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Received 30 December 2011; accepted in revised form 14 March 2012

Age and Ageing 2013; **42:** 39–45 doi: 10.1093/ageing/afs078 Published electronically 8 June 2012 © The Author 2012. Published by Oxford University Press on behalf of the British Geriatrics Society.

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# Clinical benefits of oral nutritional supplementation for elderly hip fracture patients: a single blind randomised controlled trial

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# **Abstract**

**Background:** malnutrition is an important risk factor for poor outcome in patients recovering after hip fracture surgery. This study aimed to investigate the clinical, nutritional and rehabilitation effects of an oral nutritional supplementation (ONS) in an inpatient rehabilitation setting.

Methods: this was an observer-blinded randomised controlled trial of elderly post-surgical proximal femoral fracture patients. A ready-to-use oral liquid nutritional supplementation (18–24 g protein and 500 kcal per day) in addition to

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hospital diet was compared with hospital diet only. Both groups received usual rehabilitation therapy and oral calcium and vitamin D supplements. Outcomes were compared at discharge from rehabilitation and after 4 weeks of discharge. The primary outcome parameters were the serum albumin level, the body mass index (BMI), the functional independence measure (FIM) and the elderly mobility scale (EMS). Secondary outcome parameters were frequency of complications, inpatient length of stay, mortality and acute hospital use within 6 months after discharge.

**Results:** a total of 126 patients were recruited, 65 in the supplementation arm and 61 in the control arm. There was a significant difference in change in BMI with a decrease of 0.25 and 0.03 kg/m<sup>2</sup> in the ONS group and 0.72 and 0.49 kg/m<sup>2</sup> in the control group at hospital discharge and follow–up, respectively (P = 0.012). The length of stay in rehabilitation ward was shortened by 3.80 (SE = 1.81, P = 0.04) days favouring the ONS group. The total number of infection episodes was also reduced significantly. No difference was observed in the rate of change of the serum albumin level, the FIM and the EMS.

Conclusion: clinical and nutritional benefits were seen in this trial but rehabilitation benefits could not be demonstrated.

**Keywords:** geriatric hip fracture, nutritional supplementation, rehabilitation, oral nutritional supplementation, rehabilitation outcome, clinical outcome, older people

#### Introduction

Fractures of the proximal femur cause significant morbidity and mortality in older people. Patients with hip fracture are more likely to be malnourished at the time of fracture [1–3] and suboptimal intake is common in those recovering from hip fracture in hospital Malnutrition is an important risk factor for poor outcome in patients recovering after hip fracture surgery [8]. Cochrane collaborators [9] have reviewed the effect of nutritional supplementation in this group of patients. Results indicate that multinutrient supplement by oral route has no significant effect on post-hip fracture mortality and unfavourable outcome (death or complication). Only 4 of these 10 studies [8, 10–18] involving 215 participants [11, 13, 15, 16] analysed functional outcome and found that there was no significant improvement except for the study by Tidermark et al. [16], which found that the Katz activities of the daily living score were significantly maintained in the supplemented group. Higher protein containing supplement may reduce the length of time spent in rehabilitation hospital and numbers of complications [19–22]. It was recommended that further studies with well-designed, adequately powered, trials of nutritional supplementation are required with an intention to treat design and measurement of rehabilitation outcomes.

#### **Objective**

This was a randomised controlled, observer blinded, parallel two-arms trial to study the beneficial effect of nutritional supplementation (a twice daily ready-to-serve moderate-dose oral protein and calorie supplementation) in post-hip fracture surgical patients, given for a maximum of 28 days in a rehabilitation hospital. Nutritional and functional outcomes were measured at the end of inpatient rehabilitation and 4 weeks after discharge from hospital.

#### **Method**

All post-operative hip fracture patients transferred to the Department of Rehabilitation of Kowloon Hospital were screened for eligibility for nutritional supplementation. Inclusion criteria were those 60 years or older, recent low-impact osteoporotic fracture of the proximal femur surgically repaired within 4 weeks before recruitment. Exclusion criteria were those patients who required tube feeding, those in unstable medical condition, BMI  $\geq$  25, malignancy, conditions with contraindication for high-protein diet, mentally incapacitated and inability to communicate or understand the written consent. The ethics committee of Kowloon Central and Kowloon East Clusters of the Hospital Authority in Hong Kong approved the study.

