# Short-Term Oral Nutritional Intervention with Protein and Vitamin D Decreases Falls in Malnourished Older Adults

*Floor Neelemaat, MSc, RD,[*†‡] Paul Lips, MD, PhD,[§‡] Judith E. Bosmans, PhD,[‖‡] Abel Thijs, MD, PhD,[†] Jaap C. Seidell, PhD,[‖‡] and Marian A. E. van Bokhorst-de van der Schueren, PhD, RD[*†‡]*

**OBJECTIVES:** To evaluate the effects of a short-term nutritional intervention with protein and vitamin D on falls in malnourished older adults.

**DESIGN:** Randomized controlled trial.

**SETTING:** From hospital admission until 3 months after discharge.

**PARTICIPANTS:** Malnourished older adults ($\geq 60$) newly admitted to an acute hospital (n = 210).

**INTERVENTION:** Participants were randomized to receive nutritional intervention (energy- and protein-enriched diet, oral nutritional supplements, calcium-vitamin D supplement, telephone counseling by a dietitian) for 3 months after discharge or usual care.

**MEASUREMENTS:** Number of participants who fell, fall incidents, serum 25-hydroxyvitamin D, and dietary intake. Measurements were performed on admission to hospital and 3 months after discharge.

**RESULTS:** Three months after discharge, 10 participants (10%) in the intervention group had fallen at least once, compared with 24 (23%) in the control group (hazard ratio = 0.41, 95% confidence interval (CI) = 0.19–0.86). There were 57 fall incidents (16 in the intervention group; 41 in the control group). A significantly higher intake of energy (280 kcal, 95% CI = 37–524 kcal) and protein (11 g, 95% CI = 1–25 g) and significantly higher serum 25-hydroxyvitamin D levels (10.9 nmol/L, 95% CI = 2.9–18.9 nmol/L) were found in participants in the intervention group than in controls.

**CONCLUSION:** A short-term nutritional intervention consisting of oral nutritional supplements and calcium and vitamin D supplementation and supported by dietetic counseling in malnourished older adults decreases the number of patients who fall and fall incidents. **J Am Geriatr Soc 2012.**

**Key words: falls; elderly patients; nutritional intervention; protein; energy; vitamin D; RCT.**

Falls are a common and serious cause of morbidity and mortality in older persons. Fractures as a result of falls lead to enormous healthcare costs.[1] Each year, one in three community-dwelling persons aged 65 and older experiences at least one fall.[2–4] Loss of muscle mass and strength are regarded as important risk factors for falls, functional decline, and disability.[5]

Vitamin D deficiency[6] and malnutrition[7] can decrease muscle mass and muscle strength. In well-nourished community living older people at risk of vitamin D deficiency, vitamin D supplementation has been shown to improve muscle strength, function, and balance in a dose-related pattern.[8] These benefits translate into a reduction in falls, as shown in epidemiological studies and randomized clinical trials. Several meta-analyses in healthy persons support the beneficial effects of vitamin D supplementation on falls.[9,10]

Malnutrition is also associated with a higher incidence of falls.[11,12] Although a nutritional intervention in malnourished older people has been shown to accelerate weight gain,[13] only a few studies have shown an increase in muscle mass[14] or improved muscle function.[15,16] One study in frail older adults showed a reduction in the number of falls after 12 weeks of oral nutritional supplements.[17]

A recent study of a nutritional intervention in malnourished older adults (3 months of oral nutritional

From the [*]Department of Nutrition and Dietetics, [§]Section of Endocrinology, and [†]Department of Internal Medicine, VU University Medical Center, [‖]Department of Health Sciences, Faculty of Earth and Life Sciences, VU University, and [‡]EMGO Institute for Health and Care Research, Amsterdam, the Netherlands.

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Address correspondence to F. Neelemaat, Department of Nutrition and Dietetics, VU University Medical Center, PO Box 7057, 1007 MB Amsterdam, the Netherlands. E-mail: F.Neelemaat@vumc.nl

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supplements (ONS), calcium and vitamin D supplementation, and dietetic counseling) induced weight gain and a decrease in functional impairment.[18] The aim of the current study was to assess the effects of the same intervention on fall incidents.

## METHODS

### Design

The current study is a secondary analysis of a previously conducted study that has been reported elsewhere.[18] The primary study was a randomized controlled trial comparing ONS, calcium and vitamin D supplementation, and dietetic counseling with usual nutritional care in malnourished older adults from hospital admission to 3 months after discharge. The primary outcome was changes in activities of daily living (functional limitations, physical performance, and physical activity). Secondary outcomes included changes in body weight, body composition, and muscle strength. Details about the design have been described more extensively elsewhere.[19] This secondary analysis focuses on falls.

