## EFFECT ON BODY WEIGHT, QUALITY OF LIFE AND APPETITE FOLLOWING INDIVIDUALIZED, NUTRITIONAL COUNSELLING TO HOME-LIVING ELDERLY AFTER REHABILITATION – AN OPEN RANDOMIZED TRIAL

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> Abstract: Objectives: We examined if individually-adapted nutritional counselling could prevent > 5% weight loss among elderly patients 3 months after discharge from a rehabilitation institution. In addition we assessed quality of life (QoL) and appetite. Design: An open, randomized trial. Setting: Godthaab Health and Rehabilitation Institution in Bærum, Norway. Participants: Patients identified as being undernourished or at risk of disease-related malnutrition using the Nutritional Risk Screening tool NRS-2002. Intervention: Shortly before discharge, patients in the intervention group received an individually-tailored nutrition plan. During the subsequent 3 months these patients were contacted 3 times via telephone calls and they received one visit at their homes, for nutrition counselling. Focus on this counselling was on optimizing meal environment, improving appetite, increasing food intake, advice on food preparation, and motivation and support. Measurements: In addition to weight, QoL and appetite were assessed using the EQ-5D questionnaire and a modified version of the Disease-Related Appetite Questionnaire, respectively. Results: Among 115 considered eligible for the study, 100 were enrolled (72 women and 28 men), with a mean age of 75 years and a mean body mass index of 20 kg/m<sup>2</sup>. Two in the intervention group (n = 52) and 5 in the control group (n = 48) lost > 5% of their body weight, giving an odds ratio of 0.34 (95% CI: 0.064 - 1.86; p = 0.22). We did not detect any significant differences in the QoL- or appetite scores between the two study groups after three months. Conclusion: An individually-adapted nutritional counselling did not improve body mass among elderly patients 3 months after discharge from a rehabilitation institution. Neither quality of life nor appetite measures were improved. Possibly, nutritional counselling should be accompanied with nutritional supplementation to be effective in this vulnerable group of elderly. The trial is registered in Clinical Trials (ID: NCT01632072).

Key words: Appetite, disease-related malnutrition, nutritional counselling, quality of life, rehabilitation.

## Introduction

In developed countries disease is the primary cause of disease-related malnutrition, which is often manifested as clinically relevant weight loss. Patients with cancers, diseases of the gastrointestinal tract, or cardiovascular disorders, are particularly vulnerable to develop disease-related malnutrition (1). However, disease-related malnutrition is often not registered in the hospital records and remains therefore often untreated (1). A survey of health professionals showed that nutritional care in Norwegian hospitals did not adhere to the recommendations of the European Council (2, 3). Specifically, their patients were rarely weighed, nutrient intake was seldom monitored and an individual nutrition plan often lacked. A similar survey in the primary health care system showed that the patients' nutritional needs were inadequately safeguarded, often as a consequence of lack of resources (4). Little knowledge, interest and awareness among health professionals with regard to nutritional issues, are major contributing factors to further deterioration of nutritional status following discharge from hospital (5).

Disease-related malnutrition is also an important risk factor for poor rehabilitation following treatment of various diseases. Specifically, disease-related malnutrition increases the risk of complications, reduces physical and mental capacity, and impairs immune functions; thus delaying patient recovery and increasing mortality (1, 6, 7). Collectively, this leads to an increased need for home care services, more doctor visits and re-admissions to hospital and, accordingly, a large negative impact on the individual, the family, the health care system, and possibly also the society at large.

Whereas it is fairly well documented that nutritional support in various forms reduces the risk of disease-related malnutrition and weight loss among patients admitted to hospitals for treatment or to specialized institutions in the rehabilitation phase, few studies have examined the effect of monitoring nutrition therapy among patients at nutritional risk after discharge. Some data indicate that follow-up with nutrition treatment after discharge may improve nutritional status and patient functioning (8, 9).

