

Prevention of Unintentional Weight Loss in Nursing Home Residents: A Controlled Trial of Feeding Assistance

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OBJECTIVES: To determine the effects of a feeding assistance intervention on food and fluid intake and body weight.

DESIGN: Crossover controlled trial.

SETTING: Four skilled nursing homes (NHs).

PARTICIPANTS: Seventy-six long-stay NH residents at risk for unintentional weight loss.

INTERVENTION: Research staff provided feeding assistance twice per day during or between meals, 5 days per week for 24 weeks.

MEASUREMENTS: Research staff independently weighed residents at baseline and monthly during a 24-week intervention and 24-week control period. Residents' food and fluid intake and the amount of staff time spent providing assistance to eat was assessed for 2 days at baseline and 3 and 6 months during each 24-week period.

RESULTS: The intervention group showed a significant increase in estimated total daily caloric intake and maintained or gained weight, whereas the control group showed no change in estimated total daily caloric intake and lost weight over 24 weeks. The average amount of staff time required to provide the interventions was 42 minutes per person per meal and 13 minutes per person per between-meal snack, versus usual care, during which residents received, on average, 5 minutes of assistance per person per meal and less than 1 minute per person per snack.

CONCLUSION: Two feeding assistance interventions are efficacious in promoting food and fluid intake and weight gain in residents at risk for weight loss. Both interventions require more staff time than usual NH care. The delivery of snacks between meals requires less time than mealtime as-

sistance and thus may be more practical to implement in daily NH care practice. *J Am Geriatr Soc* 56:1466–1473, 2008.

Key words: nursing homes; weight loss; feeding assistance interventions

Unintentional weight loss is a common problem in nursing home (NH) residents and one that is associated with adverse, costly clinical outcomes including increases in hospitalizations, morbidity, and mortality.^{1–4} The Minimum Data Set (MDS) defines a clinically significant weight loss episode for NH residents as a loss of 5% or more within a 30-day period or 10% or more within a 180-day period.⁵ A recent study including 900 NH residents showed that 48% experienced at least one weight loss episode of 5% or more of their body weight within 30 days, and 18% experienced this magnitude of loss more than once based on seven consecutive monthly weight values. This study also showed that weight loss of 5% or more within 30 days was associated with a greater risk of death.⁴ A separate longitudinal study of 335 institutionalized elderly subjects showed that patients who lost weight had a lower survival rate than those who gained weight or remained stable.³ Another cross-sectional study of 6,832 NH residents showed that poor oral intake and eating dependency increased the likelihood of a weight loss episode meeting MDS criteria and a body mass index (BMI) indicative of undernutrition.² Similar to weight loss, a low BMI (e.g., <20) also has been shown to be associated with morbidity and mortality.^{6,7}

Despite the prevalence of unintentional weight loss in the NH setting, there have been few controlled trials to evaluate interventions to affect weight status in this population. Most studies have focused on the effect of oral liquid nutritional supplements on weight loss outcomes, with mixed results.^{8–11} In practice, NH staff often do not provide supplements consistent with physician or dietitian orders, nor do they provide adequate assistance or encour-

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agement to promote consumption.^{12,13} Regardless, it remains questionable whether weight loss can be prevented in NH residents because of medical instability and comorbidity common in this population.¹⁻⁴

Two intervention studies showed that improvements in feeding assistance care during regularly scheduled meals (breakfast, lunch, and dinner) or through the delivery of additional foods and fluids between meals (snacks at 10 a.m., 2 p.m., and 7 p.m.) resulted in significant gains in oral food and fluid intake for 90% of residents with low intake.^{14,15} These feeding assistance interventions required a significant increase in staff time, from an average of less than 10 to 35 minutes per resident per meal and 1 minute or less to 12 minutes per resident per snack. In these studies, research staff implemented the interventions for only a 2-day period to determine the immediate effect of the interventions on residents' oral food and fluid intake. Thus, these studies did not determine the effect of maintaining the feeding assistance interventions on weight or BMI outcomes.^{14,15}

The purpose of this controlled trial was to evaluate the effect of two feeding assistance interventions (mealtime assistance and between-meal snack delivery) on residents' oral food and fluid intake, BMI, and weight status when maintained by research staff for 24 weeks. Two primary questions were addressed.

- (1) What effect did the feeding assistance interventions have on residents' oral food and fluid intake, weight status, and BMI?
- (2) How much staff time was required to implement the interventions?