#### Randomisation and blinding

A sealed opaque envelope containing the randomised group from blocks of twelves was drawn for each patient by a member of the ward staff who was not a co-investigator. The patients were accordingly assigned as the treatment or the control group. The baseline and subsequent anthropometric and physical measurements were performed by dietitians, occupational therapists and physiotherapists who were blinded to group allocation.

#### **Nutritional intervention**

A ready-to-use oral liquid nutritional supplement (18–24 g protein and 500 kcal per day) was started in the intervention group for a maximum duration of 4 weeks in addition to best medical care. The oral nutritional supplementation (ONS) was a drink of about 240 ml in volume given twice daily on top of the standard hospital diet. Four types of nutritional supplements were offered according to patient's dietary preferences. These were brands Ensure by Abbott,

Resource Breeze by Nestle Nutrition (orange or peach flavour), Compleat by Nestle Nutrition and Glucerna by Abbott. These products were provided free of charge to the patient by the hospital and there was no commercial sponsorship. The ONS was started within 3 days after hospital admission (after consent to enter the trial) and continued until discharge from hospital or 28 days which ever came first. Both groups of patients were also prescribed oral vitamin D supplement of 800–1,000 IU per day and calcium tablets containing elemental calcium of 1,200 mg. Both groups received rehabilitation therapy and regular case conference review until assessed to be fit to be discharged.

#### **Outcome parameters**

The primary outcomes measured were the changes in the serum albumin level, the body mass index (BMI), the functional independence measure (FIM) score and the elderly mobility scale (EMS). Secondary outcome parameters were frequency and severity of complications, length of stay in rehabilitation ward, mortality and accident and emergency department attendance within 6 months after discharge. Other parameters measured included mid-arm circumference (MAC), triceps skin fold (TSF), serum insulin-like growth factor-1 (IGF-1) level, bilateral quadriceps strength and dominant hand grip strength. Patient tolerability, compliance and adverse effects due to the supplementation were also documented.

#### **Power calculation**

To detect a mean difference of 3 g/l in albumin (SD = 5), a 4 points difference of the FIM score (SD = 7.5), a  $0.5 \text{ kg/m}^2$  difference in the BMI (SD = 0.9) and 3 units difference in the EMS (SD = 4) between the two study arms, at least 58–120 subjects were needed for a two-sided 0.05 significance level at a probability of 80%.

#### Assessment by dietitian

A nutritional assessment on estimated energy and protein requirement and estimated intake from the diet was made on admission and prior to discharge from the rehabilitation ward and at 4-week follow-up. A locally validated malnutrition screening test – malnutrition universal screening tool (MUST) [23, 24] was used to identify cases at risk of poor nutritional status. Anthropometric measurements were taken at baseline, before discharge and at 4-week follow-up by a dietitian blinded to study allocation. These included weight, height, BMI, TSF and MAC. For height and weight measurements two readings were taken and three readings were taken for TSF and then averaged.

# Assessments by occupational therapist and physiotherapist

The Cantonese version of mini-mental state examination (MMSE) [25] and the FIM [26] was measured by a blinded occupational therapist. The EMS [27], the hand grip using a Baseline Hydraulic Hand Dynamometer (USA) and bilateral quadriceps strength using a Nicholas Manual Muscle Tester Model 01160 (USA) were measured by a blinded physiotherapist to reflect functional mobility, general body strength and lower limb strength.

#### Assessment by physician and nursing staff

Admission, discharge and 4-week post-discharge albumin level and IGF-1 levels were measured by blood testing. Medical complications were prospectively documented. The presence of infections was defined by clinical diagnosis supported by radiological or laboratory reports and use of antibiotics. The presence of delirium was defined by positive findings on the confusion assessment method [28]. The presence of pressure sores, retention of urine, deep vein thrombosis, pulmonary embolism, anaemia requiring transfusion or iron supplements, falls and electrolyte disturbances was noted by physicians caring for the patient who were not in the team of investigators. For the ONS group, tolerability, amount of intake and compliance to the liquid supplement in hospital were documented by an intake chart by nursing staff not associated with the investigators. The patient's discharge date and destination were based on the rehabilitation team decision in conjunction with patient's and relative's opinion. The co-investigators in this study did not participate in the treatment or discharge decisions that were handled by the ward-based rehabilitation team.

