

CLINICAL NUTRITION

Positive effect of protein-supplemented hospital food on protein intake in patients at nutritional risk: a randomised controlled trial

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Keywords

food fortification, hospital food, nutritional support, protein, room service, undernutrition.

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How to cite this article

Munk T., Beck A.M., Holst M., Rosenbom E., Rasmussen H.H., Nielsen M.A. & Thomsen T. (2014) Positive effect of protein-supplemented hospital food on protein intake in patients at nutritional risk: a randomised controlled trial. *J Hum Nutr Diet.* **27**, 122–132
doi:10.1111/jhn.12210

Abstract

Background: New evidence indicates that increased dietary protein ingestion promotes health and recovery from illness, and also maintains functionality in older adults. The present study aimed to investigate whether a novel food service concept with protein-supplementation would increase protein and energy intake in hospitalised patients at nutritional risk.

Methods: A single-blinded randomised controlled trial was conducted. Eighty-four participants at nutritional risk, recruited from the departments of Oncology, Orthopaedics and Urology, were included. The intervention group (IG) received the protein-supplemented food service concept. The control group (CG) received the standard hospital menu. Primary outcome comprised the number of patients achieving $\geq 75\%$ of energy and protein requirements. Secondary outcomes comprised mean energy and protein intake, body weight, handgrip strength and length of hospital stay.

Results: In IG, 76% versus 70% CG patients reached $\geq 75\%$ of their energy requirements ($P = 0.57$); 66% IG versus 30% CG patients reached $\geq 75\%$ of their protein requirements ($P = 0.001$). The risk ratio for achieving $\geq 75\%$ of protein requirements: 2.2 (95% confidence interval = 1.3–3.7); number needed to treat = 3 (95% confidence interval = 2–6). IG had a higher mean intake of energy and protein when adjusted for body weight (CG: 82 kJ kg⁻¹ versus IG: 103 kJ kg⁻¹, $P = 0.013$; CG: 0.7 g protein kg⁻¹ versus 0.9 g protein kg⁻¹, $P = 0.003$). Body weight, handgrip strength and length of hospital stay did not differ between groups.

Conclusions: The novel food service concept had a significant positive impact on overall protein intake and on weight-adjusted energy intake in hospitalised patients at nutritional risk.

Introduction

Undernutrition remains a considerable problem in hospitalised patients despite evidence describing both its clinical and economic consequences. The prevalence of hospital undernutrition is reported to range between 20% and 50%, depending on the methods used to measure undernutrition (Norman *et al.*, 2008). Furthermore, there

is evidence that 75% of patients at nutritional risk, who remain hospitalised for more than 1 week, lose weight (McWhirter & Pennington, 1994).

If nutritional therapy is not adequately provided, undernourished patients are at risk of increased morbidity, an increased length of hospital stay, a decreased quality of life and increased mortality (Edington *et al.*, 2000; Stratton *et al.*, 2003; Norman *et al.*, 2006).

Food is traditionally recommended as the first choice for treating undernutrition and, subsequently, approximately 75% of hospitalised patients rely solely on the hospital food service menu for nutrition (Mahoney *et al.*, 2009). Hospital food therefore constitutes an important strategy for treating undernutrition within the hospital setting.

Energy-enriched hospital food has been shown to be effective in increasing energy intake in hospitalised patients at nutritional risk (Olin *et al.*, 1996; Gall *et al.*, 1998; Barton *et al.*, 2000). However, none of these studies demonstrated an increase in protein intake.

In 2009, we conducted a historically controlled pilot study aiming to investigate whether a novel food service concept would increase both energy and protein intake in patients at nutritional risk. The food concept was a novel menu of small energy-enriched dishes, on order a la carte 24 h a day (Munk *et al.*, 2013). The study showed a significant time gradient in total energy intake but protein intake did not increase accordingly. Only approximately 20% of the included patients reached 75% of their protein requirements.

The general recommendation for protein requirements during illness is $1.3\text{--}2\text{ g kg body weight (BW)}^{-1}$ (Kudsk & Sacks, 2006; Braga *et al.*, 2009). This amount is higher than the 0.8 g kg^{-1} per day recommended for healthy individuals because hospitalised patients are at risk of increased gluconeogenesis, muscle catabolism and, in some cases, decreased absorption of nutrients, as often mediated by the cytokine response to illness or injury (Kudsk & Sacks, 2006; Braga *et al.*, 2009).

This indicates that hospital food intervention trials need to focus more on increasing the protein content of the food at the same time as maintaining focus on energy intake.

The present study aimed to determine whether protein fortification of the novel menu used in the pilot study and subsequent testing of the menu in a randomised controlled trial (RCT) would impact positively on both energy and protein intake in patients at nutritional risk. To date, there have been no published RCTs employing a similar intervention.