METHODS

Setting and Recruitment

Participants were recruited from four NHs, three of which were proprietary, housing a total of 433 residents. Nurse aide-level staff-to-resident ratios across the four NHs, as reported by the directors of nursing, ranged from six to 11 residents per nurse aide on the 7 a.m. to 3 p.m. shift and 11 to 15 residents per nurse aide on the 3 p.m. to 11 p.m. shift. A total of 310 (72%) residents met study inclusion criteria, which required residents to be long stay (non-Medicare), free of a feeding tube, not receiving palliative care (hospice), and not on a planned weight loss diet at the time of the study. Written consent was obtained from the resident or the resident's responsible party designated in the medical record for 173 (56%) of the 310 eligible residents. The institutional review board at Vanderbilt University approved the study recruitment procedures. After consent, 25 participants were lost because of consent withdrawal (n = 6), transfer out of the facility (n = 5), or death (n = 14). The remaining 148 participants completed baseline assessments, and 69 residents who met study criteria were randomized into intervention or control groups for the initial 24-week period (see Study Design and Figure 1).

Study Design

This study used a crossover design wherein participants were randomized at the facility level into intervention or

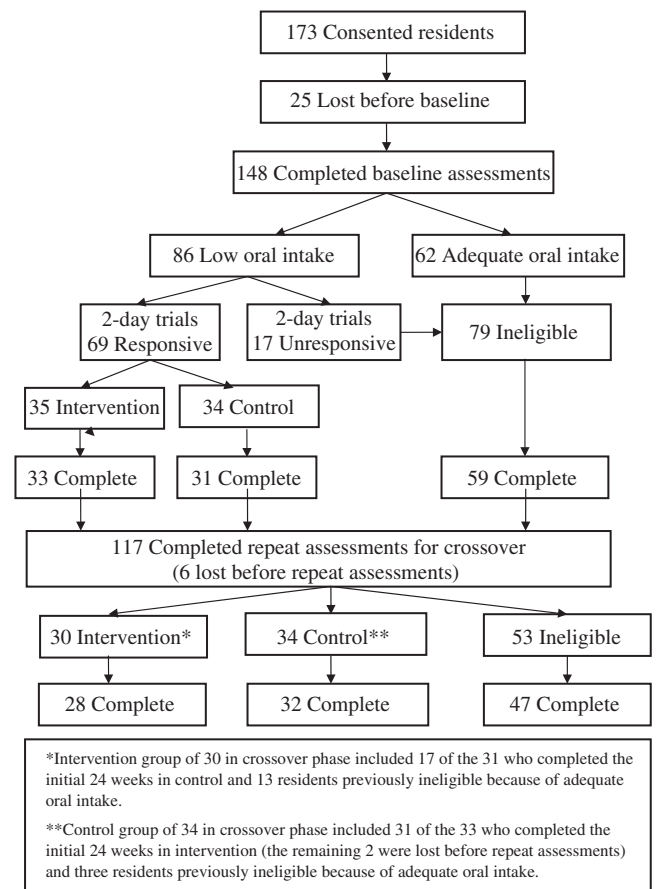


Figure 1. Flow of subjects in trial.

control groups for an initial period of 24 weeks. To randomize at the facility level, the four NHs were identified as intervention or control (in pairs of two) using a toss of the coin. To be assigned to either group, participants were required to have low oral food and fluid intake (see Oral Food and Fluid Intake) and be responsive to one of two feeding assistance interventions (see Mealtime Feeding Assistance and Between-Meal Snack Interventions) according to baseline assessments, which were completed for all consented subjects in each pair of concurrently participating NHs (one intervention and one control site in each pair). After the initial 24-week phase, all participants were reassessed for low oral intake and responsiveness to the feeding assistance interventions. Study participants who had received intervention during the initial 24 weeks crossed over into the control group for 24 weeks. Those in the control group during the initial 24 weeks crossed over into intervention for 24 weeks, if deemed eligible based on reassessment. Figure 1 shows the flow of subjects through the trial.

According to baseline assessments, participants with low oral intake who were responsive to one or both feeding assistance protocols were randomized into intervention (if residing in Facility 1) or control (if residing in Facility 2) groups. At the end of the initial 24-week period and after reassessment, participants in the control site (Facility 2) crossed over to intervention, and participants in the intervention site (Facility 1) crossed over to control. This process was repeated for Facilities 3 and 4. This design ensured that all eligible study participants would receive intervention

and avoided the possibility of contamination effects if randomization had been conducted at the resident level within each participating site.

