

# Integrated nutritional intervention in the elderly after hip fracture. A process evaluation

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## Original article

Integrated nutritional intervention in the elderly after hip fracture. A process evaluation<sup>☆</sup>

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## SUMMARY

**Background & aims:** Within a multicentre randomized controlled trial aimed at improving the nutritional status and increase the speed of recovery of elderly hip fracture patients, we performed a process evaluation to investigate the feasibility of the intervention within the present Dutch health care system. **Methods:** Patients in the intervention group received nutritional counseling during 10 contacts. Oral nutritional supplements were advised as needed until three months after hip fracture surgery. The intervention was evaluated with respect to dietitians' adherence to the study protocol, content of nutritional counseling, and patients' adherence to recommendations given.

**Results:** We included 66 patients (mean age of 76, range 55–92 years); 74% women. Eighty-three percent of patients received all 10 contacts as planned, but in 62% of the patients one or more telephone calls had to be replaced by face to face contacts. Nutritional counseling was complete in 91% of contacts. Oral nutritional supplementation was needed for a median period of 76 days; 75% of the patients took the oral nutritional supplements as recommended.

**Conclusions:** Nutritional counseling in elderly hip fracture patients through face to face contacts and telephone calls is feasible. However, individual tailoring of the intervention is recommended. The majority of hip fracture patients needed >2 months oral nutritional supplements to meet their nutritional requirements.

The trial was registered at [clinicaltrials.gov](http://clinicaltrials.gov) as NCT00523575.

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## 1. Introduction

Hip fractures are one of the most common reasons for hospital admission and transfers to nursing homes.<sup>1</sup> The incidence of hip fractures in the elderly is high and the burden for society will increase in the near future due to changes in age demographics, and increased life expectancy.<sup>2</sup> The prevalence of malnutrition in older patients admitted to hospitals is high, ranging from 25 to 60%.<sup>3,4</sup>

*Abbreviation:* ONS, oral nutritional supplements.

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Specifically, in hip fracture patients it ranges from 2%<sup>5</sup> to 63%.<sup>6</sup> During hospital admission, the nutritional status can deteriorate further due to increased energy expenditure caused by metabolic stress and blood loss, combined with a low dietary intake due to the lack of appetite, nausea and psychological factors. Poor nutritional status in hip fracture patients is associated with impaired muscle function, disability,<sup>7</sup> loss of independency, lower mental function, decreased quality of life,<sup>7</sup> delayed wound healing, higher complication rate,<sup>8,9</sup> prolonged rehabilitation time<sup>7,8,10</sup> and increased mortality both during and after hospital admission.<sup>8,11,12</sup>

Over the past decades, several studies have been conducted to determine the effectiveness of various types of nutritional intervention in elderly hip fracture patients on mortality, nutritional and functional status, length of hospital stay, and complications, such as infective complications, incomplete wound healing and pressure

sores. The results of these studies are inconsistent and evidence for beneficial effects of nutritional supplementation remains limited.<sup>13</sup> Use of oral nutritional supplements (ONS) is suited as a simple way to improve hip fracture patients' energy and protein intake,<sup>14,15</sup> although patients' compliance is poor.<sup>16</sup> Personal attention after hip fracture from a dietetic assistant can improve adherence and tolerance with nutritional supplements<sup>17</sup> and contribute to establish a prolonged effect of nutritional intervention.

ESPEN (European Society for Parenteral and Enteral Nutrition) guidelines on enteral nutrition in geriatrics<sup>18</sup> recommend standard use of ONS in elderly after hip fracture surgery to reduce complications, however, no recommendations on amount and duration of ONS use are given.

In order to improve medical outcome in vulnerable elderly hip fracture patients, to prevent further decline of nutritional status, and to improve implementation of the ESPEN guidelines for hip fracture patients, we initiated an open-label multicentre randomized controlled multicentre trial (RCT) comparing a combination of intensive dietetic counseling and oral nutritional supplementation over three months after hip fracture with usual nutritional care, i.e. no intervention except on specific request by medical doctor (MD).<sup>19</sup>

This process evaluation aimed to investigate the feasibility of the proposed nutritional intervention in the present Dutch health care practice. Based on the model of Saunders et al.,<sup>20</sup> we focused on the following aspects: Coverage of the intervention, i.e. the proportion of intended units delivered by the interventionist (dietician), general adherence of staff to the protocol, defined as: was the extent to which the intervention was implemented equal to what was planned, and patients' adherence defined as the extent to which participants were receptive to the intervention, or actively engaged with it.