## Statistical analysis

Three sets of data at three different time points were obtained for longitudinal comparison. T1 = admission, T2 = discharge from rehabilitation ward, T3 = follow-up at 4 weeks after discharge. Baseline variables were analysed for difference using the independent samples T-test and Chi-squared tests. The general linear model for repeated measures test (SPSS 15.0 for windows) was used for the comparison of continuous variables. Different time points were the within-subject factor and the arm of randomisation as the between-subject factor. The covariate was the same patient's data at baseline (ANCOVA). Mann-Whitney U and Kruskal-Wallis tests were employed to detect a statistical difference between control and intervention groups for ordinal variables. Subjects were excluded from the analysis if there was drop out before repeat assessments were made. The subjects were analysed as 'complete case' or 'available case' analysis which included only those whose outcome was known in each of the randomised arm regardless of adherence to the intervention. Only subjects with

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complete data at all three time points were included in the ANCOVA calculation.

#### **Results**

A total of 600 patients after hip fracture surgery over 24 months were screened for inclusion (Figure 1). Of these 126 met inclusion criteria and signed a written consent. Five patients were subsequently excluded due to unstable medical condition, retrospective diagnosis of cancer of the lung, colon and tuberculosis. Finally 61 patients were recruited into the intervention (ONS) arm and 60 into the control arm.

The baseline characteristics of the patients are shown in Table 1 and Appendix 1 (Supplementary data are available in *Age and Ageing* online). There were no significant differences in baseline anthropometric, biochemical, functional, strength and mobility parameters between the two groups. The mean age of the patients recruited was 80.9 and 81.7 years, respectively. The participants in both arms had

significant comorbidity with multiple underlying illnesses and peri-operative complications including delirium, sepsis and need for transfusion. The caloric and protein intakes during hospitalisation were similar at baseline on admission to rehabilitation ward but significantly increased in the ONS group during the hospital stay (Table 2) when compared with the control group by 353.1 kcal and 10.1 g protein per day (P = 0.000, P = 0.000 respectively). The overall compliance rate to ONS was 77.7% (SD: 20.9) and mean number of days of supplementation in the intervention group was 20.2 (SD: 6.9). Six patients (9.8%) reported intolerance (including dislike of the taste, nausea, abdominal bloating and diarrhoea) and one (1.6%) patient refused to consume the ONS after randomisation to the ONS group. These seven patients were included in the final analysis as their follow-up data were complete. The number of patients with adequate intake of calories and protein (meeting estimated requirements) was significantly increased (P = 0.043) in the intervention group (67.2%) versus the control group (8.6%) (see Supplementary data available in Age and Ageing online, Appendix 2).

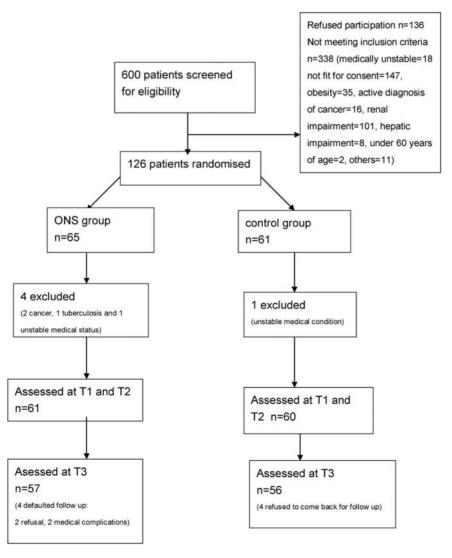


Figure 1. Patient flow.