Measures

Demographic (age, length of stay, sex, ethnicity), medical (diagnoses), and nutritional (diet and supplement orders) information was retrieved from each participant's medical record.

Research staff assessed participants' cognitive status using a standardized, performance-based assessment (Mini-Mental State Examination [MMSE]), with a score range from 0 (severely impaired or comatose) to 30 (cognitively intact).¹⁶

Weighing Procedures

Research staff conducted independent assessments of body weight monthly for 12 consecutive study months using a standardized protocol. This protocol required research staff to weigh residents in the morning, before breakfast but after incontinence care, while the resident remained in bed clothes. Research staff used the facility scale calibrated to 0. Assessments of participants' body weights were used to calculate BMI and resting energy expenditure (refer to Table 1 footnotes for formulas). A BMI less than 20 was considered indicative of undernutrition.¹⁷ Monthly weight values were also used to determine changes in weight from baseline to postintervention. The most recent monthly weight value was used as the resident's final weight value for those lost from the study before completion.

Table 1. Demographic, Medical, and Nutritional Characteristics of Participants Overall

Characteristic	Intervention (n = 61)	Control (n = 63)
Demographic		
Female, n (%)	51 (83.6)	54 (85.7)
White, n (%)	49 (80.3)	48 (76.2)
Age, mean ± SD	82.3 ± 11.9	83.5 ± 11.5
Length of stay, years, mean ± SD	3.0 ± 3.4	2.9 ± 3.5
Medical		
Diagnosis of depression, n (%)	25 (41.0)	22 (34.9)
Diagnosis of dementia, n (%)	26 (42.6)	26 (41.3)
Mini-Mental State Examination score (range 0–30), mean ± SD	15.4 ± 8.8	15.0 ± 8.6
Nutritional		
Supplement order, n (%)	30 (49.2)	35 (55.6)
Special diet order, n (%) [*]	50 (82.0)	55 (87.3)
BMI < 20, n (%) [†]	12 (19.7)	9 (14.3)
Estimated REE (daily calories), mean ± SD [‡]	1,144 ± 197	1,147 ± 183

^{*} Special diets included any restrictions (no added salt, no concentrated sugars) or altered texture (ground, mechanical soft, puree, thickened liquids).

[†] 0.454 weight in pounds/(0.254 height in inches).[‡] A body mass index (BMI) below 20 is considered indicative of undernutrition.

[‡] Harris-Benedict formulas for resting energy expenditure (REE) estimation. Male = 66.5 + 13.75 × weight in kilograms + 5.0 × height in centimeters – 6.78 × age; female = 655.1 + 9.56 × weight in kilograms + 1.85 × height in centimeters – 4.68 × age. SD = standard deviation.

Baseline Assessment: Oral Food and Fluid Intake

Research staff conducted direct observations for two consecutive days during and between regularly scheduled meals for all 148 study participants (Figure 1) to identify residents with low oral intake, which was defined according to the Minimum Data Set (MDS) criterion (leaves 25% or more of food uneaten at most meals or 4 or more of 6 observed meals).⁵ The reliability and validity of the observational protocol has been described elsewhere.¹⁸ Research staff observed each participant from the time of meal tray delivery until meal tray pickup by NH staff for all three scheduled meals (breakfast, lunch, and dinner) and between meals from 9 a.m. to 11 a.m., 1 p.m. to 3 p.m. and 6 p.m. to 8 p.m. During each observation period (meal or snack), research staff documented the total amount of time (minutes and seconds) that NH staff spent providing any type of assistance (e.g., verbal encouragement or cueing, physical help, tray setup) to the resident to promote consumption of the served food and fluid items. Research staff also estimated the percentage of each served food and fluid item (excluding coffee and water) that residents consumed and total percentage consumed (all served food and fluid items). Research staff used percentage estimates, because NH staff use the same method to identify residents with low oral food and fluid intake.^{5,18} NH guidelines suggest that residents receive an estimated total of 2,000 calories per day during regularly scheduled meals.¹⁹ Thus, an estimate of each participant's caloric intake from meals was calculated based on average total percentage consumed across the six observed meals multiplied by an estimated mean of 2,000 calories per day.