The following research questions were formulated:

1. To what extent did the study dieticians follow the study protocol with regard to
  - a. number, types, duration and location of patient contacts (face to face contacts/telephone calls); and
  - b. content of each dietetic contact (face to face contact / telephone call); i.e. dietetic counseling, nutritional recommendations and nutritional care.
2. To what extent were the given nutritional recommendations (nutritional advice and ONS) followed by the patient.

## 2. Materials and methods

### 2.1. Study population and design

We performed a prospective process evaluation of all patients in the intervention arm of an open-label, multicentre randomized controlled trial (RCT).

Patients were eligible if they were aged 55 years and above, and were excluded if they had a pathological or periprosthetic fracture; a disease of bone metabolism (e.g. M. Paget, M. Kahler, hyperparathyroidism); a life expectancy of less than 1 year due to underlying disease (e.g. cancer); used ONS before hospital admission; were unable to speak Dutch; living outside the region of the participating hospitals; or were bedridden before the hip fracture. Patients were also excluded if they had dementia or were cognitively impaired, defined as a score of <7 on the Abbreviated Mental Test (AMT) assessed before inclusion.

For patient recruitment, a daily inventory was made of hip fracture patients admitted to the surgical and orthopedic wards of three hospitals in South-Limburg in The Netherlands: Maastricht University Medical Centre (MUMC, Maastricht), Atrium Medical

Centre (AMC, Heerlen), and Orbis Medical Centre (OMC, Sittard). Eligible patients were invited to participate and written informed consent was obtained within five days after surgery. After informed consent, baseline measurements were performed by a trained researcher. Following baseline measurements, patients were stratified for hospital, gender and age (55–74 years vs. 75 years and above) and randomly assigned to the intervention group or control group using block randomization with permutation blocks of four. After randomization, all patients were visited by a study dietician who took a general dietary history and 24 h recall.

Patients allocated to the intervention group received dietetic counseling and oral nutritional supplementation for three months after fracture, while patients in the control group received usual nutritional care as provided in the hospital, rehabilitation centre or at home, i.e. dietetic care or nutritional supplements were only provided on demand of the medical doctor (MD) in charge. All patients were discharged from the hospital to either a rehabilitation centre, to a nursing home, to a home for the elderly if they had lived there before hospital admission, or to the patient's home with home care. Three and six months postoperatively, a study dietician took a general dietary history and 24 h recall to evaluate nutritional intake at the patient's home.

The study was approved by the Medical Ethical Committee (METC) of Maastricht University Medical Centre and the METC of the two other participating hospitals and conducted according to the Declaration of Helsinki.

### 2.2. Nutritional intervention in the intervention group

The nutritional intervention was a combination of regular dietetic care and consumption of a standard multi-nutrient ONS for a period of three months. The following elements were included: checking the patient's food habits and preferences, identifying possible deficiencies in nutrient intake, and checking the presence of any practical limitation that might interfere with optimal food intake. The nutritional intervention started during hospital admission and continued in the rehabilitation centre and/or at home if applicable. In Table 1 the schedule and content of contacts of the nutritional intervention according to the protocol are shown.

A study dietician visited each patient twice during hospital stay. At the first visit, immediately after baseline measurements, the

**Table 1**  
Number, timing and composition of nutritional intervention contacts according to protocol during different periods after surgery.

Time line			Elements of the concerned contact			
Nr. of contact	Days post-surgery	Type of contact	A	B	C	D
1	0–6	Face to face <sup>a</sup>	X	X	X	X
2	5–11	Face to face <sup>a</sup>		X	X	X
3	17–23	Face to face <sup>b</sup>		X	X	X
4	19–21	Face to face <sup>b</sup>		X	X	X
5	22–28	Telephone call		X	X	X
6	29–35	Telephone call		X	X	X
7	36–42	Telephone call		X	X	X
8	43–49	Face to face <sup>b</sup>		X	X	X
9	57–63	Telephone call		X	X	X
10	78–84	Telephone call		X	X	X

A: explanation oral nutritional supplement use and registration to patient; B: 24-h dietary recall; C: evaluation of nutritional intake and oral nutritional supplement intake. Discussion of findings with the patient and individual nutritional advice; and D: arranging for nutritional adaptations of the patient. Report on findings to medical and nursing staff and nutritional assistant. Arranging dietetic transfer of patient to rehabilitation centre and/ or to home (when applicable).

