the three major phases of the trial: baseline, 8-week, and 32-week postassessments (SPSS/PC+ Advanced Statistics Version 5.0, SPSS Inc., Chicago, IL). One score for each resident was calculated and used in each separate analysis to document changes in outcomes. For example, the average distance a resident walked over the eight endurance trials was calculated for each of the three assessment periods. A significant group-by-time interaction indicates that the groups changed in different ways over time. Within-group paired *t* tests were calculated to assess whether there were differences between the baseline and the 32-week postassessment period for each measure. Residents were eliminated from these analyses if post-2 assessment data (32 weeks) could not be calculated for reasons that most often included mortality or decline in functioning that precluded a performance assessment (e.g., a resident could wheel their chair at baseline but could not at post-2). If a resident could not walk during baseline endurance assessments but could walk during post-2 assessments, an endurance score of 0 was assigned as the resident's baseline endurance score. We provide specific descriptions of resident attrition and how residents complied with assessments.

RESULTS

Six hundred thirty-three residents occupied long-stay beds in the four participating NHs. Of these residents, 452 (71%) were incontinent, and 330 (73%) met inclusion criteria. Informed consent was obtained for 257 (78%) of these 330 residents. Baseline assessments were successfully completed on 190 (74%) of the 257 consented residents. Reasons for incomplete assessments included resident transfer, death, or refusal to cooperate and withdrawal of consent. The 190 residents were then randomized into an intervention group (94 residents) and a control group (96 residents). One hundred seventy-two (91%) of the residents (85 intervention and 87 control) completed the 8-week (post-1) assessments, and 148 (78%) of the residents (74 intervention and 74 control) completed the 32-week (post-2) assessments. Attrition after the baseline assessments was primarily due to death (28 residents) or a prolonged illness that prevented the resident from participating in any component of the 2-day FIT outcome assessments (10 residents). There were no differences between intervention and control residents on mortality (14 residents per group died postbaseline). Table 1 presents descriptive data for the intervention and control residents on the variables most relevant to this study. There were no significant differences between groups on any these descriptive variables.

There was a large increase in intervention residents' tolerance for exercise, with a more than 100% increase in distance walked or wheeled from week 1 to week 32 during daily FIT exercise sessions. For intervention residents, the average distance that residents walked or wheeled during daily sessions (not during the 2-day post-1 or post-2 assessments) increased from 135.4 meters per week in Week 1 to 295 meters per week in Week 32. This increase in exercise tolerance was independently documented by the motion sensor and behavioral observational measures of activity. Intervention and control residents were observed walking or standing in 3% of the observations at baseline and 6% or 3% of the time, respectively, during days when the intervention was being implemented. The motion sensor data indicated that estimated kilocalories expended per hour for the intervention and control residents, respectively, were 1.8 and 2.1 at baseline and 4.8 and 1.2 during the days the intervention was being implemented. Both measures of physical activity showed significant group-by-time differences between the intervention and control groups over the 32 weeks of the intervention ($F = 6.3$ for behavioral observation measures and 13.9 for motion sensor data; $P < .001$ for both measures).

Table 1. Resident Characteristics

Characteristic	Intervention (n = 94)	Control (n = 96)
Age, mean ± SD	87 ± 8	88 ± 7
Length of residency, months, mean ± SD	26 ± 31	29 ± 32
Mini-Mental State Examination score, mean ± SD (range 0–30)	12 ± 8	14 ± 7
Female, %	81	86
Ambulatory, %	60	63
Total Cumulative Illness Rating Scale score, mean ± SD*	19.9 ± 6.3	19.8 ± 5.2
Number of diagnoses, mean ± SD	9.3 ± 4.1	9.8 ± 5.4
Medications prescribed, mean ± SD		
Total (routine plus as needed), mean ± SD	10.1 ± 4.8	9.1 ± 4.4
Routine, mean ± SD	7.1 ± 3.6	6.6 ± 3.9

*Sum of severity scores (ranging from 0 = no problem to 4 = extremely severe) for 14 organ system categories.
SD = standard deviation.