A total of 86 (58%) of the 148 participants who completed baseline assessments (Figure 1) were identified as having low intake (i.e., ate < 75% of 4 or more of 6 observed meals). Residents received additional foods and fluids between meals on average less than once per day under usual NH care conditions; thus, the amount of additional calories beyond regularly scheduled meals did not alter the resident's classification as having "low oral intake" based on meal intake alone. This same 2-day assessment protocol was also conducted 3 and 6 months after the start of each intervention phase to document intervention effects on estimated caloric intake. During each assessment (baseline, after 3 and 6 months), a digital camera was used to take photographs before and after the meal for a sample of participants' meal trays (2 meals per participant at each assessment point) to allow a rater other than the observer who was blind to group assignment (intervention vs control) to estimate total percentage eaten for reliability purposes. The observational protocol and the photography method have been shown to be reliable methods for estimation of percentage intake in NH residents.¹⁸ In this study, interrater reliability coefficients for total percentage eaten (foods + fluids) between observation and photo estimates were 0.938 at baseline, 0.943 at 3 months, and 0.928 at 6 months (all $P < .000$).

Mealtime Feeding Assistance Evaluation: 2-Day Trial

All 86 participants with low oral intake (Figure 1) received a 2-day or 6-meal (i.e., breakfast, lunch, and dinner on 2 consecutive days) trial of mealtime feeding assistance

implemented by trained research staff using the same protocol applied in previous research.^{14,15} Briefly, the intervention consisted of individual assistance (1 staff member to 1 resident), proper positioning for eating, compliance with dining location preferences, and optional meal tray substitutions. In addition, a graduated prompting protocol that enhanced the resident's self-feeding ability, to the greatest extent possible, was used during each episode of assistance.^{14,15} Food and fluid intake was estimated for each of the six intervention meals using the same observation protocol used at baseline.

Between-Meal Snack Evaluation: 2-Day Trial

All 86 study participants with low oral intake (Figure 1) also received a 2-day or six-snack (i.e., 10 a.m., 2 p.m., and 7 p.m. on 2 consecutive days) trial of the between-meal intervention. The between-meal intervention was similar to mealtime feeding assistance in that trained research staff implemented it, and it consisted of essentially the same intervention components.¹⁵ Research staff brought a moveable cart to the participant three times per day. The participant was offered a variety of food and fluid items from which to choose purchased from a local grocery that included assorted juices (e.g., apple, orange, cranberry), yogurts, ice cream, fresh fruit (bananas, grapes), puddings, pastries (doughnuts, muffins), and cheese or peanut butter and crackers. Items appropriate for people with diabetes mellitus and other special diets, including thickeners added to fluids, were provided as needed according to diet specifications documented in participants' medical records. Research staff documented each food and fluid item and the amount consumed by the participant during each snack episode. Different research staff estimated the total amount of calories consumed from snacks based on the information printed on the package of purchased items. During the same 2-day period that research staff offered snacks, the mealtime food and fluid consumption of all participants who received snacks was estimated using the same observational protocol used in baseline assessments and the mealtime feeding assistance intervention.

Intervention: 24 Weeks

Responsiveness to the mealtime feeding assistance and between-meal snack interventions was defined as an increase in oral intake of 15% or more (i.e., ≥ 300 calories/day) based on a comparison between the 2-day assessments of oral intake under usual NH care conditions and the initial 2-day trials of the interventions. A gain of 15% or more was identified in previous research as clinically significant and reflects a gain in calories of one standard deviation or more above variation in usual daily intake.^{14,15,18} Previous research has also shown that the 2-day trials are a valid method of determining which intervention protocol is most appropriate for an individual resident.^{14,15} Of the 86 study participants with low oral food and fluid intake, 69 were responsive to mealtime assistance ($n = 35$), between-meal snacks ($n = 34$), or both ($n = 30$), and 17 were not responsive to either intervention protocol. These rates of responsiveness to the two feeding assistance interventions are consistent with the results of previous studies.^{14,15} Responsive participants ($n = 69$) were randomized at the facility

level into intervention (mealtime assistance or between-meal snacks, $n = 35$) or control ($n = 34$) groups for the initial 24 study weeks (Figure 1). For participants responsive to both intervention protocols ($n = 30$), each resident was assigned to the intervention protocol that had resulted in the largest increase in estimated total daily calories based on meal and between-meal intake. The same trained research staff who completed baseline assessments and the initial 2-day trials of the intervention protocols provided the appropriate intervention (mealtime assistance or between-meal snacks) twice per day (breakfast and lunch, 10 a.m. and 2 p.m. snacks), 5 days per week, for 24 weeks.