The study design was in accordance with the Declaration of Helsinki and was approved by the Medical Ethics Committee of the VU University Medical Center, Amsterdam.

### Participants

All older adults (aged $\geq$ 60) newly admitted (expected length of hospital stay > 2 days) to the departments of general internal medicine, rheumatology, gastroenterology, dermatology, nephrology, orthopedics, traumatology, and vascular surgery of the VU University Medical Center were screened for malnutrition.

Individuals were eligible for the study if they were identified as being malnourished according to the following criteria: body mass index (BMI) of 20.0 kg/m$^2$ or less, 5% or more self-reported unintentional weight loss in the previous month, or 10% or more self-reported unintentional weight loss in the previous 6 months.

Individuals with dementia were excluded if this diagnosis was documented in the hospital record or in a referral letter from the individual's primary care or nursing home physician.

### Randomization

A computerized random number generator was used to assign participants in blocks of 10 to the control or intervention group. At the end of the baseline interview and measurements, the primary investigator (FN) opened a consecutively numbered opaque envelope containing the participant's group assignment. Participants, research assistants, and researchers were aware of group assignment during the intervention phase. Before analysis, the primary investigator received an anonymized data set and was no longer aware of group assignment. A second independent researcher also entered all data on falls into the database. No differences between researchers were found for identifying fall incidents.

### *Control Group*

Participants allocated to the control group received usual care (given nutritional support only on prescription from their treating physician). In general, they did not receive postdischarge nutritional support.

### *Intervention Group*

Participants allocated to the intervention group received standardized nutritional support starting in the hospital and continuing for 3 months after discharge.

- Energy- and protein-enriched diet (during the in-hospital period). This diet excludes low-fat products and includes whole milk products, butter or margarine, and energy-and protein-enriched oatmeal and desserts. The oatmeal and desserts were fortified with extra cream and carbohydrates (maltodextrins). Participants were also offered one energy- and protein-enriched snack (containing approximately 250 kcal and 10 g protein) each day. This diet provided intake of approximately 750 kcal and 30 g of protein more per day than the regular hospital menu.
- Two additional servings per day of an ONS (Nutridrink®, Nutricia, Zoetermeer, the Netherlands) were offered. This was intended to provide an additional 600 kcal, 24 g of protein, 176 IU of vitamin D3, and 364 mg of calcium per day during the entire study period. ONS were first dispensed for 2 weeks (2 bottles per day × 14 days = 28 bottles) and subsequently for 4 weeks (2 bottles per day × 28 days = 56 bottles). The dietitian ordered the first batch of ONS. During telephone counseling, the dietitian asked the participant how many bottles of ONS had been consumed during the past 2 weeks. If necessary, the dietitian reminded the participant to order new ONS. After the first 2 weeks, participants (or family) ordered more by telephone from the pharmaceutical delivery service center. When participants (or their family) were not able to order themselves, the dietitian ordered for them.
- 400 IU vitamin D3/day, which in the Netherlands is usually given as a combined calcium and vitamin D supplement (400 IU vitamin D3 and 500 mg calcium per day during the entire study period, Calci-Chew D3®, Nycomed bv, Hoofddorp, the Netherlands).
- Telephone counseling by a dietitian was conducted every other week after hospital discharge (six sessions in total) to encourage adherence to the prescribed supplements. During the telephone consultation, the participant's general health status and any difficulties with the prescribed diet and supplements were discussed. For example, participants were asked how many of the prescribed ONS they had consumed during the past 2 weeks. If the intake of ONS was less than two bottles per day, participants were asked whether they (dis)liked the taste, were advised not to take the ONS just before a meal, were given recipes to try with the ONS, and were advised to order other flavors of ONS at the pharmaceutical service center. All participants had access to a telephone.

If participants took all of the prescribed supplements after discharge from hospital, this would provide an

additional 600 kcal, 24 g of protein, and 600 IU of vitamin D per day.

## Adherence

The interviews to recall adherence to ONS and calcium and vitamin D supplementation were conducted by telephone every other week. Participants did not have to keep a written record of their supplement use. The dietitian asked participants about their total supplement intake in the past 2 weeks and checked this with the deliveries from the pharmaceutical service center or pharmacy.