Materials and methods

Study design and participants

The trial was conducted in 2011–2012, as a single-blinded block RCT. We included patients over a period of 18 weeks from October 2011 to February 2012.

Study participants were recruited from the departments of Oncology, Orthopaedics and Urology at Herlev University Hospital, Copenhagen, Denmark.

We included a run-in period of 5 weeks (29 August 2011 to 30 September 2011) before randomisation of

patients and initiation of data collection. During the run-in period, a convenience sample of patients meeting the inclusion criteria for the RCT pretested the novel food service concept. The aim of the run-in period was to ensure optimal training of staff with regard to screening for eligible patients and ordering of food from the novel menu. The need for a run-in period was identified in a previous pilot study (Munk *et al.*, 2013). After the run-in period, eligible patients were randomly assigned to the intervention (IG) or control group (CG) using stratified block randomisation according to hospital wards. Patients were randomised using sealed, opaque envelopes with a total of nine blocks each consisting of 10 envelopes. The allocation sequence was generated by a secretary who was not otherwise involved in the trial. One of three research assistants (all registered clinical dietitians) recruited and enrolled patients.

Blinding of participants and data assessors was not possible; the latter because patients revealed their group allocation when interviewed about their food intake. Data analysis was blinded by allocating the letters A and B to the two groups. The analysis was undertaken by the principal investigator who was blinded to the randomisation.

Inclusion criteria were:

- newly-admitted patients ≥ 18 years old who were at nutritional risk according to the validated Nutritional Risk Screening-2002 (NRS-2002) tool (≥ 3) (Kondrup *et al.*, 2003),
- patients who were able to eat orally,
- an anticipated length of hospitalisation of ≥ 3 days,
- sufficient language proficiency.

Exclusion criteria were:

- dysphagia,
- food allergy or intolerance,
- anatomical obstructions preventing oral food intake,
- patients who exclusively received enteral or parenteral nutrition,
- terminal patients.

Nursing staff performed the nutritional risk screening and one of the three research assistants screened patients for the remaining inclusion criteria before enrolment.

Nutritional Risk Screening tool

The NRS-2002 is a validated tool for identifying patients who are likely to benefit from nutritional support. Evaluation of nutritional risk is based on two components: nutritional status and severity of disease. Nutritional status depends on three variables: body mass index (BMI), recent weight loss and dietary intake during the last week before admission. A score of 1–3 is given depending on severity of undernutrition, where 3 is given for severe undernutrition. For severity of disease, as an indicator of

stress metabolism and increased nutritional requirement, a score of 1–3 is also given. A score of 3 is given for severe disease (e.g. intensive care). The score for nutritional status is added to the score for severity of disease to give a total score, which can range from 0 to 6. Finally, if the patient is aged ≥ 70 years, a score of 1 is added to the total score to correct for age-related frailty. If the age-corrected total score is ≥ 3 , nutritional support is indicated and assumed beneficial (Kondrup *et al.*, 2003).

The intervention

The IG received a targeted food concept consisting of an a la carte menu of small dishes enriched with natural energy-dense ingredients and supplemented with a high-quality protein powder (Fig. 1). The dishes were on order by telephone. Patients, ward staff or research assistants could order the dishes, which were presented and served by kitchen staff using a 'room service' approach. We chose this solution because it was anticipated that nursing staff would not always be able to serve the dishes as a result of competing ward responsibilities.

Nursing staff were responsible for preparing patients for eating and for assisting patients who were unable to eat by themselves. Moreover, the dishes were specifically designed so that they were easy to eat with only a fork or a spoon. The novel menu was supplemental to the standard hospital food service. Patients could order as many dishes as they liked between 07.00 and 20.00 h Monday to Sunday. After an order was placed, kitchen staff delivered the dishes within 20 min. To secure nutritional intake during weekends, patients were also able to place orders 48 h in advance so that reductions in ward staff during weekends would not compromise the intervention. If a patient remained hospitalised after completion of data collection (7 days), he/she was free to continue to use the novel hospital food menu until discharge.

We selected the most popular dishes from the original menu tested in our previous pilot study (Munk *et al.*,

2013) and fortified them with a high-quality protein powder (a milk protein, 'GlanPro'; Toft Care System, Copenhagen, Denmark). The amino acid profile of the protein powder was in accordance with the recommendations of the World Health Organisation's technical report from 2007 (WHO, 2007). The final energy and protein fortified novel menu consisted of 23 small dishes (Table 1). All dishes contained a minimum (range) of 6 g (6.1–11.5 g) of protein. The mean (range) energy density was 9.4 kJ/g (2.5 kJ/g to 19.8 kJ/g). All but three dishes (baked salmon, meat loaf, meat balls of veal) contained protein powder. Portion sizes ranged from 52 to 110 g per dish. We used the MASTER CATER SYSTEM, version 3.055 (ANOVA Data A/S, Holte, Denmark) to analyse the energy and protein content of the dishes.