Crossover: 24 Weeks

At the end of the initial 24 weeks, trained research staff repeated all assessments (oral intake, 2-day trials of mealtime assistance and between-meal snacks) for all study participants who remained in the study at that time point (intervention, control, and those previously ineligible because of adequate oral intake or lack of response to the 2-day intervention trials according to baseline assessments). The purpose of repeating these assessments before the crossover phase was to identify initially eligible residents who were no longer eligible for intervention and initially ineligible residents who became eligible. The facilities initially assigned to intervention crossed over to control, and the facilities initially assigned to control crossed over to intervention. Of all 148 study participants who completed baseline assessments, 31 were lost from the study during the first 24 weeks, primarily because of death (18/31, 58%). The remaining 117 received repeat assessments before the crossover phase. Based on the repeat assessments, there were 64 eligible residents, and these were placed into intervention ($n = 30$) or control ($n = 34$) groups for an additional 24 weeks (Figure 1 Crossover Phase).

Data Analyses

Baseline demographic, medical, and nutritional characteristics of intervention and control group participants were compared using chi-square analysis for categorical measures (percentage female, white, diagnosis of dementia or depression, BMI < 20 , supplement or special diet order) and *t*-tests for continuous measures (age, length of NH residency, total MMSE score, estimated resting energy expenditure). Intervention effects were measured according to change in initial body weight and BMI over each 24-week phase. Based on preliminary analyses (Technical Appendix), data from the two phases were pooled, and an ordinary least squares linear regression of the changes on the following variables was conducted: NH site (to test for NH effects wherein NH 4 was used as the reference group, because it had the largest sample size), group assignment (intervention vs control), and other potentially confounding variables (e.g., age, sex, depression diagnosis, death, or dropout). For those who completed baseline or repeat assessments and were assigned to intervention or control groups but who did not complete all 24 weeks within each phase (death or dropout), the most recent monthly weight value collected by research staff was used to calculate change in weight and BMI for the analyses. Significance of the intervention effect and other coefficients was adjusted

for within-person correlation using the robust option in Stata (Stata Corp., College Station, TX). To better understand the mechanism of the intervention effect, the difference in total caloric intake (meals plus snacks) was evaluated from baseline to 3 and 6 months during each phase (initial 24 weeks and crossover) according to group (intervention vs control) with analysis of variance for repeated measures.

RESULTS

Subjects and Setting

Table 1 compares the demographic, medical, and nutritional characteristics of all residents who received intervention during the initial 24-week or crossover phase ($n = 61$) with those of all residents in the control group during either phase ($n = 63$). These numbers reflect the pooled data used for the analysis of treatment effects (see Data Analyses) and represent 76 unique participants. There were no significant differences between intervention and control group participants on any of the characteristics shown in Table 1, as is expected with a crossover study design wherein most participants are in each group once. Both groups were predominately female and white. Participants in both groups had an average age of 82 to 83 and a length of NH residency at baseline of just less than 3 years. Participants were moderately to severely cognitively impaired, as indicated by MMSE score (15 ± 9 in both groups) and the prevalence of dementia diagnoses at baseline (41–43%). Thirty-five percent to 41% had a physician-recorded chart diagnosis of depression at baseline (Table 1). Approximately half of the participants in each group had an order for an oral liquid nutritional supplement, and the majority had some type of special diet order before intervention. Fourteen percent to 20% had a BMI of less than 20 at baseline, and estimated resting energy expenditure was approximately 1,150 calories per person per day for both groups.

All characteristics shown in Table 1 were also compared between intervention and control group participants within each 24-week phase (initial and crossover phases, see Figure 1 for sample sizes). These comparisons showed no differences between the intervention and control groups during the initial 24-week phase and only a difference in age during the crossover phase (78.5 ± 13.6 vs 86.8 ± 8.1 ; $t = 2.91$, $P = .005$).

Intervention Effects

Table 2 shows the effects of the intervention and other covariates (age, sex, baseline diagnosis of depression) for final and average BMI change values (Table 2, Models 1 and 2) and final and average weight change values (Table 2, Models 3 and 4) as the dependent variables. The intervention group gained 0.72 units more in final BMI (Table 2, Model 1) and 4 pounds more in final body weight (Table 2, Model 3) than the control group. These findings remained significant if average change in BMI (Table 2, Model 2) and weight values (Table 2, Model 4) were used in the analyses. Participants with a baseline diagnosis of depression lost 3 pounds more than those without a diagnosis (Table 2, Column 3: Depression), although this finding was not significant ($P = .06$). Participants who did not complete all 24 weeks within each phase experienced significantly more weight loss (an average of 5.5 pounds based on their final weight measurement) than those who completed all 24 study weeks within each phase (Table 2, Model 3: Death/Dropout). When the death or dropout indicator was excluded from the analysis, the intervention effects became slightly larger, with a 0.75-unit change in final BMI value (coefficient of determination (R^2) = 0.073, $P < .05$) and a 4.2-pound gain in body weight ($R^2 = 0.079$, $P < .05$). Overall, 56% of participants maintained or gained weight during the intervention phase, compared with 28% during the control phase. Of the remainder who lost weight, 16.4% experienced at least one weight