<sup>a</sup> In the hospital.

<sup>b</sup> In the rehabilitation centre or at home, depending on habitual residence of patient.

dietician interviewed the patient regarding medical and social status (e.g. living alone, having help with household tasks, etc.), and pre-fracture mobility (e.g. use of walking aids). In addition, she took a general dietary history on the patient's diet preceding hospitalization including supplement use and feeding problems. Next, the dietician took a 24 h recall of the patient's diet during hospitalization. To optimize normal food intake all patients received an energy- and protein-enriched diet and recommendations were given with regard to choice, quantity and timing of food products, the ONS, and increasing the intake of energy-dense and protein-rich products both within and in between meals. Recommendations were based on the patient's individual requirements, including diet and texture adaptation, and took individual preferences and possibilities of the patient into account. Nutritional requirements for energy were calculated according to Harris–Benedict equation,<sup>21</sup> using a factor of 20% surcharge for medium metabolic stress due to hip fracture and additional surcharge for activity, desired increase of body weight and/or energy-losses if indicated, with a maximum surcharge of 40%. Protein requirement was calculated as body weight  $\times$  1.5 g protein.<sup>22</sup> As a part of the energy- and protein-enriched diet, all patients were advised to consume two bottles of an ONS daily in between the main meals, in order to secure optimal intake in the vulnerable period after hip fracture surgery. The nutritional supplement was a milk-based ONS (Cubitan), kindly provided by Nutricia Advanced Medical Nutrition (Zoetermeer, The Netherlands) providing 2.1 MJ (500 kcal) and 40 g of protein per two bottles. If a patient did not tolerate the milk-based supplement, a yoghurt-based supplement or a juice-based supplement (Nutridrink Yoghurt Style or Nutridrink Juice Style, Nutricia Advanced Medical Nutrition, Zoetermeer, The Netherlands) was offered. Adherence to the nutritional supplement was evaluated by 24 h recalls and by patient's registration in a diary. Based on the information of the first visit, the dietician made necessary arrangements to solve any problem, e.g. feeding problem, in collaboration with the medical and nursing staff. Finally, the dietician assisted the patient in choosing the preferred taste of the nutritional supplement and ordered the preferred supplement.

At the second visit during hospitalization, seven to eight days after surgery, the dietician evaluated food intake and the consumption of the nutritional supplement using a 24 h recall and individual tailored advice was given to the patient to optimize nutritional intake. Furthermore, transfer of the patient to the rehabilitation centre or home was prepared to safeguard optimal food and ONS intake during the stay at the rehabilitation centre or at home. For this purpose, the care for nutrition at the patient's home was discussed with the patient and, if present, with the patient's caregiver. Arrangements were made to ensure adequate food intake. Recommendations were related to the individual situation of the patient (i.e. mobility and environment) and were focused on overcoming obstacles in food availability (i.e. purchase of food by family, friends or delivery service of the supermarket), in preparation of food (i.e. support of informal caregivers of delivery by meal services), and in choosing foods which supported recovery and were easy to use and prepare. If necessary, arrangements were made to enable adequate food intake, e.g. by asking support from informal caregivers (if present) and by providing information on meal services. Patients were encouraged to increase their dietary intake from a varied choice of healthy foods, based on individual preference and were guided in organizing delivery of readymade meals if needed. Next, the dietician communicated all relevant information to the family doctor as well as to the nursing staff, and the dietician or nutritional assistant of the rehabilitation centre and (where relevant) to informal caregivers.

Continuation of the nutritional intervention in the different rehabilitation centres and at home was accomplished through close

collaboration between the study dieticians and the involved caregivers, i.e. the medical doctors, nurses, nutritional assistants and dieticians in the 15 involved rehabilitation centres and four home care organizations. In institutions, the recommendations given by the dieticians consisted of drawing the staff's attention to monitoring, delivering and supporting the patient's dietary food and fluid intake.