Disease-related malnutrition is a condition that develops over time. Short-lasting (days) insufficient nutritional intake will rarely cause persisting health problems, but if the patient experiences prolonged periods (weeks-months) with inadequate intake leading to negative energy balance, irreversible complications may occur. Hence national guidelines recommend that in order to prevent or treat diseaserelated malnutrition, patients at risk of this should also be

monitored after discharge (10). In Norway the primary health care service assumes responsibility for patient health care after discharge, including nutritional status. However, access to specialist expertise in clinical nutrition in primary health care is currently almost absent. Moreover, evidence-based guidelines are lacking with regard to how these patients should best be monitored after return to home, and it is unknown if dietary advice alone is sufficient to prevent or combat disease-related malnutrition among discharged elderly patients returning to home after an institutional stay (11).

In the present randomized trial we tested if tailor-made nutritional counselling mediated via home visits and phonecalls could reduce weight loss among undernourished patients and those at risk of disease-related malnutrition three months after discharge from a specialized rehabilitation care center. We also included specific questionnaires to examine quality of life and appetite among the participating patients as these two entities are closely associated with nutritional status.

## Methods

The study was approved by the Regional Committee for Medical and Health Research Ethics South-East Regional Health Authority in Norway (#2012/928). The data are described according to the CONSORT statement of reporting randomized trials (12).

## Study-Site

The study participants were recruited during a rehabilitation stay at Godthaab Health and Rehabilitation Institution (GHR; http://godthaab.no), a non-profit organization with financial support from the South-East Norway Regional Health Authority. This regional health authority covers about 50% of the total population in Norway. GHR offers rehabilitation to patients with musculoskeletal disorders, as well as rehabilitation of patients with cancer, lymphedema, cardiovascular disease, chronic pulmonary disease, stroke and neurodegenerative diseases. The institution also offers post-operative treatment to patients having undergone abdominal and orthopaedic surgery. Usually the patients are given a two-weeks stay with the possibility of extending their stay if needed.

## Study Design and Recruitment of Patients

We performed an open, randomized controlled trial with two arms at a ratio of 1:1; one intervention- and one controlgroup, and applied the intention-to-treat principle. Eligibility for the study was assessed while the patients were staying at the GHR in the period June 2012 to August 2015. They were identified as being undernourished or at risk of diseaserelated malnutrition if they scored > 3 using the Nutritional Risk Screening tool NRS-2002 (13, 14). In addition they had to be > 18 years and residing in the capital Oslo or the nearby municipalities of Asker or Bærum. They also had to be able to communicate in Norwegian and to provide written informed consent to participate. The exclusion criteria were (i) lack of rehabilitation potential (decided by the treating physician), (ii) duration of stay < 10 days or > 30 days at GHR, (iii) not planned to return home after the stay at GHR, (iv) expected survival less than one year, and (v) refusal to participate.

## **Study Intervention**

Shortly before discharge, the patients in the intervention group received an individual nutritional plan with documentation of nutritional status, nutrient requirements, and nutrient intake. This nutritional plan was based on information regarding swallowing function, bowel function, appetite, food preferences, and personal habits such as eating patterns, dietary intake, and estimated energy and protein requirements according to national guidelines (10). For energy we used: (i) bedridden patients: 29 kcal/kg per day; (ii) ambulatory patients: 33 kcal/kg per day; (iii) patients in recovery phase: 40 kcal/kg per day; (iv) age > 70 years: reduce by 10%; (v) overweight (body mass index > 25 kg/m<sup>2</sup>): reduce by 10%. For protein we used: (i) healthy participants: 0.8-1.5 g/kg per day; (ii) for those with disease: 1.5-2.0 g/kg per day. The swallowing function, bowel function, appetite, food preferences, and personal habits were self-reported by the patients. The nutritional plan was developed by a clinical nutritionist in collaboration with the patient. The patients did not receive any foods or other forms of support from the study organizers.

Both groups received the same standard care including general advice on nutrition during their stay at the GHR. After discharge, patients in the intervention group received extra nutritional care with focus on how to achieve and maintain good nutritional status and taking into account the eating situation at home. This counselling was individually tailormade, including e.g. to:

- ensure an eating environment that promoted eating at home (for example good lighting, hygiene, fresh air, cooking odours, decorate the table, shared meals).
- advice on how to increase food intake, nutritional content and how to improve appetite (for example, frequency, composition, appearance, flavour, size).
- motivate and support the patient to make decisions to improve and maintain a good nutritional status, encourage awareness of the importance of food intake.
- simplify food preparation and use of ready-made food, practical cooking suggestions.
- increase the frequency of consumption of foods and drinks, suggestions of good choices of small meals and snacks.
- propose use of nutrient dense foods high in energy and protein rather than foods with a low content, fortification of food.
- focus on reducing factors that affect appetite as psychological factors (stress, anxiety, worries), medical factors (disease state, side effect of medication) and environmental factors (social conditions in the meal, dining and meal routines).