Table 2. Intervention Effects on Body Mass Index (BMI) and Weight Change Using Ordinary Least Squares Regression with Robust Adjustment

Variable	Model 1 (n = 124)			Model 2 (n = 124)			Model 3 (n = 124)			Model 4 (n = 124)		
	Coefficient	t-Value	P-Value	Coefficient	t-Value	P-Value	Coefficient	t-Value	P-Value	Coefficient	t-Value	P-Value
Intervention	0.716	2.690	.009	0.608	3.520	.001	4.011	2.690	.009	3.320	3.470	.001
Age	-0.004	-0.430	.668	-0.004	-0.670	.508	-0.033	-0.630	.534	-0.029	-0.870	.388
Female	0.150	0.410	.681	0.146	0.560	.579	0.977	0.430	.665	0.977	0.600	.549
Depression	-0.527	-1.910	.060	-0.223	-1.410	.163	-2.994	-1.950	.055	-1.147	-1.310	.194
Death or dropout	-0.926	-2.200	.031	-0.447	-1.620	.110	-5.506	-2.260	.027	-2.771	-1.720	.090
NH1	-0.525	-1.380	.170	-0.320	-1.250	.214	-2.883	-1.310	.194	-1.941	-1.300	.199
NH2	0.510	1.900	.061	-0.015	-0.090	.928	3.096	2.040	.045	-0.048	-0.050	.959
NH3	-0.057	-0.150	.885	-0.246	-1.020	.313	-0.223	-0.110	.915	-1.400	-1.050	.295
NH4	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Constant	-0.014	-0.020	.988	0.065	0.110	0.909	0.356	0.070	.941	0.729	0.240	.810
Coefficient of determination	0.111			0.113			0.122			0.120		

Note: Nursing home 4 (NH4) is the reference group, because it had the largest sample size.

Model 1 final BMI change as dependent variable.

Model 2 average BMI change as dependent variable.

Model 3 final weight change as dependent variable.

Model 4 average weight change as dependent variable.

loss episode that met MDS criteria ($\geq 5\%$ in 30 days or $\geq 10\%$ in 180 days) during the intervention phase (mean 1.2 ± 0.421 episodes per person), whereas 23.8% experienced a weight loss episode that met MDS criteria during the control phase (mean 0.8 ± 0.414 per person). There were no significant differences between NH sites on BMI and weight change outcomes (Table 2, NH1-4 where NH 4 is the reference group), except participants in NH 2 experienced more weight gain than those in NH 4.

Table 3 shows the effect of the intervention on participants' estimated total daily caloric intake (meals plus snacks) at baseline and 3 and 6 months postintervention within each phase (initial 24 weeks and crossover) for the intervention and control groups. During the initial 24-week phase, the intervention group showed a significant increase in estimated total daily calories from baseline to postintervention at 3 ($t = -4.202, P = .000$) and 6 months ($t = -3.875, P = .000$), whereas the control group showed no change (Table 3, Initial 24 Weeks). During the crossover phase, the intervention group again showed a significant increase in estimated total daily calories from baseline to postintervention at 3 ($t = -2.131, P = .02$) and 6 months ($t = -3.726, P = .000$), whereas the control group showed a significant decline over time (Table 3, Crossover) from baseline to 3 ($t = 2.808, P = .003$) and 6 months ($t = 1.970, P = .03$). Most of the individuals in the control group during the crossover phase were in the intervention group during the initial 24 weeks (31 of 34 persons); thus, the baseline value for this group at crossover reflects their estimated total daily calories while the intervention was still in place for these individuals, whereas the values at 3 and 6 months reflect their estimated total daily calories while reverting back to usual NH care. An analysis of variance for repeated measures confirmed the significant difference in caloric intake between the two groups during each 24-week phase (initial $F = 9.66, P = .000$; crossover $F = 6.53, P = .000$). The average amount of NH staff time spent providing assistance to eat during meals to residents in the control group showed no significant change during the initial 24-week or crossover phase (average < 10 minutes per person per meal at each measurement point for all meals).