Dietitians, chefs and nurses from the participating departments invested considerable time and effort into achieving the right flavour, texture, volume and a minimum content of 6 g of protein in each dish.

Standard hospital food service

The CG received the standard hospital food service (Fig. 1). The standard hospital food service offers three main meals (breakfast, lunch, dinner) served from a buffet. Two main diet types are available: the 'hospital diet' for nutritionally at risk patients and the 'normal diet' for well-nourished patients. The 'hospital diet' has a higher energy and protein density than the 'normal diet'. The CG received the 'hospital diet'.

For breakfast, the CG patients could choose between hot porridge (e.g. oatmeal) and bread with butter, jam and cheese. For lunch, CG patients could choose between, five small slices of rye bread with butter and various toppings such as sliced boiled eggs, ham, shrimps and paté and, also, a hot soup of the day. For dinner, two different kinds of starters, two different kinds of hot meals and two different kinds of dessert were available. The three main meals served from the buffet are intended to provide 50–75% of nutritional requirements. The remaining requirements are covered by three in-between meals [e.g. microwaveable meals, snacks (e.g. cakes), biscuits with cheese, ice cream and/or beverages (e.g. oral nutritional supplements)]. In-between meals are served either by the buffet-staff or by nursing staff.

The national nutritional guidelines for the 'hospital diet', energy and protein rich beverage included, recommend that the hospital diet on average contains 9000 kJ, 95 g of protein (15–20% of energy), 100 g of fat (40–50% of energy) and 225 g of carbohydrate (40–45% of energy) (Danish Veterinary & Food Administration, 2009).

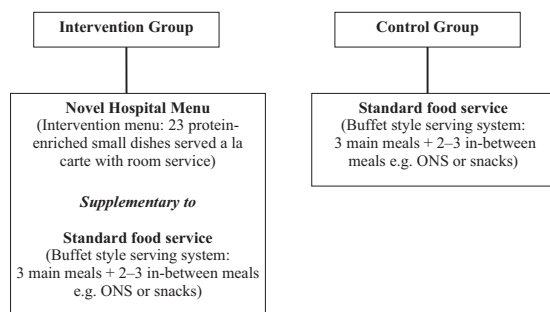


Figure 1 Food concept in the control group compared to the intervention group. ONS, oral nutritional supplements.

Table 1 The novel food service concept menu*

Menu	Portion size g	Energy kJ	Energy density kJ g ⁻¹	Protein g	Orders Ranked [†]
Breakfast dishes					
Omelette with bacon	60	699	11.7	9.1	4
Breakfast muffin with butter, cheese and jam	100	1518	15.2	11.5	5
Ryebread porridge with fresh vanilla cream	90	371	4.1	7.4	6
Soups					
Clear soup with vegetables, meatballs and dumplings	79	195	2.5	6.9	1
Classical mushroom soup	75	468	6.2	8.2	5
Fish dishes					
Terrine of smoked eel	60	555	9.3	7.6	4
Baked salmon with egg coleslaw, hazelnuts and olive tapenade	70	763	10.9	8.9	4
Slightly smoked trout seasoned with egg salad and fresh chervil	55	540	9.8	8.0	5
Meat dishes					
Meat loaf with game sauce and cranberries	73	448	6.1	7.6	4
Meat balls of veal with stewed cabbage and bechamel sauce	55	451	8.2	6.5	4
Crispy fried fish crêpine with Jerusalem artichokes in cream sauce	75	720	9.6	7.5	5
Chicken sticks with peanut butter	55	739	13.4	7.9	5
Side dishes					
Mashed sweet potatoes with onion and bacon	68	658	9.7	6.4	3
Torta di risotto with fried mushrooms, herbs and lemon peel	47	412	8.8	7.7	5
Warm potato omelette with a compote of pickled red onions	50	537	10.7	6.1	5
Baked cauliflower cream with roasted nuts and pickled cucumbers	60	389	6.5	7.1	5
Mashed root vegetables with browned butter	75	628	8.4	6.1	5
Desserts					
Chocolate confection of marzipan and nougat	52	1028	19.8	6.3	2
Crunchy apple cake with peel of orange	90	815	9.1	7.3	2
Mild fromage with cream and chocolate	68	623	9.2	7.6	3
Buttermilk dessert with lemon and small cookies	100	835	8.4	6.9	3
Hot chocolate with whipped cream	110	801	7.3	6.2	4
Ice cream of avocado with fresh fruit	70	772	11.0	7.1	5

*Reflects portion size, the energy density, energy and protein content of all 23 dishes of the novel menu.