Patients in the intervention group received repetition (and individual adjustments if needed) of this counselling during three telephone calls (1/2 h duration; 1, 7 and 10 weeks after discharge) and at one home visit (1 h duration) 4 weeks after discharge. During these contacts the patients were also asked if they actually followed the advice in order to ensure compliance.

Patients in the control group received no particular nutritional advice at the time of discharge.

The participants in both groups were evaluated three months after discharge by a clinical nutritionist, either at their home or as an outpatient visit at the GHR, according to what the patient preferred.

## Measurements of End-Points

Patient characteristics and information about their medical history were obtained from their hospital- and GHR-records. Body weight was measured to the nearest 100 g using a SECA scale (Hamburg, Germany). Weight and height were measured in the erect position, and body mass index (BMI) was calculated as weight (kg) divided by height (m) squared.

We used the research tool EQ-5D, available in Norwegian, to assess quality of life (QoL) among the patients (15). The EQ-5D questionnaire comprises five dimensions: (i) mobility (ability to walk), (ii) self-care (ability to wash or dress), (iii) usual activities (ability to cook, clean or perform usual activities), (iv) anxiety or depression/discomfort, and (v) pain. There are three levels of response: no problems, moderate problems or severe problems (score 1–3). The patient also rates self-perceived state of health on a visual analogue scale (VAS; scores 0-100; from worst to best imaginable state of health).

Appetite was evaluated using the research tool Disease-Related Appetite Questionnaire (DRAQ) (16) which is a modified version of the validated Council on Nutrition Appetite Questionnaire (CNAQ) (17). DRAQ, which is available in Norwegian, is composed of a total score based on 10 items focusing on (i) semi-quantification of the appetite, (ii) day-today variations in appetite, (iii-iv) food tastes, (v-vi) frequency of eating, (vii) presence of nausea, and (viii-x) impact of mood/ co-existing disease on food intake. The modifications of the CNAQ are the additions of items xi-x. Each item is scored by using a 5-point scale, yielding a total score ranging from 10 (worst appetite) to 50 (best appetite).

## **Randomization and Statistics**

Eligible patients were, prior to discharge, block-randomized (10 patients per block) to either the intervention- or the control group. The randomization was performed by a person not involved in the study with the software program www. randomization.com, and using numbered, sealed and opaque envelopes. Both the patients and the researchers were aware of allocation (intervention or control), the assessors of the study outcomes were blinded to the allocation.

Generally, a weight loss exceeding 5% among elderly adults usually is a risk factor for a range of different morbidities

(18, 19). Based on an unpublished pilot study at GHR we found that 1/4 of the patients experienced an unintentional weight loss > 5% three months after discharge. We considered that reducing this number further to 1/20 would be a clinical meaningful result, and hence this was the primary end-point of our study. Using a power of 0.8 and a p-value of 0.05, a total of 100 patients were needed. To account for dropouts we added another 15. The secondary end-points included data from the assessments of the quality of life domains and VAS score, and the appetite scores.

Differences between the intervention- and control group were evaluated with parametric (odds ratio) or non-parametric tests (Mann-Whitney's test, Fisher's exact test, Wilcoxon signed rank test) as appropriate. Two-tailed tests were performed. Significance was assumed for p-values less than 0.05.

#### **Results**

#### **Characteristics of Study Patients**

Among the 169 patients who were consecutively considered for eligibility, 115 (68%) were enrolled into the study and randomized (Figure 1). Among these 115, 15 (13%) were lost to follow-up at 3 months, leaving 100 patients available for analyses. Table 1 shows that the randomization had been satisfactory since the two groups were highly comparable for all the characteristics that were determined. Notably, few of the patients were undernourished (NRS 2002 score > 4); whereas most of them had a NRS 2002 score of 3 or 4, thus being at risk of disease-related malnutrition (14).

