

The Effect of Megestrol Acetate on Oral Food and Fluid Intake in Nursing Home Residents: A Pilot Study

Sandra F. Simmons, PhD, Kathleen A. Walker, and Dan Osterweil, MD, CMD

Objectives: The objective of this study was to evaluate the effect of megestrol acetate (Megace[®]OS; Bristol-Myers Squibb, Princeton, NJ) on the oral food and fluid intake of nursing home (NH) residents under two conditions: usual NH care and optimal mealtime feeding assistance.

Design and Setting: We conducted a prospective, preliminary trial in four NHs.

Participants: Participants (n = 17) were recruited from a larger study designed to assess nutritional care quality. Eligibility for the Megace[®]OS trial required participants to consistently eat less than 75% of most meals under both usual NH care and optimal feeding assistance conditions at baseline.

Intervention: Megace[®]OS, an oral liquid suspension of megestrol acetate, was given daily in a 400-mg dose for 63 days.

Measurements: Each participant's oral food and fluid intake was monitored weekly for 1 day (three meals) during which research staff conducted direct observations of usual NH care (weeks 1, 3, and 5 and day 63) or provided optimal feeding assistance (weeks 2, 4, and

6). Average total percent intake was compared from baseline across the assessment weeks of the trial under the two mealtime care conditions.

Results: Megace[®]OS had a significant effect on oral food and fluid intake only under the optimal mealtime feeding assistance condition, in which average total percent eaten increased from 50% ($\pm 15\%$) at baseline to 63% ($\pm 14\%$) post-63 days of the trial. There was no change in participants' oral food and fluid intake under the usual NH care condition (average total percent intake at baseline 43% $\pm 12\%$ vs. 43% $\pm 20\%$ post-63 days).

Conclusion: The results of this preliminary study suggest that Megace[®]OS is not an effective nutritional intervention to increase oral intake under usual NH care conditions, which is often characterized by inadequate feeding assistance. However, Megace[®]OS in combination with optimal mealtime feeding assistance does significantly increase oral intake in a frail NH sample at high risk for weight loss. (*J Am Med Dir Assoc* 2005; 6: S5–S11)

Keywords: Megace; oral intake; nursing home; feeding assistance

A decrease in appetite, and, consequently, a decrease in daily food intake, can lead to weight loss and malnutrition. The results of multiple studies have shown that 64% to 80%

of nursing home (NH) residents have low oral food and fluid intake as defined by the federal criterion.^{1–4} Low oral food and fluid intake is federally defined as any person who consistently eats less than 75% of the food offered during most meals.⁵ Nursing home residents with low oral food intake have a greater risk for numerous adverse clinical outcomes, including delayed wound healing and increases in the rates of infections, hospitalizations, and mortality.^{6–8}

Commonly prescribed routine medications with appetite-suppressant side effects and special diet orders are likely to contribute to a decrease in appetite and poor oral intake in the NH population.⁹ However, the results of recent studies strongly suggest that behavioral and environmental factors

University of California, Los Angeles, School of Medicine, Department of Geriatrics, Borun Center for Gerontological Research, Los Angeles, CA (S.F.S., K.A.W., D.O.); the Jewish Home for Aging Research, Reseda, CA (S.F.S. and K.A.W.).

Address correspondence to Sandra F. Simmons, PhD, Jewish Home for the Aging/UCLA Borun Center for Gerontological Research, 7150 Tampa Avenue, Reseda, CA 91335. E-mail: ssimmons@ucla.edu

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could be more important contributing factors to low oral intake among NH residents. These factors, which also could be more amenable to intervention, include: staff failure to identify residents with poor oral intake; inadequate staff to provide feeding assistance; feeding assistance that fails to promote independence; and social isolation during mealtime.^{3,10–15} The results of a recent controlled intervention study showed that approximately 50% of residents with low intake significantly increased their intake with improvements in the adequacy and quality of mealtime feeding assistance.³ Nursing home residents who are not responsive to mealtime feeding assistance could be appropriate for an appetite-stimulant medication such as Megace (Bristol-Myers Squibb, Princeton, NJ) to improve appetite and daily oral intake.