## Monitoring Adherence

### *Dietary Intake*

Dietary intake was recorded in a diary on admission to the hospital and 3 months after hospital discharge. On each occasion, seven meals or snacks (breakfast, in between morning, lunch, in between afternoon, dinner, in between evening, night) were recorded. Average daily intake of food and drinks during the past 2 weeks was documented.

Dietary energy (kcal/d) and protein (g/d) intake were calculated using a nutrition analysis software application with the use of the most recent Dutch Food Composition table(20).

### *Serum 25-Hydroxyvitamin D*

For measurement of 25-hydroxyvitamin D, serum was kept frozen at −20°C until analysis at the Endocrine Laboratory of the VU University Medical Center. One sample was collected at baseline and the other one 3 months after discharge. Both samples from each participant were analyzed together in one run to decrease variation within participants; 25-hydroxyvitamin D in serum was analyzed using radioimmunoassay (Diasorin, Stillwater, MN). The interassay coefficient of variation was 10%.

The Health Council of the Netherlands advises levels of 50 nmol/L or greater to improve bone quality and reduce the risk of fracture and falling in older people.[21]

## Outcome Parameters

### *Measurements*

All measurements were made at baseline (within 3 days after hospital admission) and 3 months after hospital discharge. Measurements of fat-free mass, hand grip strength, and physical activity were part of the parent study. Assessment of falls was part of the secondary analysis.

### *Fat-Free Mass and Hand Grip Strength*

Bioelectrical impedance spectroscopy (BIS) was used to determine changes in fat free mass (kg).[22,23] Measurements were performed using an ECF/ICF Bio Impedance Spectrum Analyzer, Hydra 4200 (Xitron Technologies, San Diego, CA).

Hand grip strength (kg) was measured using a hydraulic hand dynamometer (Baseline, Fabrication Enterprises, Inc., Elmsford, NY).[24] Participants were asked to perform two maximum force trials with their nondominant hand in a standing position and, if not possible, from a seated position. The highest value was used.

### *Physical Activities, Functional Limitations, and Physical Performance*

Physical activity was assessed using the validated Longitudinal Aging Study Amsterdam Physical Activity Questionnaire, which includes questions on walking, cycling, light and heavy household activities, gardening, and sports (yes = 1 point, no = 0 points). Total score was calculated by summing the scores of all activities, ranging from 0 (does not have difficulty with any of the activities) to 6 (has difficulty with all activities).[25]

Functional limitations were assessed using the validated LASA Functional Limitations questionnaire as the degree of difficulty that participants experienced with six activities (e.g., climbing stairs and getting up from and sitting down in a chair. Participants scored between 0 and 6 points; lower scores indicate less functional limitation.[26,27]

Physical performance was assessed using the validated LASA Physical Performance questionnaire, which includes three tests: timed walk test, chair-stand test, and tandem stand.[28] Participants scored between 0 and 12 points (4 points for each test); lower scores indicate poorer physical performance.

## Fall Incidents

Participants recorded their falls weekly. A fall was defined as an unintentional change in position resulting in coming to rest at a lower level or on the ground.[29] The time of recording was documented in the fall diary. Participants were asked to return their first diary by mail 6 weeks after discharge from hospital. When it was not received within 1 week after week 6, participants were telephoned and reminded to send it. In a few cases, sending back the diary was not possible, and the information on falls was obtained over the telephone. This procedure was repeated for the second fall diary covering the period 7 to 12 weeks after discharge. The described procedure of collecting data on fall incidents has been shown to be valid and reliable in earlier studies.[18]

## Statistical Methods

Differences in dichotomous variables between the intervention and control groups were tested using chi-square tests. Differences in continuous variables between the groups were tested using independent t-tests. These tests were performed for baseline and follow-up measurements. The statistical analyses for the main outcome parameters were restricted to participants with complete follow-up. For skewed data (number of fall incidents) a nonparametric test (Mann Whitney *U*) was used.

Logistic regression analysis was used to evaluate the difference in falling (yes or no) between the intervention and control groups. A time-to-event analysis was performed calculating a hazard ratio using Cox regression, log rank, and a Kaplan-Meier curve.

The presence of effect modification and confounding was investigated. Hazard ratios with accompanying 95% confidence intervals (for differences in means) and *P*-values are presented. Chi-square tests were applied to compare numbers of participants with vitamin D levels at different cut-off points. Statistical significance was defined as $P \leq .05$. Statistical analyses were performed using the SPSS for Windows, version 16.0 (SPSS, Inc., Chicago, IL).