## **Body Weight During the Intervention Period**

After three months, a non-significant trend towards better weight gain was observed among the patients in the intervention- compared to the control group: Two (3.9%) patients in the intervention group and five (10%) patients in the control group (p = 0.15) had lost more than 5% of their baseline body weight; yielding an odds ratio of 0.34 (95% confidence interval 0.064 – 1.86; p = 0.22). Figure 2A shows that the body weight remained fairly stable throughout the intervention study, however, in the intervention group we found an increase (p = 0.0026) in body weight from baseline to 3 months (Figure 2B).

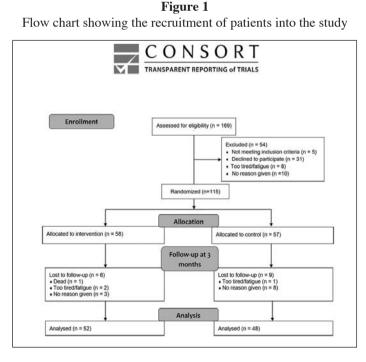
Over- and undernutrition at baseline may have impacted on the loss of body weight. Hence, we next sub-classified the patients in the two study groups according to their baseline BMI-values: < 20 kg/m<sup>2</sup>; 20-25 kg/m<sup>2</sup> and > 25 kg/m<sup>2</sup>. The corresponding odds ratios (95% confidence interval) were 0.075 (0.0041 – 1.40; p = 0.082); 0.92 (0.018 – 47.4; p = 0.97) and 2.82 (0.11 – 71.0; p = 0.53), respectively. Thus we did not detect any significant differences among the two study groups in the number of patients who lost > 5% of their baseline body weight in any of these 3 BMI-subgroups.

| Characteristic                       | Intervention group<br>(n = 52) | Control group<br>(n = 48) |
|--------------------------------------|--------------------------------|---------------------------|
| Gender [n (%)]                       |                                |                           |
| Female                               | 36 (69)                        | 36 (75)                   |
| Male                                 | 16 (31)                        | 12 (25)                   |
| Age (years)                          | 75.2 (7.8)                     | 75.5 (9.4)                |
| Duration of hospital stay (days)     | 19.2 (6.1)                     | 18.5 (5.8)                |
| Body weight (kg)                     | 59.4 (15.4)                    | 57.0 (11.3)               |
| Body mass index (kg/m <sup>2</sup> ) | 20.3 (3.6)                     | 20.0 (3.0)                |
| NRS 2002 score [n (%)]               |                                |                           |
| 3-4                                  | 46 (88)                        | 43 (90)                   |
| 5-7                                  | 6 (12)                         | 5 (10)                    |
| Diagnostic categories [n (%)]1       |                                |                           |
| Cardiovascular                       | 3 (6)                          | 5 (10)                    |
| Respiratory                          | 3 (6)                          | 2 (4)                     |
| Neurological                         | 0 (0)                          | 1 (2)                     |
| Gastrointestinal                     | 7 (13)                         | 7 (15)                    |
| Orthopedic                           | 3 (6)                          | 7 (15)                    |
| Cancer                               | 30 (58)                        | 22 (46)                   |
| Other internal disorders             | 6 (12)                         | 4 (8)                     |

 Table 1

 Baseline characteristics of the study patients

Values are means (SD) unless otherwise stated; 1. The diagnoses were established according to the International Classification of Diseases, version 10.



Cancer may regulate body weight in various ways, e.g. through altered energy intake and/or inflammation. We

therefore also separately analyzed those who had cancer and those who did not have cancer. The corresponding odds ratios (95% confidence interval) were 0.29 (0.030 - 2.92; p = 0.30) and 0.18 (0.0083 - 3.79; p = 0.27), respectively. Hence we did not detect any significant differences among the two study groups in the number of patients who lost > 5% of their baseline body weight when classified as cancer or cancer-free patients.