Megace has been effective in improving the appetite and nutritional health of patients with chronic pulmonary obstructive disorder, terminal cancer, and AIDS, although its specific mechanism is currently unknown.^{16–18} According to one study, Megace is suspected to reduce cytokine levels, but the exact way that reduced cytokine levels lead to weight gain remains unclear.¹⁹ There have been few controlled evaluations of the effectiveness of Megace for promoting weight gain among NH residents.^{20–22} The results of a recent study with a sample of predominantly male geriatric veterans showed that Megace improved appetite after 12 weeks and promoted weight gain over 25 weeks since the start of the trial and 13 weeks after discontinuation of the medication.²² Other studies, each with a small sample, have shown a delayed effect of Megace in promoting weight gain.^{20,21} In addition, studies have reported few to no side effects attributable to Megace.^{20–22} In each of these previous studies, weight gain was evaluated as the primary outcome measure rather than oral intake, although clinically meaningful weight gain can only be mediated by an increase in daily oral intake. Inadequate feeding assistance as a contributing factor to weight loss was also not considered in these previous studies.^{20–22}

For Megace to be a practical treatment in the NH setting, the mechanism that mediates weight gain effects of the medication must be on residents' daily oral food intake, and the adequacy of feeding assistance must be considered. The purpose of this study was to evaluate the effect of Megace on the oral intake of NH residents under two conditions: usual NH care and when optimal feeding assistance was provided during meals.

METHODS

Subjects and Setting

Participants were recruited from a larger study designed to assess the quality of nutritional care practices. The larger study was conducted in four NHs, two of which were for-profit. The mean bed size of the four NHs was 156 (± 42). Nurse-aide level staff-to-resident ratios across the four NHs, as reported by the Directors of Nursing, ranged from seven to 10 residents per nurse aide on the 7 AM to 3 PM shift (eg, breakfast and lunch) and seven to 14 residents per nurse aide on the 3 PM to 11 PM shift (dinner). Licensed staff ratios ranged from 13 to 30

and 20 to 44 residents per licensed staff during the day and evening shifts, respectively.

Inclusion and Exclusion Criteria

Inclusion criteria for the larger study required participants to be long-stay (non-Medicare), free of a feeding tube, and not receiving palliative care (hospice). Additional inclusion criteria for the Megace trial required participants to consistently eat less than 75% of most meals (federal criterion for low oral intake) under both usual NH care conditions and when optimal mealtime feeding assistance was provided during a 2-day trial (six meals).

Exclusion criteria for the Megace trial included the presence of any one of the following medical conditions: active gastrointestinal or dental disease that precluded eating orally, active cancer, thromboembolic disease within the last 6 months, uncontrolled hypertension, a history of adverse reactions to Megace use or current medications that included Megace, cyproheptadine (PeriactinTM), or mirtazapine (RemeronTM). These medical exclusionary criteria were determined based on medical record review and consultation with each eligible participant's respective primary care physician.

Recruitment

Written consent was obtained from the resident, if capable of informed consent, or from the resident's responsible party

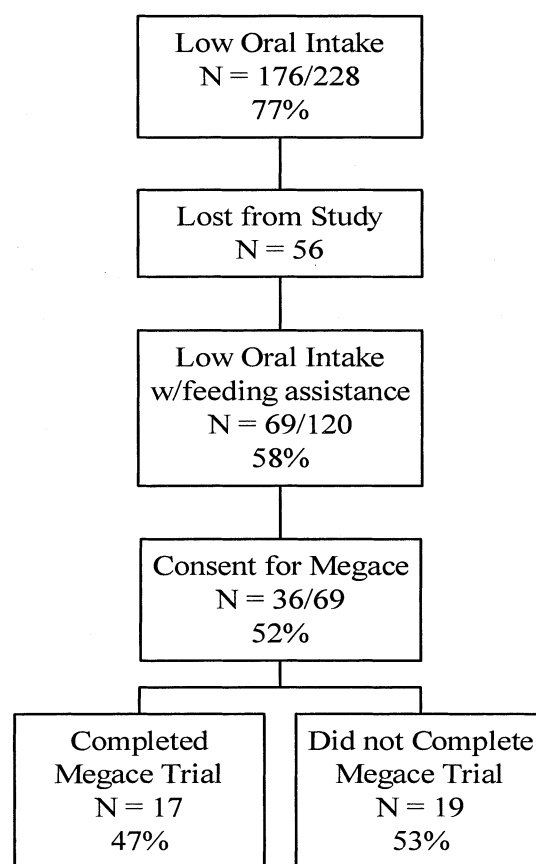


Fig. 1. Recruitment of participants into Megace trial.

designated in the medical record. Consent procedures were approved by the University of California, Los Angeles, Institutional Review Board. A total of 247 of 358 eligible residents (69%) provided informed written consent to participate in the larger nutrition study. Figure 1 shows the recruitment procedures for the Megace trial. Of the 247 consented residents, 228 (96%) completed baseline assessments of oral food and fluid intake under usual NH care conditions. A total of 176 of 228 residents (77%) who completed assessments had low oral intake (ate less than 75% of four or more of six meals), which is similar to the proportion of residents with low oral intake that has been reported in other studies based on the federal criterion.^{1–4} After baseline assessments, 56 participants were lost from the study as a result of consent withdrawal, transfer out of the facility, insertion of a feeding tube, hospitalization, or death.