Of the 76 participants who completed intervention, 19 (25%) received mealtime assistance, and 57 (75%) received assistance with snacks, thus, most of the gain in estimated total daily calories for the intervention group was from snacks. A greater proportion of participants was assigned to assistance with snacks, because more than half of those responsive to both intervention protocols showed a greater

gain in total daily calories as a result of the snack intervention; thus, these residents were assigned to assistance with snacks even though they were also responsive to mealtime assistance. Research staff spent an average of 42.2 ± 19.1 minutes per person per meal providing mealtime assistance. Most often (87% of care episodes), assistance was provided one to one, and occasionally (13% of care episodes), research staff were able to group participants together in small groups of two to three for mealtime assistance to make the intervention more time efficient. The snack intervention required an average of 13.9 ± 10.3 minutes of research staff time per person per snack. Research staff were able to group residents together more often for snack delivery (24% of care episodes) and in larger groups (up to 4 residents per group).

DISCUSSION

The prevalence of unintentional weight loss reported for NHs is considered an indicator of nutritional care quality, although it has been unclear in previous work to what extent unintentional weight loss is preventable in long-stay NH residents.²⁰ The results of this study show that sustained optimal feeding assistance can affect weight-loss outcomes in residents at risk for weight loss due to low oral intake. This study is the first controlled intervention trial to evaluate the effects of sustained feeding assistance on NH residents' oral food and fluid intake, BMI, and weight. Results showed that optimal feeding assistance provided during or between regularly scheduled meals, twice per day, 5 days per week, for 24 weeks had a significant effect on all three outcome measures. Mealtime feeding assistance required an average of 42 min/resident per meal, whereas the delivery of snacks between meals required an average of 14 min/resident per snack. These staff time estimates to provide feeding assistance in a manner that promotes oral food and fluid intake and independence in eating are consistent with the results of previous studies.^{14,15} Unfortunately, the amount of staff time spent providing feeding assistance under usual NH care conditions averaged less than 10 minutes per person per meal and less than 1 minute per person per snack in this and previous studies.¹³⁻¹⁵ More than half of the participants in this study were responsive to both interventions (mealtime assistance and between-meal snack delivery), and between-meal snack delivery resulted in the largest caloric gain for many of these participants even though they were also responsive to mealtime assistance. Only occasionally (13% of care episodes) were re-

Table 3. Estimated Total Caloric Intake According to Group and Phase

Measure	Initial 24-Week Intervention (n = 33)	Initial 24-Week Control (n = 31)	Crossover Intervention (n = 28)	Crossover Control (n = 32)
	Mean \pm Standard Deviation			
Baseline	1,237 \pm 302	1,189 \pm 398	1,204 \pm 377	1,504 \pm 356
Post 3 Months	1,615 \pm 420	1,243 \pm 401	1,451 \pm 481	1,281 \pm 259
Post 6 Months	1,539 \pm 322	1,316 \pm 476	1,583 \pm 331	1,323 \pm 339

Average total daily calories was estimated based on an average 2,000-calorie/day diet provided by the facility across three scheduled meals plus any additional calories from food and fluid items provided between meals (2-day assessment at each of three time points). Daily caloric intake estimates are reported per person per day and rounded to the nearest whole number.

search staff able to group residents together to make daily care provision more time efficient. Previous studies have shown that group feeding assistance is as effective as one-to-one care.^{14,15} Given that most U.S. NHs do not have adequate nurse aide staffing to provide feeding assistance for all residents in need, it may be more feasible in daily care practice to group residents at risk for unintentional weight loss for snack delivery at least twice daily.^{14,15,21,22}

The results of this study also showed that residents with a diagnosis of depression lost more weight than those without a diagnosis. Previous studies have shown that depression is a major cause of unintentional weight loss, and depressive symptoms often are undetected and thus untreated in NH residents.^{23–25} Thus, future intervention studies should combine feeding assistance interventions with optimal treatments for depression.

Participants who did not complete the study also experienced more weight loss than those who did, and the primary reason for not completing the study was death. Numerous studies have shown that unintentional weight loss and low BMI are both predictive of mortality.^{2–4,6,7} Thus, it is not surprising that the findings from this study showed that most of those lost from the study because of death experienced weight loss.

This study has a few important limitations. First, it was conducted in only four NHs located in one geographic region, and participants were predominately female and white. Thus, these findings may not be generalizable to NHs in other geographic regions or to minority or male NH residents. In addition, the number of residents included in the trial was small relative to the total resident population in each facility, although the proportions of NH residents with low oral intake who were responsive to the feeding assistance interventions were comparable with those shown in previous studies.^{14,15} Finally, research staff provided the interventions; it is unknown whether indigenous NH staff could maintain these interventions with sufficient consistency in daily care practice to have the same effects on residents' oral intake, weight, and BMI status.