Outcomes

Table 2 illustrates the main outcome measures that were assessed during the 2-day assessment periods at baseline (preintervention), post-1 (8 weeks), and Post-2 (32 weeks). Interrater agreement on these measures was high, with kappa values ranging from 0.68 to 0.96 ($P < .001$).

There were significant group-by-time interactions on all major outcome measures, except average meters wheeled (see last column of Table 2). Within-group paired *t* test comparisons (column 6) provide more specific information on the nature of the intervention effects and show that the intervention was more effective in preventing decline than in improving performance for some measures. This is especially clear for the walking, wheeling, and standing independence measures. There were no significant pre to post changes to indicate improvement in the in-

Table 2. Outcome Measures for Intervention (I) and Control (C) Groups over Three Phases

Outcome Measure	N	Pre	Post 18 Weeks	Post 32 Weeks	T-value	F-value Group by Time
		Mean ± Standard Deviation				
Average meters walked	I, 53	110.9 ± 99.0	110.3 ± 86.1	116.7 ± 92.6	1.3	5.1†
	C, 38	140.8 ± 97.8	118.0 ± 98.7	105.6 ± 80.5	2.8†	
Average meters wheeled	I, 21	47.2 ± 34.6	54.1 ± 35.6	51.9 ± 38.4	0.54	2.2
	C, 27	41.7 ± 40.1	40.2 ± 35.0	28 ± 23.5	2.6*	
Maximum meters walked	I, 53	151.1 ± 117.4	150.2 ± 104.6	170.5 ± 107.7	1.7	6.1†
	C, 38	199 ± 113.3	174.5 ± 107.4	169.2 ± 103.5	2.8†	
Maximum meters wheeled	I, 21	78 ± 44.4	92 ± 50.8	82.1 ± 52.2	0.45	3.2*
	C, 27	79.4 ± 52.5	75.3 ± 48.3	57.7 ± 36.6	2.9†	
Average meters walked + wheeled	I, 74	92.9 ± 90.3	87.2 ± 77.9	98.3 ± 85.9	1.4	6.5*
	C, 65	99.6 ± 92.6	85.6 ± 87.3	73.3 ± 73.8	3.7†	
Maximum meters walked + wheeled	I, 74	130 ± 106.9	133.5 ± 95.8	145.1 ± 102.9	1.7	8.9†
	C, 65	150.4 ± 110.1	134.2 ± 100.5	123.9 ± 99.3	3.7†	
Average stands 30 seconds	I, 50	4.5 ± 2.5	5.8 ± 3.2	5.9 ± 2.6	2.2*	4.6†
	C, 41	5.0 ± 2.7	5.3 ± 2.8	4.6 ± 3.2	0.37	
Maximum stands 30 seconds	I, 50	5.6 ± 2.6	7.1 ± 2	7.2 ± 2.8	2.2*	3.6*
	C, 41	6.4 ± 2.9	6.6 ± 2.7	6.3 ± 3.1	0.37	
Stand levels of assistance	I, 54	1.8 ± 1.1	1.8 ± 1.0	1.7 ± 0.7	1.1	4.7†
	C, 51	1.7 ± 0.9	1.9 ± 1.1	2.2 ± 1.2	3.5†	
Arm raise	I, 57	8.6 ± 6.5	10.5 ± 6.4	12.6 ± 7.5	8.1†	21.5†
	C, 54	7.3 ± 4.5	7.2 ± 4.4	7.5 ± 4.6	0.45	
Arm curl	I, 61	11.6 ± 7.7	14.6 ± 7.5	16.1 ± 8.7	7.1†	8.5†
	C, 63	10 ± 5.8	10.6 ± 5.9	11.3 ± 5.9	1.9	
Urinary incontinence frequency	I, 73	37% ± 23	—	23% ± 21	4.8†	11.6†
	C, 74	34% ± 21	—	35% ± 21	0.26	
Appropriate urine toileting ratio	I, 73	15% ± 23	—	59% ± 34	12.1†	106.2†
	C, 74	20% ± 28	—	16% ± 25	1.6	
Fecal incontinence frequency	I, 73	7% ± 10	—	3% ± 8	2.8†	4.5*
	C, 74	6% ± 11	—	7% ± 10	0.32	
Appropriate fecal toileting ratio	I, 73	17% ± 33	—	73% ± 35	7.5†	25.2†
	C, 74	31% ± 43	—	28% ± 36	0.36	