## RESULTS

Participant inclusion, participant characteristics, and clinical outcomes have been described extensively elsewhere.[18] In summary, 210 participants were included in the study: 105 randomized to the intervention group and 105 to the control group (Figure 1).

Seventeen percent of the 3,291 individuals screened for inclusion in the study were identified as malnourished; 55% of the malnourished individuals had a BMI less than 20.0 kg/m$^2$, and 23% had a BMI below 18.5 kg/m$^2$. Seventeen percent of individuals reported more than 10% weight loss over the last month (acute weight loss) and 49% had more than 10% weight loss over the last 6 months.

Follow-up data were incomplete for 60 participants; in the intervention group, 16 withdrew and 14 died, and in the control group, 19 withdrew and 11 died. Participants without complete follow-up were older than those with complete follow-up (77.3 ± 9.5 vs 73.4 ± 9.3, 95% CI = 1.0–6.7).

No significant differences between the intervention and control groups were observed at baseline for functional limitations, body weight, grip strength, and physical performance, all of which are known potential predictors of falling (Table 1).

At baseline, 30 of 105 (29%) participants in the control group and 23 of 105 (22%) in the intervention group were receiving nutritional support with a prescription from their treating physician or dietitian. Three months after hospital discharge, 23 of 75 (31%) and 63 of 75 (84%) participants, respectively, were receiving such nutritional support.