A 2-day trial of optimal feeding assistance was completed during meals for each of the remaining 120 study participants. Briefly, research staff provided optimal feeding assistance for 2 consecutive days (six meals) in which both the adequacy and quality of assistance were improved from usual NH care conditions. A total of 69 (58%) participants continued to have low oral intake (ate less than 75% of most meals) even with optimal mealtime feeding assistance. Informed written consent to participate in the Megace trial was obtained from 36 of the 69 (52%) eligible (low oral intake under both usual NH care and optimal feeding assistance conditions) participants. The 63-day Megace trial was completed by 17 (47%) participants. The remaining 19 participants did not complete the trial as a result of hospitalization ($n = 1$), medical reasons ($n = 9$), or death ($n = 9$). Specifically, 12 participants were lost before beginning the trial and the remaining seven were lost after the trial had begun.

Measures

Demographic, medical, and nutritional information was retrieved from each participant's medical record. Cognitive status was assessed with the standardized Mini-Mental State Examination (MMSE) for each participant.²³ Megace was given in 400-mg daily doses of megestrol acetate oral liquid suspension in the morning for a 63-day trial period.²⁴ A 400-mg daily dose is a low dose compared with that used in other studies (800 mg per day).^{20–22} However, this study evaluated the minimum possible effective dose in a frail, elderly NH population. Research staff reviewed medical records (ie, medication book, nurses' notes) weekly for documentation of medication delivery by licensed staff.

Monitoring of Side Effects

The following symptoms have been noted as potential deleterious side effects of Megace: edema or swelling, diarrhea, rash, nausea, male sexual problems such as impotence and loss of libido, vomiting, and blood clots.²⁴ The presence of each of these symptoms in addition to cough, fever, decreased strength, increased fatigue, shortness of breath, nervousness, gas or bloating, and weakness was examined at baseline for each study participant. Side effects were then monitored weekly throughout the 63-day trial to identify the onset of any

new symptoms (ie, not present at baseline). In addition, participant report of an increase in appetite or energy was also monitored weekly. These weekly data were collected from three data sources: participant interview using a standardized form, charge nurse interview, and medical record review (licensed nurse and physician notes). A side effect was deemed "present" if there was corresponding documentation based on any one of these three data sources.

Baseline Assessment of Oral Food and Fluid Intake

Research staff conducted direct observations for 2 consecutive days during meals (six meals) to identify residents with low oral intake. Percentage estimates for each food and fluid item on the meal tray and total intake were estimated during meals based on the direct observations. Total time (in minutes) that NH staff spent providing feeding assistance was also documented during the direct observations. Participants who consumed less than 75% of the foods and fluids offered during four or more of six observed meals were identified as having low oral intake. In addition, direct observations were conducted during the following time periods for 2 days to capture NH staff delivery of any food or fluid items, including oral nutritional supplements, between meals: 9 AM to 11 AM, 1 PM to 3 PM, and 6 PM to 8 PM. Research staff documented each type of food and fluid item given, including the amount and the percent (food) or amount (fluid ounces of fluids) consumed by the resident between meals.

Mealtime Feeding Assistance Protocol

Research staff provided optimal feeding assistance to each participant with low oral intake during a separate 2-day (six-meal) period. The feeding assistance protocol consisted of the following components: one-on-one, continuous assistance; a standardized graduated prompting protocol that enhanced self-feeding capabilities; social stimulation throughout the mealtime period; compliance with resident's preference for dining location and type of assistance; proper positioning for eating; meal tray substitutions if preferred by a resident; and, extended access to tray, up to 1.5 hours per meal. The reliability and validity of this protocol has been reported elsewhere.³ Participants who continued to have low oral intake during meals with optimal feeding assistance were identified based on this 2-day trial.