After hospital discharge, the study dietician visited each patient three times (1, 2 and 6 weeks after discharge) at the patient's home or in the rehabilitation centre (whatever was applicable) in order to evaluate dietary intake, to evaluate the bottlenecks in the nutritional care at home, and to give nutritional advice if necessary. During each contact continuation of ONS was advised to patients who were still unable to meet nutritional requirements by normal food intake. In addition, in between and after these face to face contacts, telephone calls were made (3, 4, 5, 8, and 10 weeks after discharge) to evaluate both the diet and the intake of the nutritional supplements, if still consumed, by a 24 h dietary recall. If necessary, a telephone call was replaced by a home visit. As the patient's diet increased toward the nutritional requirements (according to the guidelines of the Health council of the Netherlands) the amount of ONS advised was gradually decreased and the patient was advised to maintain a healthy diet. If dietary intake of vitamin D did not meet the nutritional requirements, a vitamin D supplement was advised. The contacts were conducted by dieticians in a standardized way, guided by a checklist and standardized forms for each study contact. To ensure continuity of care, patients were contacted by the same dietician throughout the intervention period.

In special meetings on site medical staff, and nutritional assistants were informed about the study and their role in the execution of the study was highlighted, i.e. supplying the ONS to the patient, supporting the patient with regard to food and ONS intake, weighing the patient at regular intervals, and reporting nutritional problems to the study dietician.

### 2.3. Data collection

In the present process evaluation, the planned nutritional intervention according to the study protocol was compared with the practice of execution of this intervention within the intervention group regarding the following aspects.<sup>20</sup>

- Adherence of staff to the protocol; i.e. the extent to which the intervention had been implemented according to the underlying protocol with regard to the number of contacts, duration of contacts, type of contacts (face to face, telephone calls), and location of visits (hospital, rehabilitation centre, home).
- Coverage of content; i.e. the extent to which the intended content of each contact was delivered by the dieticians, with regard to dietetic counseling, nutritional recommendations including ONS and nutrition care (e.g. safeguarding availability of food and meals, and assistance with shopping, cooking, and meal preparation).
- Patient's adherence to recommendations, i.e. the extent to which recommendations given by the dieticians, i.e. dietary intake and ONS use, were followed by the patients.

For this purpose, process data of the nutritional intervention were recorded by a study dietician during all study contacts, with regard to date, type, location, and duration of contacts; content of nutritional recommendations, content of ONS advice, and nutritional care recommendations. Deviations from the protocol were noted. Also, patients were requested to register their ONS intake (date and time, type and quantity of the ONS) in a diary.

Patients' adherence to recommendations regarding the ONS and on improving dietary intake were evaluated over two periods. (1) Early post-surgery period: from day 0 until day 10 after inclusion, and (2) late post-surgery period: from day 11 until the end of the intervention period 3 months after inclusion. Patients were considered to be compliant with ONS advice when the reported intake was 75% or more of the recommended amount. Patients were considered to be compliant with the content of the intervention if they had followed the recommendations in at least 75% of the contacts. Patients who needed no advice were considered to be compliant.

#### 2.4. Data analysis

Quantitative data analysis on data from the intervention group only was performed using descriptive statistics from SPSS-15.0 for Windows (SPSS Inc. Chicago, IL, USA). Open text data were categorized in codes and also assessed using descriptive statistics.

### 3. Results

#### 3.1. Patient characteristics

Of the 73 patients in the intervention group, four patients (5%) died during the study, three patients (4%) stopped their participation due to lack of interest ( $n = 1$ ) or lack of motivation to participate with regard to extra consultations ( $n = 1$ ) or ONS use ( $n = 1$ ). The 66 remaining patients had a mean age of 76 years (range 55–92) on admission; 49 (74%) were women and 17 (26%) were men.

#### 4. Dieticians' adherence to the study protocol

Table 1 shows the structure and content of the nutritional intervention as planned. During a period of 3 months after surgery, 10 contacts (both face to face and telephone calls) were planned to be performed, consisting of intensive dietetic counseling, and ONS. A comparison between the planned nutritional intervention and the actual execution of the intervention is shown in Table 2.

##### 4.1. Number of contacts

The mean number of study contacts was 10.0 ranging from 6 to 18 (Table 2). Of the 66 patients, 55 (83%) received all 10 planned contacts with the dietician, 8 (12%) received nine contacts and 3 (5%) six to eight contacts.

Out of a total of 660 planned contacts, 17 (4%) contacts were canceled in 11 patients.

- 8 contacts (3 patients) because the patients considered the visit to be too burdensome;

**Table 2**  
Dieticians' adherence to the study protocol.

		Number of contacts	
		Protocol	Execution
Consultation <sup>a</sup> Type	Total	10	10.0 (6–18) <sup>b</sup>
	Face to face contact <sup>c</sup>	5	6.8 (4–18)
	Telephone call	5	3.3 (0–6)
Location of face to face contact	Hospital	2	2.3 (1–14)
	RC or at home	3	4.4 (1–10)

<sup>a</sup> Consultations by a dietician.