Table I. Baseline demographic data

	ONS $(n = 61)$	Control $(n = 60)$	P-value
Female gender $[n \ (\%)]$	42 (68.9)	38 (63.3)	0.568
Age [mean (SD)]	80.9 (6.5)	81.7 (6.4)	0.516
Mean pre-operative length of stay in hours [(mean (SD)]	56.6 (58.6)	44.8 (33.2)	0.176
Type of fracture [ $n$ (%), NOF:TOF:subTOF]	28:30:3 (45.9:49.2:5)	24:33:3 (40555)	0.802
Type of operation [ $n$ (%), HA:DHS:others]	27:24:10 (44.3:39.3:16.3)	19:33:8 (31.7:5 5.0:13.3)	0.220
Mean post-operative length of stay until admission to rehabilitation	8.8 (4.2)	9.1 (4.4)	0.721
ward (days) [mean (SD)]			
ASA class 1:2:3:NA [n (%)]	1:38:19:3 (1.7:65.5:32.8:3.3)	1:46:11:2 (1.7:79.3:19.0:3.0)	0.235
Peri-operative sepsis $[n \ (\%)]$	19 (31.1)	21 (35)	0.652
Peri-operative delirium [n (%)]	11 (18.0)	7 (11.7)	0.325
Peri-operative anaemia requiring transfusion [n (%)]	24 (39.3)	19 (28.3)	0.378
History of diabetes $[n (\%)]$	18 (29.5)	17 (28.3)	0.887
History of stroke $[n \ (\%)]$	11 (18.0)	7 (11.7)	0.325
PWB status after operation [n (%)]	4 (6.6)	6 (10)	0.492
MMSE [mean (SD)]	19.9 (5.4)	20.0 (5.3)	0.960
MUST number of patients with high-risk score $[n \ (\%)]$	13 (21.3)	9 (15.3)	0.692
Protein intake on admission to rehabilitation ward (g) [ mean (SD)]	55.8 (14.5)	57.7 (16.8)	0.376
Caloric intake on admission to rehabilitation (kcal) [ mean (SD)]	1,028.2 (262.2)	1,037.7 (282.4)	0.508

NOF, fracture neck of femur; TOF, trochanteric fracture; subTOF, subtrochanteric fracture; HA, hemi-arthoplasty; DHS, dynamic hip screw; ASA, The American Society of Anesthesiologists Physical Status Classification System; NA, information not available; PWB, partial weight bearing status; MUST, malnutrition universal screening tool.

Table 2. Clinical outcomes

	ONS $(n = 61)$	Control $(n = 60)$	P-value
• • • • • • • • • • • • • • • • • • • •			
Length of stay in days in rehabilitation ward [mean (SD)]	26.2 (8.2)	29.9 (11.2)	0.040*
All complications episodes	30	60	0.068
All infections episodes	14	29	0.019*
Estimated energy requirement (kcal) [mean (SD)]	1,408.1 (142.4)	1,435.8 (155.8)	0.317
Actual energy intake during hospital stay (kcal) [mean (SD)]	1,480.5 (207.5)	1,127.4 (211.2)	0.000*
Estimated protein requirement (g) [ mean (SD)]	50.7 (9.2)	51.4 (9.9)	0.696
Actual protein intake during hospital stay (g) [ mean (SD)]	73.6 (10.6)	63.5 (12.3)	0.000*
Deaths within 6 months post-discharge [n (%)]	1 (1.6)	1 (1.7)	0.748
AED attendance episodes within 6 months after discharge	39	30	0.807

AED, Accident and Emergency Department.

Table 3. Nutritional and rehabilitation outcomes

Outcome	Mean change (SD) between	Mean change (SD) between T1 and T2		Mean change (SD) between T1 and T3	
Parameter	ONS	Control	ONS	Control	
D. G. ( 2	0.05 (0.00)		0.00 (4.04)	0.40.41.01.	
$BMI* (kg/m^2)$	-0.25 (0.83), n = 61	-0.72 (0.91), n = 59	0.03 (1.21), n = 58	-0.49 (1.01), n = 57	
MAC (cm)	-0.01 (0.99), n = 61	-0.09 (0.83), n = 56	-0.07 (1.16), $n = 57$	-0.12 (1.16), $n = 57$	
TSF (mm)	-0.13 (1.16), $n = 61$	-0.66 (1.78), $n = 56$	0.12 (1.76), n = 57	-0.15 (2.24), $n = 57$	
Albumin (g/l)	4.28 (3.39), n = 60	3.85 (3.12), n = 60	6.05 (3.72), n = 56	4.98 (3.46), n = 54	
IGF-1 (nmol/l)	2.98 (3.41), n = 55	2.12 (3.81), n = 60	2.23 (4.18), n = 54	2.78 (4.83), n = 49	
FIM total score	13.38 (7.11), <i>n</i> = 6 1	12.00 (7.91), $n = 60$	21.14 (9.24), <i>n</i> = 57	20.25 (10.71), n = 60	
EMS	8.63 (4.13), n = 60	8.50 (4.66), n = 60	10.28 (4.25), $n = 58$	10.24 (4.42), <i>n</i> = 58	

\*F = 6.585, P = 0.012 statistically significant outcome for change in BMI over 3 time points using ANCOVA.