Reliability of Intake Estimates

Photographs were taken of a sample of participants' meal trays before and after at least two meals per condition (usual care and optimal feeding assistance). Estimates of total percent consumed based on the photographs were conducted by different research staff who were blind to the condition (usual NH care or optimal feeding assistance). The agreement between oral intake estimates based on the direct observations and the photographs was high ($r = 0.974$, $P < 0.001$). Both the direct observation and meal tray photograph methods have been shown to yield reliable and valid estimates of NH residents' oral food and fluid intake.⁴

Outcome Measure: Oral Food and Fluid Intake By Condition

The same methods used to assess baseline oral intake under the two care conditions (usual NH care and optimal feeding assistance) were used to monitor participants' oral intake weekly during the 63-day trial. Specifically, research staff conducted direct observations of usual NH care or provided optimal feeding assistance 1 day per week (breakfast, lunch, and dinner). The mealtime care condition (usual care vs. optimal feeding assistance) alternated weekly, as displayed in Table 1. Specifically, assessments of each participant's intake under the usual NH care condition during meals were conducted 1 day per week during weeks 1, 3, and 5 and day 63 (for a total of four measures). Assessments of each participant's intake under the optimal feeding assistance condition were conducted 1 day per week during weeks 2, 4, and 6 (for a total of three measures).

Outcome Measure: Weight Status

Research staff independently weighed participants using a standardized protocol at baseline and day 63 of the trial. Specifically, each participant was weighed in the morning before breakfast but following incontinence care, although they remained in their bedclothes using the NH scale, which was calibrated to zero, at each time point.

Data Analyses

Demographic, medical, and nutritional characteristics were compared between the 36 eligible, consented residents and the 33 eligible residents who did not consent to the Megace trial using *t* tests for independent samples for continuous variables (eg, age, length of stay, baseline oral intake) and chi-squared analyses for categorical variables (eg, sex, ethnicity, dementia or depression diagnoses). These characteristics were also compared between the 17 participants who completed the Megace trial and the 19 participants who did not complete the trial. To evaluate the effect of Megace on participants' oral food and fluid intake over the 63-day course of the study by care condition, a repeated-measures analysis of variance with Bonferroni adjustments for multiple comparisons, 95% confidence intervals, and a significance level of *P* < 0.05 was conducted to compare the average total percent intake for the group (*n* = 17 completed the trial) from baseline across the weeks of the trial under the two conditions: (1) usual NH care (assessment weeks 1, 3, and 5 and day 63) and (2) optimal feeding assistance (assessment weeks 2, 4, and 6). Each participant's change in weight was calculated from baseline to

day 63 of the trial to identify episodes of weight loss or gain; and, weight status was compared for the group of participants between the two time points using *t* tests for paired samples.

RESULTS

Participant Characteristics

Table 2 shows the demographic, medical, and nutritional characteristics of the 17 participants who completed the Megace trial. The participants were predominantly female (88%) and white (88%). They had mild to moderate cognitive impairment, as indicated by the prevalence of physician- recorded chart diagnoses of dementia (41%) and an average MMSE total score of 16.2 (±5.0). The prevalence of physician-recorded chart diagnoses of depression was 35%. The body mass index (BMI) of participants showed that 41% (*n* = 7) had values below 20, which is indicative of undernutrition. The majority (65%) received at least one routine medication with appetite-suppressant side effects. Most participants had an order to receive a special diet (59%) or a daily oral liquid nutritional supplement (94%). In addition to consuming less than 75% of most meals, the majority (82%) of participants also consumed less than 50% of most meals, which has been shown to be a more clinically significant predictor of weight loss than the federal criterion.²⁵ There were no significant differences between the 36 eligible, consented participants and those who were eligible but who did not consent (*n* = 33) on any of the characteristics displayed in Table 2. There were also no significant differences on any of these characteristics between the participants who completed the trial (*n* = 17) and those who did not complete the trial (*n* = 19).

The results of the baseline assessments are also shown in Table 2. Participants consumed an average of 43% (±12%) of their meals and received an average of 2.8 minutes (±4.0) of assistance per meal from staff under usual NH care conditions. In comparison, participants consumed an average of 50% (±15%) of their meals when research staff provided optimal feeding assistance, which included an average of 31.0 minutes (±7.4) of assistance per meal. The amount of feeding assistance received by participants throughout the trial was comparable to baseline values for each condition. Specifically, participants continued to receive an average of less than 5 minutes of assistance per meal under usual NH care conditions and 30 minutes per meal under the optimal feeding assistance condition. Baseline assessments (not shown in Table 2) also showed that participants consumed few calories between meals under usual care (mean = 45 ± 92 calories per day; mode = zero). Nursing home staff offered participants predominantly fluids (juice or supplements) on average 1.7 (±1) times per day between regularly scheduled meals but little to no assistance to encourage consumption.