*$P < .05$; †$P < .01$.

tervention group for these measures, but there were significant pre to post changes to indicate a decline for the control group. In addition, the intervention group significantly improved performance on all other measures from the pre- to the 32-week postintervention period, whereas the control group showed no changes.

Although attempts were made to repeat performance assessments on all 74 intervention and control residents still participating at the end of the 32-week intervention period, the frailty and dementia level of this population influenced how many assessments could successfully be completed. Variability in the resident's ability or motivation to comply with assessments explains the number of residents who were available for the different comparisons listed in Table 2, column 2. For example, endurance data (walking, wheelchair propulsion) were not calculated for intervention or control residents who required weight-bearing physical assistance (Level 4 or 5) to walk or stand during a pre- or postintervention assessment. For this reason, these data could not be calculated on post-2 assessments for nine of the 74 control residents who were still participating at the end of the intervention, because they had declined over the 8-month intervention period to the point that they required weight-bearing physical assistance to walk or physical assistance to wheel during the post-2 assessment. Thus, data are reported for only 65 control residents for the combined walking/wheeling assessment outcome measures. We report data on all 74 intervention residents, because walking or wheelchair endurance data could be collected on all intervention residents during the pre- and postintervention periods. We did not impute a 0 score for the post-2 assessment data for those control subjects who showed decline, because such a strategy would inflate even further the differences between the intervention and control groups. In addition, seven intervention subjects, but no control subjects, improved over the 32-week trial from needing weight-bearing assistance for walking at baseline to being able to walk with less assistance (assistance levels 1–3) during intervention. We regard this improvement as a clinically significant outcome. These data reinforce the conclusion that the control group showed significantly higher rates of decline and less improvement than the intervention group. A large number of intervention and control residents also could not comply with the arm raise and the arm curl exercises (27 intervention and 30 control) during at least one of the assessment periods. Limited range of motion and pain were the primary limitation on residents'compliance. Similarly, 20 in-

tervention residents and 23 control residents could not stand even with maximal assistance because of contractures or paralysis problems. We therefore report standing independence or level of assistance data for the 54 intervention and 51 control residents who could stand after being brought to a standing position.

To test whether baseline resident characteristics predicted resident change over time, we calculated change scores (follow-up–baseline) for the outcomes listed in Table 2. No resident descriptive variable listed in Table 1 was correlated with change scores on any outcome measure for the intervention or the control group.

Resident Preferences Relevant to the Intervention

Attempts were made to assess preferences regarding exercise and incontinence care of all 132 residents in two of the homes. Of these residents, 105 provided complete preference information on two separate interviews. There was a statistically significant correlation within each care domain for the frequency of desired care between the two interviews, indicating that the expressed preferences were stable. The correlations ranged from 0.49 to 0.66, and all were significant at the $P < .01$ level. Intervention and control residents who provided a frequency estimate for preferred care indicated that, on average, over an 8-hour day, they preferred to be changed 3.1 times (range 0–6), toileted 2.2 times (range 0–6), walked 2.7 times (range 0–6), and wheeled 2.7 times (range 0–5). Residents were not asked to make a choice between toileting and changing care processes, and the statistically significant correlation between the two interviews support the contention that the average preference statistics reported for the group reflects the care frequency ranges preferred by these residents. There were no differences in these preferences between intervention and control residents. These preferences for care frequency approximated what actually occurred when the intervention was being implemented.