BMI, body mass index; MAC, mid-arm circumference; TSF, triceps skin fold; IGF-I, insulin-like growth factor I; FIM, functional independence measure; EMS, elderly mobility scale; n, number of patients included in analysis.

For clinical outcomes (Table 2), it was noted that the length of stay in rehabilitation ward for the ONS group was significantly lower than the control group with a

mean difference of 3.80 (SE = 1.81, P = 0.04) days. The total number of complications was lower in the intervention group but this did not reach statistical significance.

<sup>\*</sup>Statistically significant.

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The overall number of infection episodes showed significant reduction in the intervention group, whereas there was no significant difference in individual infections or other types of complications. The number of patients who were transferred back to acute hospital for complications were similar in both groups as were the proportions of patients being discharged to nursing homes (see Supplementary data available in *Age and Ageing* online, Appendix 3).

Analysis of nutritional outcome data (Table 3) showed that there was a significant difference in the change in BMI with a decrease of 0.25 and 0.03 kg/m<sup>2</sup> in the ONS group and 0.72 and 0.49 kg/m<sup>2</sup> in the control group at T2 and T3 (P = 0.012). The MAC, TSF, albumin level and IGF-showed a trend of improvement more in the intervention group than the control group from T1 to T2 but these trends were not statistically significant.

The motor subscale and the total FIM over the three assessments showed no statistically significant difference between two groups. Although the FIM scores increased similarly in both groups during the hospitalisation period, the FIM efficacy for the intervention group showed a non-significant but larger change than the control group (0.524 versus 0.485 per day in hospital, P = 0.452). ANCOVA was also performed for other physical parameters including EMS, affected and unaffected lower limb quadriceps strength and dominant hand grip strength. These also showed no significant difference. Detailed data of rehabilitation outcome are presented as Supplementary data available in Age and Ageing online, Appendix 4.

#### **Discussion**

In this study, oral supplementation with a moderately highprotein content liquid supplement was found to have beneficial effect on the amount of caloric and protein intake in the subjects, leading to a beneficial effect on the maintenance of the BMI and the number of infective episodes in the subjects. The number of rehabilitation days was reduced significantly which may be explained by the reduced number of infective complications. Another reason may be that patients reaching a certain level of functionality were being discharged earlier and may explain why this study could not show a superior functional outcome. The second assessment at T2 was conducted at discharge from hospital rather than a pre-determined time point after starting the ONS for convenience in data collection. As the mean length of stay of the intervention group was only 26.2 days, the full effect of taking a 28-day-long supplement could not be evaluated, whereas the control group received a mean of 29.9 days of inpatient diet and rehabilitation therapy.

Regarding the insignificant difference in the outcome measurements of muscle strength measurements and other nutritional parameters (MAC, TSF, albumin, IGF-1) which showed a larger rising trend in the intervention group than the control group, the power of the study may have been inadequate to detect differences in these variables. Another reason may be because actual protein intake during hospital stay exceeded the estimated requirement in both ONS and control groups (i.e. both groups were well nourished in terms of protein intake).

An inherent weakness of this study was that the identification of infections and complications as well as discharge decisions was made by mostly non-blinded staff members who were not investigators in this study. Due care was taken to ensure objectivity by using clinical criteria to define infections and complications and a multi-disciplinary case conference was held for each patient's discharge planning.

Although functional and mobility benefits were not seen, clinical outcomes were favourable, so we agree with the recommendation: 'in geriatric patients after hip fracture and orthopedic surgery use ONS to reduce complications' [29] to be generalised to patients in rehabilitation settings in Hong Kong.

#### **Conclusion**

Oral nutrition supplementation prevents weight loss during hospitalisation for hip fracture rehabilitation. It may also shorten the length of stay and reduce the number of infective complications during inpatient rehabilitation. We recommend ONS for all elderly patients after fracture hip surgery who are not contra-indicated to supplemental protein diet.

### **Key points**

- Nutritional supplementation after hip fracture improves weight gain post-operatively.
- Nutritional supplementation may reduce infective complications and the length of stay in rehabilitation.
- A moderate dose protein calorie supplementation is acceptable and well tolerated by patients.

#### **Conflicts of interest**

None declared.

# **Funding**

Funding provided by Kowloon Hospital.

#### Supplementary data

Supplementary data mentioned in the text is available to subscribers in *Age and Ageing* online.

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Received 30 December 2011; accepted in revised form 14 March 2012