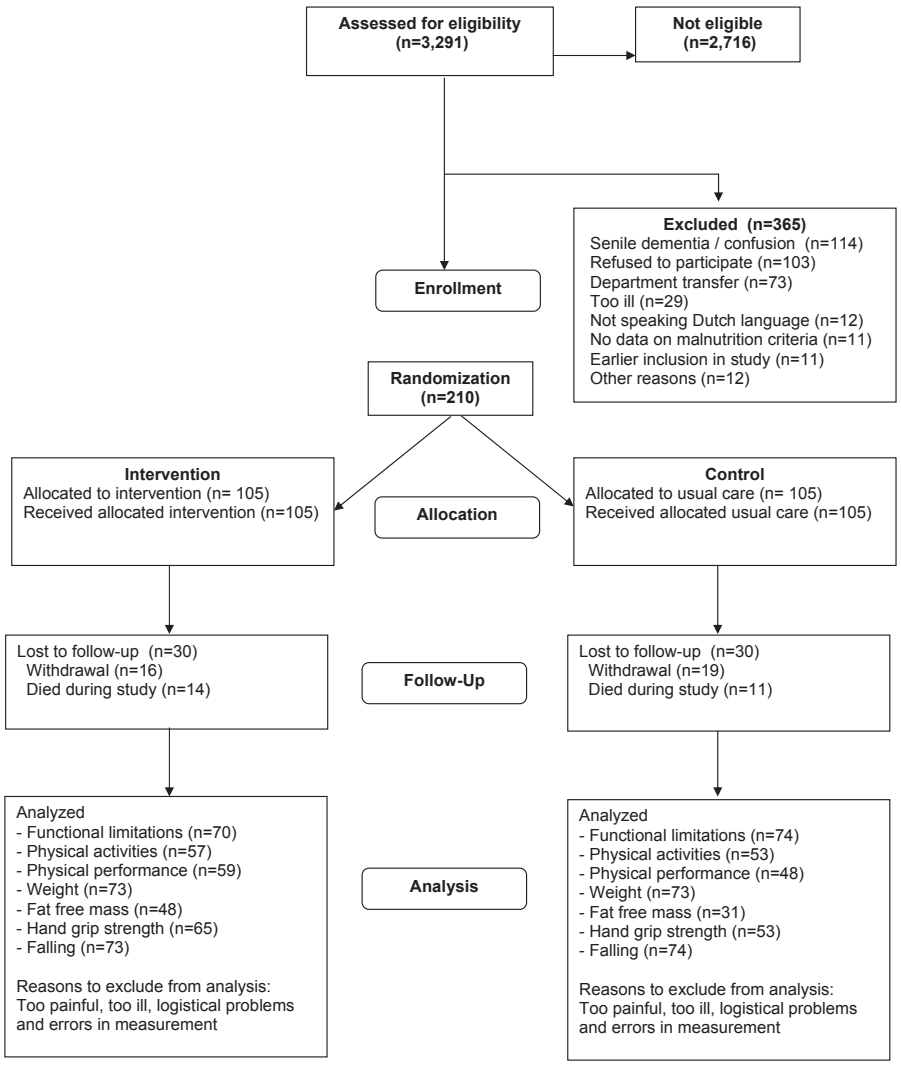


**Figure 1.** The CONSORT diagram.

**Table 1. Baseline and Clinical Characteristics of Participants**

| Characteristic | Intervention Group (n = 105) | Control Group (n = 105) | *P*-Value |
|---|---|---|---|
| Female, n (%)> | 56 (53.3) | 60 (57.1) | .58 |
| Age, mean ± SD | 74.6 ± 9.7 | 74.4 ± 9.3 | .88 |
| Living situation, n (%) | | | >.99 |
| Alone | 54 (51.4) | 54 (51.4) | |
| With partner or family | 51 (48.6) | 51 (48.6) | |
| Preadmission residence, n (%) | | | .20 |
| Living independently | 86 (81.9) | 90 (85.7) | |
| Nursing home | 9 (8.6) | 11 (10.5) | |
| Home for the elderly | 6 (5.7) | 4 (3.8) | |
| Hospital | 4 (3.8) | 0 | |
| Consulting dietitian before admission, n (%) | 25 (23.8) | 23 (21.9) | .74 |
| Use of supplemental drinks before admission, n (%) | 23 (21.9) | 30 (28.6) | .27 |
| Body weight, kg, mean ± SD | 61.0 ± 13.1 | 58.9 ± 12.3 | .25 |
| Men | 66.2 ± 13.4 | 66.2 ± 11.2 | .99 |
| Women | 56.4 ± 11.1 | 53.4 ± 10.2 | .14 |
| Body mass index, kg/m$^2$, n (%) | | | .42 |
| < 20.0 | 58 (55.2) | 56 (53.3) | |
| 20.0–24.9 | 32 (30.5) | 39 (37.1) | |
| ≥ 25.0 | 15 (14.3) | 10 (9.6) | |
| Weight change in last month,% (range) | −4.5 (−19.8–16.9) | −4.0 (−35.7–17.7) | .62 |
| Weight change in last 6 months,% (range) | −9.4 (−30.1–16.9) | −9.1 (−30.3–26.2) | .84 |
| Medical specialty, n (%) | | | .31 |
| Surgical | | | |
| Trauma | 7 (6.7) | 3 (2.9) | |
| Vascular surgery | 13 (12.4) | 16 (15.1) | |
| Nonsurgical | | | |
| Internal medicine | 32 (30.5) | 43 (41.0) | |
| Gastroenterology | 30 (28.6) | 30 (28.6) | |
| Nephrology | 14 (13.3) | 8 (7.6) | |
| Rheumatology | 5 (4.8) | 4 (3.8) | |
| Dermatology | 4 (3.7) | 1 (1.0) | |
| Primary diagnosis in categories, n (%) | | | .50 |
| Acute infection | 20 (19.0) | 13 (12.4) | |
| Vascular disease | 16 (15.2) | 16 (15.2) | |
| Kidney insufficiency | 13 (12.4) | 8 (7.6) | |
| Fracture or orthopedic disorder | 12 (11.4) | 10 (9.5) | |
| Malignant neoplasm | 10 (9.5) | 18 (17.1) | |
| Chronic bowel disease | 10 (9.5) | 17 (16.2) | |
| Diabetes mellitus, heart failure, or other | 10 (9.5) | 10 (9.5) | |
| Gastrointestinal bleeding | 7 (6.8) | 8 (7.6) | |
| Liver, gall bladder, or pancreatic insufficiency | 7 (6.7) | 5 (4.9) | |
| Hand grip strength, kg, mean ± SD | 17.9 ± 9.1 | 17.9 ± 8.0 | .93 |
| Physical activities (range 0–6), mean ± SD | 1.7 ± 1.3 | 1.4 ± 1.3 | .23 |
| Functional limitations (range 0–6), mean ± SD | 1.9 ± 2.0 | 1.8 ± 1.9 | .73 |
| Physical performance (range), mean ± SD | | | |
| Total score (0–12) | 3.1 ± 4.2 | 2.8 ± 4.0 | .61 |
| Walking time (0–4) | 1.1 ± 1.5 | 1.1 ± 1.4 | .78 |
| Chair-stand test (0–4) | 0.8 ± 1.4 | 0.8 ± 1.3 | .60 |
| Tandem stand (0–4) | 1.1 ± 1.7 | 1.0 ± 1.7 | .13 |
| Kcal intake, kcal/d, mean ± SD | 1,473 ± 625 | 1,462 ± 615 | .90 |
| Protein intake, g/d, mean ± SD | 52 ± 27 | 54 ± 29 | .60 |
| Protein intake g/kg per day, mean ± SD | 0.9 ± 0.5 | 0.9 ± 0.6 | .40 |
| Protein intake < 0.8 g/kg per day, n (%) | 46 (49) | 41 (43) | .39 |
| Serum vitamin D level, nmol/L, mean ± SD | 39.8 ± 19.3 | 42.5 ± 21.8 | .39 |
| Serum vitamin D level ≥ 50 nmol/L, n (%) | 21 (20) | 32 (30) | .08 |