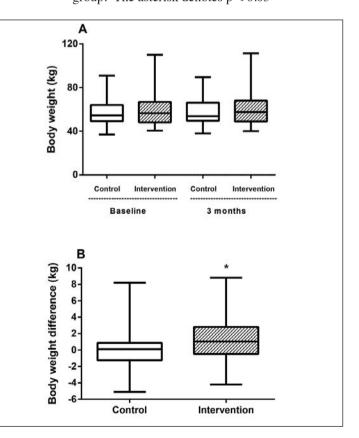
## Quality of Life During the Intervention Period

We next evaluated the self-perceived state of health using the VAS scale of the EQ-5D tool. It is evident from Figure 3 that the VAS-score remained unaltered (p > 0.05) from baseline to three months after study start in both study groups. To further gain insight into possible changes in their QoL, we next examined the five dimensions of the EQ-5D descriptive part (Table 2). We could, however, not detect any changes (p > 0.05) in any of the dimensions when comparing values obtained at 3 months with those obtained at baseline, neither in the intervention group nor in the control group.

## Figure 2

Body weight in the two study groups at baseline and after three months (A) and the concomitant changes during that period (B).

Values are expressed as box plots with whiskers (minimum; 25th, 50th, 75th percentiles; and maximum values). Open boxes are the controls while hatched boxes represent the intervention group. The asterisk denotes p < 0.05



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## Table 2

## Quality of life as measured with the EQ-5D questionnaire

| EQ-5D dimension    | Intervention group (n = 52) |                |             | Control group (n = 48) |                |            |
|--------------------|-----------------------------|----------------|-------------|------------------------|----------------|------------|
|                    | Baseline                    | After 3 months | Difference  | Baseline               | After 3 months | Difference |
| Mobility           | 2 (1,2)                     | 1.5 (1,2)      | 0 (-1,0)    | 2 (1,2)                | 1 (1,2)        | 0 (-1,0)   |
| Self-care          | 1 (1,2)                     | 1 (1,1)        | 0 (-0.75,0) | 1 (1,2)                | 1 (1,1)        | 0 (0,0)    |
| Usual activities   | 2 (2,2)                     | 2 (1,2)        | 0 (-1,0)    | 2 (2,2)                | 2 (1,2)        | 0 (-1,0)   |
| Pain/discomfort    | 2 (1,2)                     | 1 (1,2)        | 0 (-1,0)    | 2 (1,2)                | 2 (1,2)        | 0 (-1,0)   |
| Anxiety/depression | 1 (1,2)                     | 1 (1,2)        | 0 (-1,0)    | 2 (1,2)                | 2 (1,2)        | 0 (0,0)    |

The values are medians (25th and 75th percentiles). Difference denotes change between the data collections at 3 months and baseline. No significant changes were found for any of the dimensions when comparing values obtained at 3 months with those obtained at baseline, neither in the intervention group nor in the control group.

| DRAQ-item | Inte        | <b>Intervention group</b> (n = 52) |             |             | Control group (n = 48) |                 |  |
|-----------|-------------|------------------------------------|-------------|-------------|------------------------|-----------------|--|
|           | Baseline    | After 3 months                     | Difference  | Baseline    | After 3 months         | Difference      |  |
| Item 1    | 2 (2, 3.75) | 3 (2, 4)                           | 0 (0, 1)    | 3 (2, 3.25) | 3 (2.75, 4)            | 0 (0, 1)        |  |
| Item 2    | 3 (2, 4)    | 4 (2, 5)                           | 0 (-1, 1)   | 3 (2, 4.25) | 3 (2, 4)               | 0 (-0.75, 0.75) |  |
| Item 3    | 3 (2, 4)    | 4 (3, 4)                           | 0 (0, 1)    | 3 (3, 4)    | 4 (3, 4)               | 0 (0, 1)        |  |
| Item 4    | 2 (1, 3)    | 3 (2, 4)                           | 1 (0, 2)    | 2 (1, 3)    | 2.5 (2, 4)             | 0 (0, 1)        |  |
| Item 5    | 3 (3, 4)    | 4 (3, 4)                           | 0 (0, 1)    | 3 (3, 4)    | 4 (3, 4)               | 0 (0, 1)        |  |
| Item 6    | 3 (2, 3)    | 3 (2.25, 3)                        | 0 (0, 1)    | 3 (2, 3)    | 3 (2, 3)               | 0 (0,0)         |  |
| Item 7    | 4 (3, 4)    | 4 (3, 5)                           | 0 (0, 1)    | 4 (3, 4)    | 4 (3, 5)               | 0 (0, 1)        |  |
| Item 8    | 2 (2, 2)    | 2 (2, 3)                           | 0 (0, 0.75) | 2 (2, 3)    | 2 (2, 2)               | 0 (-0.75,0)     |  |
| Item 9    | 2 (2, 4)    | 4 (3, 4)                           | 1 (0, 2)    | 2 (2, 4)    | 3 (2, 4)               | 0(0,1)          |  |
| Item 10   | 3 (3, 4)    | 4 (3, 4)                           | 0(0,1)      | 3 (3, 4)    | 3 (3, 4)               | 0 (0, 0)        |  |