[†]The dishes are ranked according to how often the dishes were ordered. Ranking order: 1 = dishes ordered >50 times; 2 = dishes ordered ≥40 to <50 times; 3 = dishes ordered ≥30 to <40 times; 4 = dishes ordered ≥20 to <30 times; 5 = dishes ordered ≥10 to <20 times; 6 = dishes ordered <10 times.

Nutritional content of the novel food service concept compared to the 'hospital diet'

The novel food service concept was designed to fulfill, as a minimum, the same criteria for energy and protein content as described above. To reach daily nutritional requirements solely from the novel menu, patients needed to consume two dishes of the novel menu six times daily and drink two glasses of whole milk. This would on average provide patients with 8700 kJ and 102 g of protein. As noted earlier, the intention of the novel menu was to comprise a supplementary offer to the standard hospital food menu (Fig. 1).

Outcomes

The primary outcome was the percentage of patients reaching ≥75% of their protein and energy requirements. This nutritional target was based on a previous trial

reporting that weight stability is achieved with this level of intake (Kondrup, 2001).

Secondary outcomes were mean energy and protein intake, changes in body weight (BW), hand grip strength (HGS) and length of hospital stay (LOS). BW and HGS were recorded at baseline and every second or third day.

Body weight was measured with patients wearing underwear and immediately after they had urinated. Values were rounded to the nearest 0.1 kg.

Hand grip strength was measured in the patients' right hand using the Jamar 5030J1 hydraulic hand dynamometer (SAEHAN Corporation, Changwon, Korea). This dynamometer is reported to produce the most accurate measurement of HGS (Mathiowetz *et al.*, 1984).

We standardised the measurement of HGS in each patient by using the same position in individual patients for repeated measurements. HGS was only measured in the right hand because this is a valid method to use in

both right- and left-handed people (Petersen *et al.*, 1989; Incel *et al.*, 2002). We demonstrated the technique once to patients and then encouraged them to squeeze the hand dynamometer quickly and with maximum strength three times within 15-s intervals. The highest of three consecutive measurements was used in the data analysis.

We included the baseline data: age, sex and self-reported height, with the data being collected by research assistants.

Energy and protein intake

We calculated energy and protein intake as a mean intake over 3, 4, 5, 6 or 7 days, depending on the patient's LOS after inclusion. A detailed nutritional registration form was used to distinguish between different meal components. The amounts consumed of each portion of food/beverage were visually assessed and recorded in quartiles (0%, 25%, 50%, 75% and 100%) by nursing staff or patients. This is a validated method to assess food intake (Olin *et al.*, 1996). To ensure and verify the content of patients' dietary records, the research assistants collected records daily and conducted short daily dietary recall interviews with both IG and CG patients.

Estimation of energy and protein requirements

Patients' energy requirements were estimated according to Danish guidelines for hospitalised patients; the basic metabolic rate (BMR) multiplied by an estimated activity factor¹ (i.e. and by a stress factor in case of fever² [i.e. or, if BMI < 18.5, a factor for weight gain³ (i.e. (Danish Veterinary & Food Administration, 2009)). The BMR was calculated by Harris–Benedict equation⁴. Protein requirements were set at 18% of the energy requirement as recommended in Danish institutional diets guidelines (Danish Veterinary & Food Administration, 2009).

Statistical analysis

Statistical analyses were carried out using SPSS, version 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to calculate the mean (SD). We used Pearson's chi-squared tests and Fisher's exact test, as appropriate, to test differences between categorical data. Independent *t*-tests were used for interval scale variables. Mean energy

¹($\times 1.1$ if bedridden and $\times 1.3$ if being able to walk around on the ward)

²($\times 1.2$ (38 °C), 1.3 (39 °C), 1.4 (40 °C))

³($\times 1.3$)

⁴Harris–Benedict equation for calculating BMR: men: $BMR = 66.5 + 13.8 \text{ weight} + 5.0 \text{ height} - 6.8 \text{ age}$; women: $BMR = 655 + 9.6 \text{ weight} + 1.8 \text{ height} - 4.7 \text{ age}$

and protein intake according to BW was calculated. Mean difference in HGS and BW was adjusted for baseline using univariate analysis of variance. For categorical outcomes, we calculated risk ratios (RR) with 95% confidence intervals (CI) and, for significant results, numbers needed to treat (NNT); for continuous outcomes, we calculated mean differences with 95% CIs. Data were analysed according to intention-to-treat.

In an exploratory analysis using the chi-squared test, we examined the effect of reaching $\geq 75\%$ of energy and protein requirements on stability/increase in HGS.