Standardized protocols have been developed based on previous research and made available on-line (<http://borun.medsch.ucla.edu> "Weight Loss Prevention" module, and <http://www.cms.internetstreaming.com> "How to Enhance the Quality of Dining Assistance in Nursing Homes" Web cast) to assist supervisory NH staff in identifying residents appropriate for feeding assistance care during or between meals and ensuring that direct care staff consistently provide this care in practice.^{26,27}

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Conflict of Interest: The editor in chief has reviewed the conflict of interest checklist provided by the authors and has determined that the authors have no financial or any other kind of personal conflicts with this paper.

Author Contributions: Simmons and Schnelle were involved in all aspects of the study. Keeler and Zhuo conducted data analyses; interpreted data; and prepared the analyses section, tables, and appendices. Sato and Hickey were involved in acquisition of subjects and data.

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Appendix 1. Technical Appendix for Data Analyses

The data passed most checks for potential complications, which allowed the use of simple methods. Following is a description of eight issues related to the data analyses and the results of some sensitivity checks.

1. Use of differences from initial weight as the dependent variable. Body weight and height-adjusted body mass index (BMI) were stable over time. As a result, adjustment for initial values improved the precision of the estimated intervention effects. The most common adjustment methods are regressing final values on initial values and intervention assignment or studying changes from initial values. Using changes from initial values is equivalent to assuming that the regression coefficient on initial values is 1. The coefficients on initial values were in all cases between 0.9 and 1, so the two methods led to comparable estimates for the treatment effect. For simplicity, change from initial values was used as the dependent variable.

2. Nursing home (NH) fixed effects. Randomization was at the facility level, so some aspect of the NH (e.g., resident samples, staff) might have influenced treatment effects. Thus, fixed effects for the NH site (i.e., indicator variables for all but one NH) were included in the analyses to control for the effect of NH site on intervention effects. Because of the crossover design (each of the four NHs is a control site in one 6-month period and a treatment site in the other 6-month period), NH site is not identical with treatment.

3. Use of ordinary least squares (OLS) regression. The studentized residuals from simple OLS models were roughly normally distributed. Residuals were checked for heteroscedasticity for NH site, initial weight value, and influential observations (e.g., outliers that increase or decrease the estimates to a great extent), and none were found. Because residuals from OLS regression were well behaved, hierarchical models were not used, and the dependent variable was not transformed.

4. Unit of analysis is the person/6-month phase, with the data from participants in both phases counting as two observations. The correlations of residuals across phases for participants was small (-0.05) and not significant. For this reason, neither repeated measures nor panel data methods were used, although robust tests of significance clustering on participants were used in the regressions.

5. Inclusion of deaths and dropouts. There were six deaths or dropouts of intervention participants and nine of control participants with usable data. Deaths or dropouts may be controlled for in the analysis by excluding these cases or including an indicator in the regression that adjusts for deaths and dropouts. Because low BMI or weight loss is predictive of death and may be affected by intervention, persons lost from the study due to death or dropout were included in the final analyses using their most recent monthly weight value as their final weight. Results without the death or dropout indicator made the intervention effects slightly larger (0.2 pounds on average over the entire sample.) Intervention effects were similar in magnitude but slightly less significant when these cases were omitted from the sample.

6. Choice of covariates in the regression. Although this was a randomized trial, and the analyses controlled for initial weight, other differences in the NH participants also might affect weight. Thus, the analyses also controlled for age, sex, and depression.

7. Average weight or final weight as the outcome. The intervention aimed at maintaining or increasing weight of NH residents at risk for unintentional weight loss due to low oral intake. Research staff measured weight monthly, and the effect of low weight on health status presumably depends on how long a resident is in that vulnerable state, so there is some reason to use average weight change as the dependent variable. In addition, fluctuations in weight over time make the one-time final weight measure noisier than an average weight measure. Alternatively, weight change is a long, slow process, and the differences in final weight values for a successful intervention will be larger and easier to interpret than changes in average weight. Ultimately, separate analyses were conducted for each measure (average and final weight as the dependent variable), as well as a measure of undernutrition (average and final BMI value).

8. Interactions with treatment. Interactions of the treatment effect were tested with depression and death or dropout, which were the two covariates with the largest effect on weight loss. The treatment effects were similar in all groups with or without these indicators.