# Table 3 Appetite assessed with the DRAQ questionnaire

The values are medians (25th and 75th percentiles). Difference denotes change between the data collections at 3 months and baseline. No significant changes were found for any of the items when comparing values obtained at 3 months with those obtained at baseline, neither in the intervention group nor in the control group.

## Appetite During the Intervention Period

Possible changes from baseline to after three months in appetite were assessed with the DRAQ questionnaire. Figure 4 shows that the total DRAQ scores were apparently similar (p > 0.05) in the two study groups, and did not change appreciably (p > 0.05) during the three months of intervention. We then performed a detailed analysis of the 10 items included in the DRAQ questionnaire (Table 3). We could, however, not detect any changes (p > 0.05) in any of these items when comparing values obtained at 3 months with those obtained at baseline, neither in the intervention group nor in the control group.

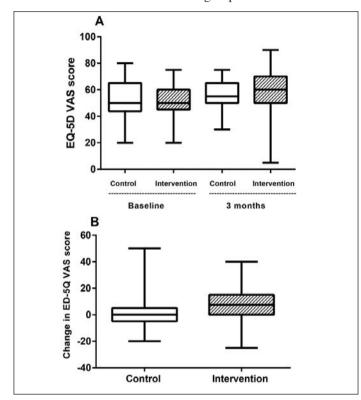
## Discussion

In this randomized trial we tested the effect on body weight of nutritional counselling offered to elderly home-living patients following discharge from a rehabilitation institution. The number of patients losing more than 5% of their body weight three months after discharge was not significantly different between the intervention- and control group. However, patients in the intervention group experienced a significant gain in body weight during the study period. When using the EQ-5D research tool, we found no significant effect of our intervention on global QoL or on the five descriptive domains of EQ-5D. Furthermore, the nutritional counselling had no significant effect on appetite as measured with the questionnaire DRAQ.

There is no universally accepted screening tool for assessing nutritional risk (20). Here we chose to use the NRS-2002 to identify undernourished patients and those at risk of disease-related malnutrition, since this questionnaire is primarily recommended in Norwegian guidelines regarding nutritional assessment in health-institutions (10). Due to the low participant number we did not perform separate analyses of the undernourished patients compared to those at risk of diseaserelated malnutrition.

## Figure 3

Global health-related quality of life rated as VAS scores from the EQ-5D tool in the two study groups at baseline and after three months (A) and the concomitant changes during that period (B). Values are expressed as box plots with whiskers (minimum; 25th, 50th, 75th percentiles; and maximum values). Open boxes are the controls while hatched boxes represent the intervention group

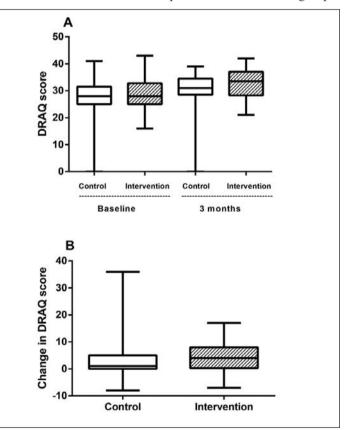


A major goal in rehabilitation following medical or surgical treatment of disorders with potential negative impact on nutritional status, is to preserve body weight (21-23). While studies have shown beneficial effects of nutritional intervention while in hospital (1, 24), few studies have been specifically targeted to prevent weight loss upon return to home, and most of these are disease-specific as opposed to the current study where several diagnoses were included. In a prospective, non-randomized trial, Lee et al. examined nutritional status following intensive nutritional counselling three months after hospital discharge among patients treated with surgery due to gastric cancer (25). No significant differences were noted in anthropometric measures or energy intake between the intervention and control group. In contrast, in their randomized trial, Feldblum et al. found lower mortality and moderate improvement in nutritional status among patients (with diabetes, liver-, renal- or infectious diseases) receiving individualized nutritional treatment (counselling and nutritional supplements) for 6 months after hospitalization (9). Nykänen et al. observed an improvement in the Mini Nutritional Assessment test scores and serum albumin among community