Power

In a previous pilot study, 75% of the last 20 enrolled patients consumed $\geq 75\%$ of their energy needs (Munk *et al.*, 2013). With a run-in period before initiation of the present trial, it was considered realistic to expect that 75% of IG patients would be able to cover $\geq 75\%$ of their energy. Based on results from an earlier observational study (Hansen *et al.*, 2008), we further expected that 44% of the CG would be able to consume $\geq 75\%$ of their energy and protein needs. With these expectations, 40 patients in each group were required to detect a significant difference in the percentage of patients achieving $\geq 75\%$ of their energy and protein needs (from 44% to 75%) with a power of 80% and a 5% two-sided significance level. To take a potential 20% drop-out into account, we planned to include an additional 16 patients.

Ethical aspects

The Danish Regional Committee on Biomedical Research Ethics and the Danish Data Protection Agency approved the protocol, as well as the safety of the protein enrichment powder. The trial was registered at <http://clinicaltrials.gov> (ID nr: H-1-2011-048).

Before inclusion, patients received both oral and written information about the project from the research assistants. Before inclusion in the trial, patients were asked to provide their written informed consent.

Results

Study population

Overall, 105 patients were eligible for inclusion (Fig. 2). Twenty-one patients refused to participate.

The reasons for not wanting to participate were lack of resources to engage ($n = 11$), no interest in trial participation ($n = 2$), anticipation of short LOS ($n = 1$), dissatisfaction with hospital treatment ($n = 1$) and no reason given ($n = 6$).

Eighty-four patients were randomised and 81 patients completed the trial, giving a completion rate of 96%.

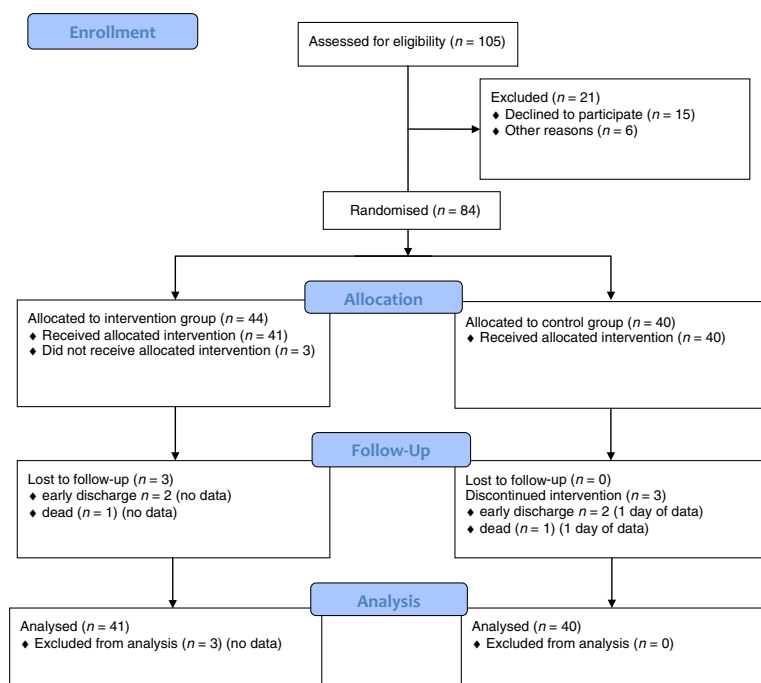


Figure 2 Consolidated Standards of Reporting Trials flowchart of patient enrolment, random assignment and follow-up.

Demographic data are shown in Table 2. IG and CG patients were similar with respect to age, sex, anthropometry and nutritional status at baseline. All patients were moderately undernourished [mean (SD) nutritional score of 1.9 (0.8)] and, overall, had a mild severity of disease score [mean (SD) severity of disease score of 1.1 (0.5)]. The distribution of cancer diagnoses was similar in the groups.

Outcome

Primary outcome

Significantly more IG patients compared to CG patients achieved an intake of $\geq 75\%$ of their protein requirements ($P = 0.001$) (Table 3). The RR for reaching $\geq 75\%$ of their protein requirements was 2.20 (95% CI = 1.3–3.70), with NNT = 3 (95% CI = 2–6) (Table 3).

The IG and CG did not differ with respect to achieving $\geq 75\%$ of energy requirements, with a RR of 1.1 (95% CI = 0.8–1.4) (Table 3).

Secondary outcomes

The difference in mean energy intake was 693 kJ between IG and CG, with the IG achieving the highest energy intake. However, the difference did not reach significance ($P = 0.08$) (Table 3). Calculating energy intake according to BW, the energy intake was significantly higher in the IG (mean difference: 20 kJ kg⁻¹, $P = 0.013$) (Table 3).