There were no significant differences in characteristics between the intervention and control groups.
SD = standard deviation.

For the primary outcome parameters, a trend toward greater body weight and fewer functional limitations was observed in participants receiving nutritional intervention than in those receiving usual care.[18]

## Monitoring Adherence

Results on intake and serum 25-hydroxyvitamin D are shown in Table 2. Energy and protein intake and serum

**Table 2. Energy, Protein, and Serum 25-Hydroxyvitamin D Between Intervention Group and Control Group After 3-Month Follow-Up and Difference Between Baseline and Follow-Up**

| | Intervention Group | | Control Group | | | |
|---|---|---|---|---|---|---|
| Characteristic | End, n = 75 | End – Baseline | End, n = 75 | End – Baseline | Difference in Improvement, Intervention – Control | *P*-Value |
| Kcal intake per day, mean ± SD | 2,152 ± 752 | 595 ± 753 | 1,766 ± 661 | 315 ± 640 | 280 | .002 |
| Protein intake, g/d, mean ± SD | 78 ± 34 | 21 ± 29 | 63 ± 30 | 10 ± 29 | 11 | .04 |
| Protein intake, g/kg per day, mean ± SD | 1.3 ± 0.5 | 0.3 ± 0.4 | 1.0 ± 0.5 | 0.1 ± 0.5 | 0.2 | .07 |
| Protein intake < 0.8 g/kg per day, n (%) | 10 (16) | | 21 (30) | | | .049 |
| Serum vitamin D level, nmol/L, mean ± SD | 65.7 ± 25.5 | 24.0 ± 20.3 | 54.8 ± 25.4 | 13.1 (17.3) | 10.9 | .008 |
| Serum vitamin D level ≥ 50 nmol/L, n (%) | 32 (37) | | 23 (47) | | | .30 |

SD = standard deviation.

25-hydroxy vitamin D levels were significantly higher in the intervention group than in the control group.

Adherence to ONS, vitamin D supplementation, and dietetic counseling was 80%, 96%, and 96%, respectively. Eighty percent of participants in the intervention group consumed ONS, with a mean intake of 1.6 bottles per day (target 2/day). Ninety-six percent of participants in the intervention group consumed the calcium and vitamin D supplement, with a mean intake of 0.9 tablets per day (target 1/day). The dietitian contacted 96% of participants by telephone, with a mean of 5.8 contacts (target 6 contacts per participant).

Results of adherence to ONS and vitamin D supplementation as reported by participants compared well with distribution data from the pharmaceutical service center and participants' pharmacies.

### Body Weight and BMI

Body weight and BMI at baseline are presented in Table 1.

Three months after discharge, body weight increased to 64.7 ± 14.4 kg in the intervention group and 61.0 kg ± 12.2 in the control group. (Three months after discharge, the mean difference between the groups was 3.7 kg, 95% CI = 0.6–8.1.)

BMI increased to 22.1 ± 4.5 kg/m$^2$ in the intervention group and 21.0 ± 3.7 kg/m$^2$in the control group. (Three months after discharge, the mean difference between the groups was 1.1 kg/m$^2$, 95% CI = 0.3–2.4.)

### Fat-Free Mass and Hand Grip Strength

Neither fat-free mass nor hand grip strength changed significantly from baseline in the intervention or the control group. Mean increase in fat free mass was 3.3 ± 4.3 kg in the intervention group and 2.8 ± 4.1 kg in the control group (95% CI = 1.5–2.4). Mean increase in grip strength was 0.2 ± 5.6 kg in the intervention group and 1.0 ± 6.7 kg in the control group (95% CI = 3.0–1.5).