dwellers (> 75 years) after two years following an intervention with dietary counselling (26). In addition to preservation of body weight, maintenance of muscle mass and muscle strength is important among elderly. According to recent systematic analyses, interventions with e.g. protein supplementation have yielded contradictory results regarding maintenance of muscle mass in diverse elderly populations (27, 28); a combination of nutritional counselling and nutritional supplementation should therefore be examined, possibly also in combination with physical activity (29).

#### Figure 4

Appetite scores based on the DRAQ questionnaire in the two study groups at baseline and after three months (A) and the concomitant changes during that period (B). Values are expressed as box plots with whiskers (minimum; 25th, 50th, 75th percentiles; and maximum values). Open boxes are the controls while hatched boxes represent the intervention group



Nutrition impacts on QoL and poor nutritional status is associated with reduced QoL. EQ-5D is a frequently used research tool to explore relations between QoL and various nutritional aspects among elderly (30, 31). Our findings of no significant differences in the EQ-5D dimension scores and in the VAS score suggest that nutritional counselling alone does not confer any benefit to our research population in terms of QoL. This is supported by a recent study from Parsons et al. showing that nutritional supplementation was superior to dietary advice at improving QoL among elderly living at home (32), in addition to being cost-effective (33). Notably the EQ-5D scores, both from the VAS and the five dimensions, were lower among our total patient cohort compared with a general population (34).

Poor appetite is common in elderly patients and can contribute to weight loss and thus impact negatively on health outcomes. Therefore early detection of poor appetite is important. To assess appetite we adopted the DRAQ tool, a slightly modified version of the CNAQ tool, an easy-to-use questionnaire that predicts weight loss among elderly living at home (17). At variance with other nutritional screening tools that combine appetite assessments into multiple nutritional domains, DRAQ targets only appetite-related domains, hence limiting the possibility of confounding. The lack of significant differences in the DRAQ scores between the two study groups, suggests that nutritional counselling alone was inadequate to improve appetite as a means to prevent weight loss. This corroborates the negative findings regarding the nutritional counselling alone on body weight and QoL reported above. Nutritional supplementation seems to be necessary for increasing appetite among patients with poor nutritional status, as systematically reviewed by Baldwin et al. (8). Our DRAQ scores were not apparently different from those obtained among a cohort of general community-dwelling adults when using the CNAQ tool (17).

We assumed that 25% of the patients in control group would experience > 5% weight loss, but only 10% did, implying that our study may have been under-powered. Another limitation of this study is the lack of measures of body composition and lack of dietary information prior to admission to GHR and during the 3-months observation period after discharge. Moreover, we did not include any biomarkers of nutritional status and inflammation. Due to the limited sample size we reduced the number of sub-analyses, e.g. regarding the various diagnoses. Notably, the outcomes body weight, quality of life and appetite must be considered highly relevant for this patient group. Moreover, since the two study groups were so well randomized with no apparent differences in their baseline characteristics, confounding is likely to be negligible. Although we had no quantitative measure of compliance, experiences from the phone conversations and home visits pointed unambiguously to a high adherence to the counselling.

To conclude, in this randomized trial we failed to demonstrate any beneficial effect of nutritional counselling alone on preventing body weight loss > 5%, or on quality of life scores, or on appetite scores among elderly home-living patients three months after discharge from a rehabilitation institution. A small, but significant increase in body weight was observed in the intervention group. Nutritional counselling should therefore be combined with nutritional supplementation to prevent body weight loss in this patient group, and should therefore be tested prospectively. Future research should also include measures of physical- and cognitive functions, two outcomes of particular

relevance in home-living elderly patients.

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Conflict of Interest: Joanna Andersson, Erik Hulander, Elisabet Rothenberg and Per Ole Iversen each declare no conflict of interest.

*Ethical Standards:* The authors declare that the trial procedures comply with the current ethical standards for investigation involving human participants in Norway.

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