Table 2 Baseline data for intervention and control group

	Intervention	Control
<i>N</i>	41	40
Sex (<i>n</i>)		
Male	16	18
Female	25	22
Age (years)*	75 (10)	74 (11)
Anthropometric data*		
Weight (kg)	60 (14)	65 (13)
Body mass index (kg m ⁻²)	21 (4)	22 (4)
Departments (<i>n</i>)		
Urology	15	15
Orthopaedic surgery	12	10
Oncology	14	15
Nutritional risk assessment (<i>n</i>)		
Score for nutritional status (0–3)		
0	1	0
1	10	15
2	18	17
3	12	8
Score for severity of disease		
0	2	3
1	30	34
2	8	3
3	1	0
Total score		
3	18	27
4	13	9
5	7	4
6	3	0

*Mean (SD).

Table 3 Results of primary and secondary outcomes of intervention group versus control group

	Intervention group (IG) (n = 41)	Control group (CG) (n = 40)	Risk ratio (95% confidence interval)	Mean difference between IG/CG (95% confidence interval)	P-value
Primary outcome					
Coverage of $\geq 75\%$ of nutritional requirements					
Energy, n (%)	31 (76)	28 (70)	1.1 (0.8–1.4)		0.57*
Protein, n (%)	27 (66)	12 (30)	2.2 (1.3–3.7)		0.001*
Secondary outcome					
Mean energy and protein intake					
Energy, kJ (SD)	5843 (1660)	5149 (1832)		693 (–80 to 1466)	0.08 [†]
Protein, g (SD)	53 (16)	43 (17)		9.6 (2–16)	0.011 [†]
Mean intake (kJ kg ⁻¹)					
Energy, kJ kg ⁻¹ (SD)	103 (39)	82 (33)		20 (5–36)	0.013 [†]
Protein, g kg ⁻¹ (SD)	0.9 (0.4)	0.7 (0.3)		0.2 (0.1–0.4)	0.003 [†]
Mean difference in body weight (BW) [‡]					
BW, kg (SD) [§]	0.4 (2.6)	–0.4 (1.8)		–0.8 (–1.9 to 0.3)	0.17 [†] /0.33
Mean difference in hand grip strength (HGS) [¶]					
HGS, kg (SD) **	–0.1 (2.9)	–0.4 (4.3)		–0.3 (–1.9 to –1.4)	0.76 [†] /0.95 ^{††}
Length of hospital stay (LOS) ^{‡‡}					
LOS1 ^{§§} , day (SD)	15 (10)	14 (8)		1.8 (–2 to 6)	0.38 [†]
LOS2 ^{¶¶} , day (SD)	10 (8)	10 (8)		0.6 (–3 to 4)	0.73 [†]

*Pearsons chi-squared test.

[†]t-test.[‡]n = 66 (IG: 37).[§]Mean difference from baseline to day 3. Subsequent follow-up data (>3 days) are not presented because of many missing data.[¶]n = 76 (IG = 41).^{**}Mean difference from baseline to day 3. Subsequent follow-up data (>3 days) are not presented because of many missing data.^{††}Result adjusted for baseline using an univariate analysis of variance.^{‡‡}n = 79 (death: IG = 1 and CG = 1).^{§§}LOS1 = days from admission to discharge.^{¶¶}LOS2 = days from inclusion to discharge.

Mean protein intake was significantly higher (mean difference: 9.6 g day⁻¹; $P = 0.011$) in the IG, also according to BW (mean difference: 0.2 g kg⁻¹; $P = 0.003$) (Table 3). No significant differences were found with respect to BW, HGS and LOS between groups (Table 3). Adjusting mean differences in HGS and BW for baseline values did not change the results.

Seven patients received oral nutritional supplements (ONS) (IG: two patients). We did not observe any significant difference between the groups in consumption of ONS ($P = 0.26$). The ONS used were products from Fresenius Kabi (Bad Homburg, Germany) or Nutricia (Schiphol, The Netherlands). The ONS contained 1260 kJ, with protein varying from 8 to 12 g. The seven patients received a maximum of one ONS per day during the intervention period. No patients received enteral or parenteral nutrition during the study period.

Data revealed no significant differences in energy intake between the groups according to the distribution of quartiles. The distribution showed that 6% of CG and 2% of IG patients achieved an energy intake below 50% of

requirements; 20% of CG and 10% of IG patients had a protein intake below 50% of requirements (Table 4). There was a significant difference between quartiles with respect to protein intake. The majority of CG patients (81%) achieved a protein intake $\geq 50\%$ of requirements. The main difference between the groups was that significantly more IG patients achieved $\geq 75\%$ of their protein requirement.

An exploratory analysis of the data revealed a significant effect of achieving $\geq 75\%$ of energy requirement on stability or increase in HGS. In the group achieving >75% of energy requirements, 68% (27/40) either increased or stabilised HGS versus only 43% (16/37) of those not reaching >75% of energy requirements ($P = 0.015$). It should be noted that this analysis was performed on nonrandomised material.