Effect of Megace on Oral Intake

The effect of Megace on oral intake under both usual NH care and optimal feeding assistance conditions is shown in Figure 2. There was a significant increase in the average total percent consumed of participants from baseline (50% ± 15%) to weeks 4 (66% ± 26%) and 6 (63% ± 14%) of the Megace

Table 1. Care Condition Monitored Each Week of Megace Trial

Week 1	Usual care—3 meals
Week 2	Feeding assistance—3 meals
Week 3	Usual care—3 meals
Week 4	Feeding assistance—3 meals
Week 5	Usual care—3 meals
Week 6	Feeding assistance—3 meals
Day 63	Usual care—3 meals

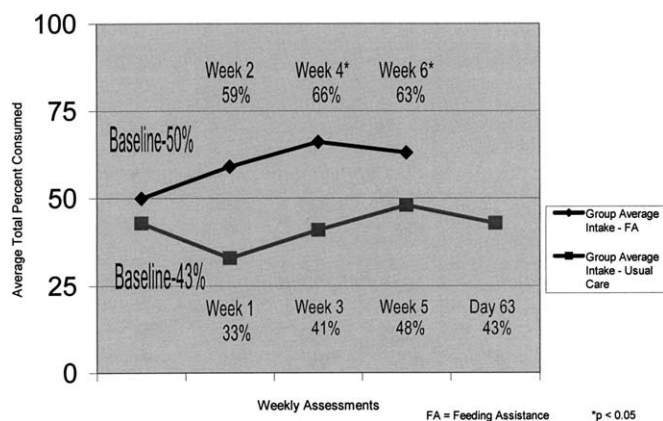
Table 2. Demographic, Medical, and Nutritional Characteristics of Participants (n = 17)

Characteristic	Percent (no.) or Mean (± standard deviation)
Demographic	
Percent female	88% (15)
Percent white	88% (15)
Age	91.9 (±5.8)
Length of stay (years)	2.3 (±1.9)
MMSE total score (0–30)	16.2 (±5.0)
Medical	
Physician-recorded diagnosis of dementia	41% (7)
Physician-recorded diagnosis of depression	35% (6)
Routine medications with appetite-suppressant side effects	1.1 (±1.0)
Proportion with ≥1 routine medication with appetite-suppressant side effects	65% (11)
Order for special diet	59% (10)
Order for nutritional supplements	94% (16)
Nutritional status measures	
Body mass index <20*	41% (7)
Percent of participants consuming <50% of most meals	82% (14)
Baseline percent of meals consumed under usual care	43 (±12)
Baseline percent of meals consumed w/feeding assistance	50 (±15)
Time (min.) spent per resident per meal under usual care	2.8 (±4.0)
Time (min.) spent per resident per meal w/feeding assistance	31.0 (±7.5)

MMSE, Mini-Mental State Examination.

* BMI formula = $0.454 \text{ weight in pounds} / (0.254 \text{ height in inches})^2$.

trial under the optimal feeding assistance condition ($F = 5.73$, $P < 0.05$). The gains in average total percent consumed of 16% and 13% from baseline to weeks 4 and 6, respectively, translate into an estimated gain of 320 or 260 calories based on a 2000-calorie per day diet, which is the federal requirement for NH food service. In comparison, there was no change in the average total percent consumed of participants under the usual NH care condition ($43\% \pm 12\%$ vs. $43\% \pm 20\%$ baseline to final 63-day assessments, respectively). Based on weekly assessments, 53% of participants reported an increase in appetite and 41% reported an increase in energy during the 63-day trial.

**Fig. 2.** Effects of Megace on oral food and fluid intake by care condition (n = 17).

Effect of Megace on Weight Status

Megace did not have a significant effect on the weight status of the group of participants. Specifically, the group of participants experienced a mean weight loss of $2.13 (\pm 9.32)$ pounds from baseline to day 63 of the trial. Individual-level data showed that nine (53%) participants experienced a weight loss (mean loss = 9.3 ± 5.4 lbs.), whereas the remaining eight (47%) participants experienced a weight gain (mean gain = 5.9 ± 4.9 lbs.).