Labor Requirements to Implement the Intervention

Intervention group residents completed an average ± standard deviation of 3.2 ± 0.3 episodes of FIT per day of the four that were attempted each day. An average of 2.1 of these FIT episodes each day involved walking or wheeling exercise, and an average of 0.9 each day involved upper body exercise. Resident refusal and participation in a social activity were the primary reasons that FIT was not performed completely on any particular day. The average total time per episode of FIT over the entire 32-week intervention period was 20.7 ± 7.2 minutes when travel time and the time needed to provide exercise and incontinence care were all considered together. Incontinence care consumed an average of approximately 7 minutes per resident per episode of care, and the average travel time to locate residents was 3.4 minutes per resident per episode of care. The exercise portion of the episode accounted for the remaining 10.3 minutes per episode.

Based on the time required to provide FIT, and assuming a ratio of 10 residents to one nurses' aide on the 7:00 a.m. to 3:00 p.m. shift (a ratio that characterizes many NHs), staff would need 60 minutes of every hour—virtually all their time—to provide care to the two or three residents under their care who would be anticipated to be eligible for the intervention. This calculation reflects three assumptions that are justified based on the data reported in this paper: five of every 10 residents would qualify and want the intervention, the average amount of time per episode of care is 20.7 minutes, and two or three of these "eligible" residents would need care every hour, if the intervention is implemented every 2 hours (e.g., one group of two to three would receive care at 8:00 and 10:00 and the other group would receive care at 9:00 and 11:00). Moreover, taking into account variability in the amount of time per episode of care (± 7.2 minutes), the time required to implement FIT varied from 26 to 81 minutes per hour. Thus, even if NH staff dedicated themselves solely to these five residents, they still could not complete all care with all residents every hour for three residents. This situation grows even more difficult on the 3:00 p.m. to 11:00 p.m. shift, where typical staffing ratios are 12 to 15 residents per one nurses' aide.

DISCUSSION

The FIT intervention resulted in improvement or prevented decline in mobility, upper body strength, and continence in the majority of intervention group residents in this clinical trial. These data support conclusions from other studies in similar NH populations that document the efficacy of continence and exercise interventions.[8–14] Nevertheless, the staffing requirements needed to implement the intervention are high and exceed the staffing resources available in most NHs. We believe that limitations in staffing resources will prevent the successful transfer of the FIT intervention and other efficacious clinical interventions to NH practice.

There are several factors underlying our contention that current NH staffing is inadequate to implement the FIT intervention. First, many residents of typical NH units are likely to be candidates for the intervention. Fifty-two percent of all residents in the four NHs in this trial were eligible for FIT based on their continence status and their ability to respond to simple verbal instructions. This percentage is similar to those we have reported in other clinical trials conducted in more than 20 NHs in multiple states.[8,9,28] Based on these eligibility data, we estimate that 21 residents on a typical 40-bed NH unit would be candidates for FIT. It would be difficult to reduce this pool of eligible residents based on ethically defensible targeting criteria, because the care processes involved in FIT are consistent with regulatory guidelines, which specify that a resident's highest level of functioning should be attained.[29] Theoretically, one could exclude residents from the FIT intervention in a manner consistent with these regulations if the intervention was contrary to the resident's preferences or if objective criteria could be identified that predicted that a resident would not benefit from the intervention, but our data demonstrate that most residents preferred the intervention, and objective criteria to predict responsiveness could not be identified. The fact that 21% of the residents did not provide consent should not be taken as evidence that these residents also did not prefer the intervention. The consent process involves formal language required by human subjects committees and is sufficiently invasive to influence some families not to provide consent even if they prefer better incontinence care and exercise. Thus, we be-

lieve it would be difficult for NHs to deny eligible residents this intervention and still conform to regulatory standards. These standards contain wording that implies that the resident's highest level of functioning should be attained and their preferences considered.