The novel menu

The dishes from the novel menu accounted for 30% [mean (SD) 1691 (1225) kJ day⁻¹] of the energy intake

Table 4 Coverage of energy and protein requirements in quartiles in intervention group (IG) versus control group (CG)

Quartiles	0–24%	25–49%	50–74%	≥75%	Total
Energy intake*					
CG, n (%)	1 (2.5)	1 (2.5)	10 (25)	28 (70)	40
IG, n (%)	0 (0)	1 (2.4)	9 (22)	31 (75.6)	41
Total	1	2	19	59	81
Protein intake†					
CG, n (%)	2 (5)	6 (15)	19 (47.5)	13 (32.5)	40
IG, n (%)	0 (0)	4 (9.7)	10 (24.4)	27 (65.9)	41
Total	2	10	29	40	81

*Fisher's exact test, $P = 0.846$.†Fisher's exact test, $P = 0.013$.

and 40% [mean (SD) 35 (22) g day⁻¹] of the protein intake in the IG.

A varied distribution of dishes was ordered. However, patients appeared to prefer sweet and/or soft dishes such as: soup, buttermilk dessert, mild fromage, confections of marzipan and mashed potatoes (Table 1). Patient preferences did not appear dependent on whether protein powder was added because the preferred dishes all contained protein powder.

Discussion

Primary outcome

The novel menu significantly increased the number of IG patients achieving ≥75% of their protein requirements, although without increasing the number of patients achieving ≥75% of their energy requirements accordingly. Indeed, the menu doubled the number of patients achieving ≥75% of their protein requirements. With a NNT of three for one patient to achieve ≥75% of their protein requirements, and considering that the novel menu accounted for 40% of the protein intake in the IG, we consider the novel menu a relevant and feasible intervention for hospitalised patients at nutritional risk.

Surprisingly, the percentage of patients achieving an energy intake ≥75% of energy requirements, did not differ between groups. It is possible that the increased focus on nutritional intake in the CG as a result of the registration of nutritional intake may have influenced the awareness of food intake in CG patients and thereby increased their energy intake.

Previous RCTs report similar results. However, the interventions tested in these studies were considerably more time consuming, requiring daily attention from a dietitian or nurse to motivate patient and staff, daily adjustments of individualised nutritional plans, ordering of food in collaboration with patients, and securing the supply of food ordered (Johansen *et al.*, 2004; Starke

et al., 2011). The present study, in comparison, demonstrated that a relatively simple and feasible nutritional intervention was as effective.

To this date, we have not identified other RCTs of similar interventions using the same primary outcome as in the present study. This is unfortunate because comparing mean values for energy and protein intake alone between intervention and control groups may mask the proportion of severely underfed patients in either of the groups.

Our results point towards the value of protein enrichment. Previous studies with similar settings, interventions and primary outcome (i.e. increasing energy and protein intake) have demonstrated increased mean energy intakes but, in contrast to the present study, did not increase protein intake (Gall *et al.*, 1998; Barton *et al.*, 2000; Munk *et al.*, 2013). This is not surprising because these studies primarily enriched the food with naturally energy-dense ingredients. In our experience, it is easier to increase energy content without compromising taste, texture and volume. Increasing protein content, on the other hand, is more difficult, especially when using high-quality protein powder because aromatic amino acids can alter taste negatively.

However, it is definitely possible to develop a delicious menu using high-quality protein powder. Three key issues need to be taken into consideration: (i) a chef should be responsible for developing the menu because of his/her professional knowledge of producing foods with excellent taste; (ii) experienced clinical dietitians are vital for supplying the chef with knowledge about the taste preferences of hospitalised patients at nutritional risk, as well as for securing the energy and protein content of the menu; and (iii) sufficient time should be allocated for taste testing sessions in the development phase, including test sessions where patients are included.

Energy and protein intake <50% of requirement has been shown to be associated with increased 6-month mortality (Holst *et al.*, 2010). A minority of patients in the present study had a protein intake below this level. The effect of the novel food service concept tested in the present study was rather that patients consuming 50–74% of protein target further increased their protein intake, thus moving up to the ≥75% of protein target.

Secondary outcomes

We observed no differences in weight change between groups. We did not take oedema, ascites or degree of hydration into account. Registration of food intake over a maximum of 7 days might also have been too brief to detect a significant difference between groups. The high energy intake in both the IG and CG may also have contributed.