Side Effects

Table 3 shows the proportion of participants who showed evidence (resident interview, charge nurse interview, or medical record review) of a new (not present at baseline) side

Table 3. Proportion of Participants Experiencing New Side Effect Symptoms (N = 17)

Symptom	No. (%)
Cough complaints ≥1	5 (29%)
Fever complaints ≥1	0 (0%)
Strength complaints ≥1	8 (47%)
Fatigue complaints ≥1	7 (41%)
Nausea complaints ≥1	1 (6%)
Breathing complaints ≥1	3 (18%)
Diarrhea complaints ≥1	2 (12%)
Nervousness complaints ≥1	5 (29%)
Gas complaints ≥1	2 (12%)
Weakness complaints ≥1	4 (24%)
Leg Swelling complaints ≥1	4 (24%)
Rash symptoms ≥1	4 (24%)

effect at least once during the 63-day trial. The most common new deleterious symptoms experienced by participants were a decrease in strength (47%) and an increase in fatigue (41%).

DISCUSSION

The results of this preliminary study showed that Megace did not increase the oral food and fluid intake or weight status of NH residents under usual care conditions, which consisted of inadequate feeding assistance (an average of less than 5 minutes of assistance from staff per meal). In contrast, oral intake did improve when optimal feeding assistance (an average of 30 minutes of assistance per meal) was provided to participants. Specifically, Megace given in combination with optimal feeding assistance resulted in participants eating more than 50% of their meals on average, which could lower weight loss risk,²⁵ although it is notable that the intake of many participants still remained below the federal 75% criterion.⁵ Because optimal feeding assistance was not provided consistently throughout the 63-day trial, we would not expect an effect on weight status. These preliminary results suggest that Megace in combination with optimal feeding assistance could improve oral intake during meals for residents who were not previously responsive to feeding assistance alone. Optimal feeding assistance would have to be provided consistently (ie, daily at every meal) in combination with Megace to evaluate if this combined nutritional intervention approach would result in clinically meaningful effects such as a reduction in weight loss episodes. We have demonstrated in other studies that optimal feeding assistance can be effectively provided in small groups of three (one staff member to three residents) to allow for more time-efficient daily care provision.^{3,26}

There are limitations of this preliminary study. First, the participant sample was small, and there was a high rate of attrition. Second, this was not a randomized, placebo-controlled trial. Most important, given the results, there was an absence of a control group who received optimal feeding assistance alone. However, participants of the larger nutritional study who were initially unresponsive to mealtime feeding assistance based on a 2-day trial remained unresponsive with repeated exposure to the intervention.^{3,26} Thus, it is unlikely that a feeding assistance alone control group in this study would have altered the results. Third, the intervention did not include discontinuation of routine medications with appetite-suppressant side effects, which were common among participants. Finally, oral intake and weight status were not monitored for participants after completion of the trial. Other studies have shown a delayed effect of Megace on weight status.^{20,21}

Since the completion of this trial, other behavioral interventions have been evaluated for NH residents who were not responsive to optimal mealtime feeding assistance. Specifically, the results of a recent controlled trial showed that the provision of foods and fluids between meals, which included adequate staff assistance, was effective in improving the oral intake of the majority of residents who were not responsive to mealtime feeding assistance.²⁶ The results of this behavioral intervention study suggest that only a small proportion (estimated 10%) of NH residents with intake below the federal

criterion will not improve their intake if provided with one of two behavioral interventions.²⁶ However, Megace in combination with either of these behavioral interventions could be appropriate for NH residents at particularly high risk for weight loss. It is notable that participants in this study received little food or fluid items, including oral liquid nutritional supplements, between meals under usual NH care. These results are consistent with previous findings that NH staff do not consistently deliver supplements to residents between meals or provide adequate assistance to encourage consumption.²⁷

Family members of NH residents express a preference for behavioral intervention approaches to improve residents' oral intake. A recent study showed that family members rated improving the adequacy and quality of mealtime feeding assistance and the provision of foods and fluids between meals as significantly more preferable to oral liquid nutritional supplements or a medication to stimulate appetite, which was consistently rated as least preferable.²⁸ Finally, it is important to note that a low dose (400 mg per day) of Megace was used in this study compared with the dose evaluated in previous studies (800 mg per day).^{19,22} A higher dose of the medication could have resulted in a greater increase in oral intake by participants in both usual NH care and optimal feeding assistance conditions.

CONCLUSION

The results of this preliminary study showed that Megace was not an effective nutritional intervention to increase the oral food intake of NH residents given inadequate feeding assistance during meals. Megace was only effective in improving oral intake when given in combination with optimal mealtime feeding assistance.

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