### Physical Activities

Physical activities did not change significantly in the intervention or control group. Mean improvement in score was 0.5 ± 1.5 in the intervention group and 0.6 ± 1.5 in the control group (95% CI = 0.7–0.5).

### Fall Incidents

Results on fall incidents are shown in Table 3. Participants in the control group fell more than twice as often as participants in the intervention group. In total, 57 fall incidents occurred: 16 in the intervention group and 41 in the control group. Ten participants (10%) in the intervention group and 24 (23%) in the control group had one or more fall incidents (HR = 0.41, 95% CI = 0.19–0.86, $P$ = .02, log rank); 56% of participants in the intervention group and 68% of those in the control group who had fallen had more than one fall incident (not significantly different). The mean number of falls per participant in participants who had fallen was 1.6 ± 1.1 in the intervention group and 1.7 ± 0.9 in the control group. This was not significantly different between groups ($P$ = .55). In 94% of fall incidents, participants fell in their home, and only one participant (in the control group) reported a fracture after a fall incident. Figure 2 shows a Kaplan-Meier curve for the time (days) to a fall incident for participants in the intervention group versus participants in the control group.

Confounding or effect modification was not observed for age, sex, body weight, BMI (<20.0 vs ≥ 20.0 kg/m$^2$), unintentional weight loss in the previous month, unintentional weight loss in the previous 6 months, fat-free mass, hand grip strength, physical activities, functional limitations, or physical performance.

## DISCUSSION

A short-term nutritional intervention, consisting of oral nutritional supplements and vitamin D supplementation,

**Table 3. Fall Incidents After 3 Months of Follow-Up in Malnourished Older Adults**

| Characteristic | Intervention Group | Control Group | Effect |
|---|---|---|---|
| Participants who fell, n (%) | 10 (10) | 24 (23) | 0.41* ($P = .02$) |
| Number of fall incidents, mean ± standard deviation | | | |
| Whole group (76 intervention, 75 control) | 0.21 ± 0.57 | 0.55 ± 0.84 | 0.001† |
| Participants who fell (10 intervention, 24 control) | 1.6 ± 1.1 | 1.7 ± 0.91 | 0.550† |

* Hazard ratio.
† Mann Whitney *U*-test.

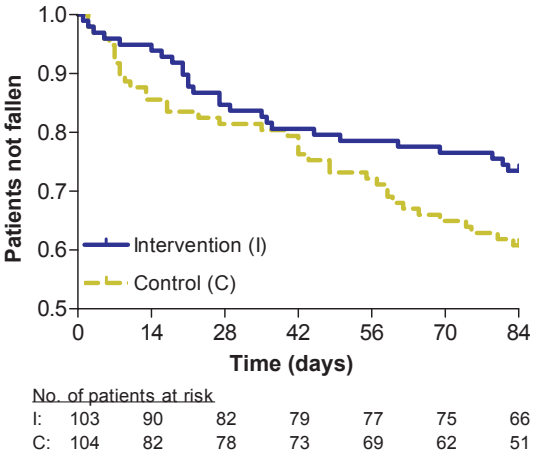


**Figure 2.** Kaplan-Meier curve for time (days) to a fall incident for participants in the intervention and control groups.

supported by dietetic counseling, decreases the number of individuals with falls and fall incidents in malnourished older adults. There were no statistically significant differences in physical activity between the groups.

Approximately 30% of community-dwelling persons aged 65 and older fall once a year, and 15% fall at least twice a year.[30–32] The occurrence of falls in intervention participants (10% in 3 months) was as expected. In contrast, the occurrence of falls in the control group (30% in 3 months) was higher than expected.

Because this study was designed as a secondary analysis of a parent study, data were not collected on all well-known risk factors for falling, but no statistically significant differences were observed between intervention participants and controls for functional limitations, body weight, grip strength, and physical performance. Data were not collected on, for example, polypharmacy or vision impairment, other well-known risk factors that could have influenced the results. It can be assumed that the randomized design of the trial accounted for similar distribution of all fall risk factors between the groups.