The large number of NH residents who are eligible for and express a preference for the intervention, together with the amount of staff time needed to provide it, suggest that staffing resources will be a barrier in any effort to transfer these incontinence and exercise care processes to everyday practice in most NHs. In fact, the data reported in this study provide evidence that the nurses' aide staffing ratios advocated in recent government studies and by consumer groups as necessary to provide high-quality NH care (five residents to one aide) may be justified.[15] We project that two to three of these five residents could benefit from the FIT intervention and that it would be possible to provide FIT to this number of residents if one made conservative assumptions about how much time the remaining two to three residents in a five-resident caseload would require. Unfortunately, a recent report by the Center for Medicare and Medicaid Services estimates that 92% of the nation's NHs are staffed below a five resident to one aide staffing level; it is unlikely that volunteers could be used to offset these staffing limitations. The intervention is physically and mentally demanding to implement and involves personal incontinence care activities that volunteers do not find appealing.[30]

The data reported in this paper raised several important policy and ethical issues. First, if NH staffing resources do not change, consideration should be given to revising the regulatory standards based on a more realistic analysis of what care it is possible to provide with existing resources. This revision should rethink the goal of attaining the highest level of functioning for all residents, and should include advice to NHs about how to target care if a decision is made that we cannot afford to provide recommended interventions to everyone. Alternatively, more pragmatic outcome criteria that go beyond functional outcomes might have to be met before interventions are recommended for use in NHs. For example, although the FIT intervention significantly improved functional outcomes, there were no differences between groups in the incidence of acute illness, hospitalization, or mortality. These health outcome and related cost data raise questions about whether the interventions that restore a resident's "highest level of functioning" should be recommended for use in NHs if they require increased staffing investments but do not reduce healthcare costs. Cost offsets in other areas that might result from improved functioning can be identified but are difficult to document. For example, NHs currently receive survey deficiencies and can be fined or sued if they fail to provide care processes consistent with Omnibus Budget and Reconciliation Act regulations that contain abstract language about maintaining the highest level of functional status possible. Unfortunately, the imperfect ability of survey staff and lawyers to accurately determine whether optimal care processes are provided makes cost offsets in these areas difficult to prove, and it is likely that many NHs have never been penalized, even though they provide care that does not maintain functional status. Similarly, if NHs invested in the resources necessary to provide care that better maintains function, it is still possible and even likely that their effort would not be recognized or would result in fewer deficiencies. In addition, we do not see other cost offsets resulting from implementing care that improves or maintains functional status that accrue directly to the NH. All residents in this study continued to require labor-intensive staff assistance despite improved or maintained function, because no residents improved to the point that they became independent. It is unrealistic to assume that any intervention will improve functioning in these frail people to the point that they can independently and safely self-initiate exercise and toileting behaviors in the absence of staff supervision or assistance. In short, we believe that "maintaining a resident's highest level of functioning" will require care processes that are more labor intensive than the care processes that contribute to an increase in the rate of decline (e.g., occasionally changing the diapers of wet residents vs providing toileting assistance). We believe that the best argument for maintaining functioning in the frail NH population can be made based on quality-of-life benefits as opposed to tangible cost savings.

Research has demonstrated that efficacious care processes in multiple clinical areas are not successfully used in NHs.[6] The failure of clinical trials to identify the staffing requirements needed to implement these interventions are partially responsible for creating problems in translating these interventions into daily NH care.[31] This failure has spurred the development of technology transfer and dissemination models that emphasize educational methodologies, feedback (e.g., quality indicators), and regulatory incentives to change NH provider behavior. These models operate on the assumption that NH staff will implement better care if they know what to do and are properly motivated, but they ignore the fact that staffing resources are likely to be a barrier to improved care no matter how well trained or motivated the staff.

The data reported herein suggest that much more fundamental issues regarding staff resource limitations and NH reimbursement levels must be considered before launching dissemination efforts that rely on educational or other incentives. Labor requirement analyses similar to the one conducted in this study should also be an integral component of developing clinical practice guidelines and regulatory standards for clinical care in NHs. In light of this study's findings, NH staffing resources are likely to emerge as a major barrier to the translation of many efficacious clinical interventions into everyday practice in U.S. NHs. The increasing public outcry over the quality of care in our nation's NHs should include careful consideration of the resources that will be required to implement the standards of care we expect for our rapidly growing, frail older population.

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