Muscle function is a clinically relevant outcome parameter that responds rapidly to insufficient nutritional intake, making HGS a popular surrogate outcome for changes in nutritional status (Norman *et al.*, 2011). We did not identify a difference between groups in HGS. The present study was not powered to detect differences between groups in HGS. The high mean age in the included patients could also have contributed, especially because, in elderly patients, HGS may not consistently reflect nutritional therapy (Norman *et al.*, 2011). Indeed, a meta-analysis found no positive effect of nutritional intervention on HGS in older people (Milne *et al.*, 2009).

Length of hospital stay did not differ between groups. The primary reason was a lack of power. However, a supplemental reason could be that the difference between energy and protein intake in the groups was too small. Some studies argue that a minimum difference is required to influence LOS (Johansen *et al.*, 2004; Starke *et al.*, 2011). An energy intake of 155 (8) kJ kg⁻¹ and a protein intake of 1.4 (0.1) g kg⁻¹ may lead to reduced LOS (Johansen *et al.*, 2004). LOS furthermore depends on a plethora of patient-related, treatment-related and organisational factors, all of which may be unrelated to nutritional intake.

Even though the results of the present trial are promising, we need to continue to set even higher standards so that more patients achieve at least their minimum energy and protein requirements when hospitalised. ONS are effective for increasing energy and protein intake in hospitalised patients (Stratton *et al.*, 2003). Surprisingly, in the present study, only seven patients received ONS.

By supplementing the novel food service concept tested in the present study with two ONS a day, we might further increase the percentage of patients reaching 75% of their minimum energy and protein requirements. Another approach could be to supplement the novel food service concept with dietary counselling. However, this should be investigated in further RCTs including the economic implications of such an intervention.

Furthermore, to increase the level of evidence in future food interventions studies, we emphasise the value of conducting RCTs using relevant and comparable outcomes. Koller *et al.* (2013) recommend the use of biomedical outcomes in combination with patient-reported outcomes (e.g. quality of life and health economic outcomes to assess the effect of nutritional therapies).

Strengths and limitations of the study

The use of a randomised controlled design and the low drop-out rate increases the strength of the results of the present study. Blinding of ward staff and data assessors

would have been preferable to minimise the risk of performance and detection bias. However, blinding of patients and staff was not possible and, because of the way in which nutritional intake was monitored, only a single-blinded design with blinded data analysis was possible.

The use of a validated method to estimate energy and protein intake is also a strength. We calculated mean energy and protein intake over as many days as possible for each patient (maximum 7 days). This may have inflated the overall mean energy and protein intake as a result of an expected increase in nutritional intake over time. Patients who were followed for 7 days, however, did not have an increased intake compared to those followed for <7 days (data not shown).

Furthermore, we attempted to use a standardised protocol for measuring HGS. This protocol proved to be difficult to apply in a hospital setting. Many patients were unable to get out of bed or sit up in a chair, a position that is part of the standardisation. Instead, we chose to use the same position in individual patients for repeated measurements. This may influence the comparability of our study with other similar studies.

If this novel food service concept is to be implemented, economic implications should be considered. We did not conduct an economic evaluation of the costs associated with our approach.

Future studies should include this aspect. The risk of increasing costs might limit the translation and subsequent implementation of the novel menu model. However, given the major economic consequences of undernutrition, individually and for society (Ljungqvist & de Man, 2009), translation of the novel menu could potentially constitute a relatively low-cost intervention for addressing undernutrition in hospitalised patients.

Although time-consuming at the start, we argue that adaptation of the novel menu to local food cultures and hospital menus, as carried out in the present study, is feasible.

Conclusions

The intervention had a significant positive impact on overall protein intake and on weight-adjusted energy intake compared to the standard hospital menu, indicating that the novel food service concept can be a simple and effective strategy for increasing protein and energy intake in hospitalised patients at nutritional risk.

However, the impact of the food concept on relevant treatments outcomes (i.e. physical function, LOS and quality of life) needs to be studied further in larger RCTs. Finally, the economic implications of the intervention also require additional investigation.

Acknowledgments

We thank the patients and the wards of Orthopaedic surgery, Oncology and Urology at Herlev University Hospital for participating in the study. We also thank Tobias W. Klausen for statistical support, Line L. Jensen for helping with data collection, Christian Bitz for helping with designing the menu card, and Ulla Tolstrup Andersen for academic discussions during the writing of the manuscript.

Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

This study has been funded in part by the Herlev University Hospital Research Unit, which we acknowledge. We also thank the company 'Toft Care System' (Copenhagen, Denmark) for giving us the protein powder used free of charge. The sources of funding had no influence on the design of the study; the collection, analysis, or interpretation of the data; the writing of the manuscript; or the decision to submit for publication.

TM, MAN and TT designed the research. ER and AMB conducted the research. TM performed the statistical analysis. TM, TT, HHR, MH and AMB interpreted the data. TM and TT wrote the manuscript. TT and TM have primary responsibility for the final content. All authors critically read and approved the final version submitted for publication.

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