A recent meta-analysis of randomized clinical trials showed that serum 25-hydroxyvitamin D concentrations of 60 nmol/L or higher were associated with fewer falls, and lower concentrations were not.[33] A study of a sample of the Longitudinal Aging Study Amsterdam (LASA) cohort found that a serum 25-hydroxyvitamin D level less than 30 nmol/L was associated with a higher fall incidence than a higher level.[34] In the present study, participants' mean serum 25-hydroxyvitamin D levels were inadequate in both groups at baseline. After the intervention period, serum 25-hydroxyvitamin D levels in both groups had improved, more so in the intervention group than in the control group. In the intervention group, mean serum level reached 65 nmol/L, which is above the 50 nmol/L that the Institute of Medicine[35] and the Health Council of the Netherlands[21] have suggested. Still, 37% of all participants in the intervention group did not reach a serum 25-hydroxyvitamin D above the threshold of 50 nmol/L, even after supplementation.

The study was conducted with a low-dose vitamin D (400 IU/d from calcium and vitamin D supplementation and 176 IU/d from ONS). After the start of this study in 2006, the dose of vitamin D supplementation advised by the Health Council of the Netherlands for older people increased to 800 IU/d.[21] It is possible that a higher dose of vitamin D would reduce fall incidence even further. Further research in a study with a dose-response design is needed.

When studying the absolute number of participants with levels less than 30 nmol/L or less than 50 nmol/L, there were no statistically significant differences between groups at baseline or at 3-month follow-up. This supports the idea that the combined intervention, rather than only the vitamin D, was effective in the reduction of falls. The intervention consisted of a combination of energy, protein, vitamin D, and calcium. In addition, a dietitian counseled participants every other week. This study does not give an answer to which specific nutritional component or combination of components and counseling is responsible for the effects found.

Falling is associated with activity pattern, muscle mass, and strength. Increasing physical activity was not a primary aim of this study. Reported activity levels were measured using a questionnaire. They did not change in the intervention group or the control group, suggesting that changes in activity level did not account for the difference in falls.

The results of the present study did not confirm an increase in falls because of decreased muscle mass and strength. Measurements of muscle mass (using bioelectric impedance) and strength (using handgrip dynamometry) were crude and probably not sensitive enough to pick up small changes. Nevertheless, function improved.[18] Results may be ascribed to changes in neuromuscular function rather than to changes in muscular strength. A vitamin D supplementation study showed neuromuscular improvements after a short-term intervention (16 weeks), which confirms that neuromuscular improvements may take place over a short period of time.[36]

One of the strengths of this study is that the adherence to the nutritional intervention was higher than 80%, which may explain the better results than in other studies. For ONS, earlier studies have shown adherence rates of only approximately 50%.[15] In a similar trial, adherence was 38% in the ONS group and 50% in the matched placebo group.[15] Low adherence rates have also been reported for vitamin D supplementation. According to a

meta-analysis, 21 of 29 trials had an adherence rate of calcium (and vitamin D) supplementation of less than 80%.[8]

In contrast to most other studies, a dietitian counseled participants in the present study every other week (six times during the study period). The excellent adherence may be attributed to this counseling. This is supported by a recent study that also showed greater energy intake in the group that received counseling.[37]

The study population was heterogeneous and differed in medical diagnosis, nutritional status, age, and health status. To increase homogeneity, individuals from only two wards were included: internal medicine and traumatology/vascular surgery, representing the specialties general internal medicine, rheumatology, gastroenterology, dermatology, nephrology, orthopedics, traumatology, and vascular surgery. This population was carefully chosen and excluded individuals undergoing major surgery.

This study has certain limitations. First, it was not blinded. Participants and investigators were aware of group assignment. Blinding the researcher during the analyses partially adjusted for this limitation, but socially desirable answers of participants could have biased the results. Therefore, a double-blind controlled design would have been preferable.

Second, a 2-week dietary history was used to assess participants' nutritional intake. The method of collection of nutrition data was not optimal, but it was the best available method considering the health status of the participants. Twenty-four-hour recall was not considered appropriate because most participants were very ill the day before hospital admission, so this would not give an accurate impression of usual intake. In addition, performing 24-hour recall would be too much an effort for this ill, frail population.

Finally, loss to follow-up was 30% because of mortality and withdrawal. These data could have biased the results. Fifty-three percent of these individuals died or withdrew within the first 6 weeks. For these individuals, no falls data were available. The fall incidence in individuals who completed the first 6 weeks of the study and subsequently dropped out was not different from the incidence in individuals who completed the whole study.

In summary, significantly fewer falls were seen in malnourished elderly adults receiving short-term nutritional intervention consisting of the combination of ONS, calcium and vitamin D, and dietetic counseling. This is one of the first studies showing these effects in such a short period and in a participant sample consisting of exclusively malnourished individuals. It would be of interest to study the cost effectiveness of this intervention in the future.

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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.

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