<sup>b</sup> Mean (range).

<sup>c</sup> Face to face contact on the site of residence (i.e. hospital, rehabilitation centre, home).

- 5 contacts (4 patients) were considered to be unnecessary by the dietician because these patients had a sufficient nutritional intake and no nutrition-related problems and therefore prolongation of dietetic guidance was no longer needed; and
- 4 contacts (4 patients) due to time constraints of the dietician.

Eight patients (12%) received additional study contacts, of whom five received one extra contact; the remaining three patients received two, five and eight additional contacts. Reasons for the additional contacts were: readmission to hospital ( $n = 2$ ), change in location of patient (2), deteriorating clinical status or weight loss (3), and inability to deal with the amount of information in one visit (1).

##### 4.2. Location of face to face contacts; hospital rehabilitation centre and home

As for the location of the face to face contacts, the two planned hospital contacts were generally executed as planned (Table 2). In contrast, the mean actual number of face to face contacts after hospital discharge was 4.4 (range 1–10) instead of the planned three. Of these face to face contacts, an average of 2.3 (range 0–9) were in a rehabilitation centre and 2.1 (range 0–8) were performed at the patient's home.

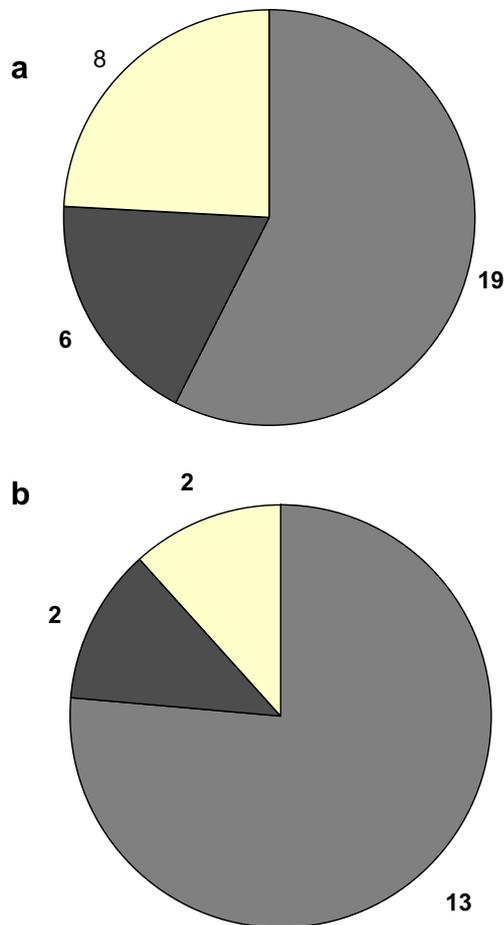
##### 4.3. Type of contacts: face to face contacts and telephone calls

The actual number of face to face contacts was higher than planned (mean 6.8 vs. 5.0, Table 2), whereas the number of telephone calls was lower than planned (mean 3.3 vs. 5.0, Table 2). In 41 out of 66 patients (62%) one or more telephone calls were changed into a visit; for 13 patients (20%) this happened one time, for 10 patients (15%) two times and for 18 patients (27%) three times or more. On the other hand, only four face to face contacts were changed into a telephone consultation.

Reasons for the change of telephone calls into face to face contacts were: communication difficulties related to distant speaking: i.e. hearing difficulties or problems to contact patients by telephone (25%), loss of body weight, dietary problems or deteriorating health (20%), change in location of stay (18%), arrangements to be made in rehabilitation centre, e.g. explanation on nutritional intervention to nursing staff or delivery of ONS supplies (13%), non-adherence with intervention (8%), readmission to hospital (5%), combination with other visit on the same site (5%), and other reasons (8%). The reported reason for the changing face to face contacts into telephone calls was in all cases rapid recovery, rendering face to face contact superfluous.

##### 4.4. Duration of patient contacts

The actual duration of patient contacts was 32 min for face to face contacts, and 17 min for telephone calls. This agreed well with expectations (30 min and 15 min, respectively). In Fig. 1, the mean time expenditure within each consultation spent on nutritional counseling, ONS-counseling and organizational issues is shown. During telephone calls, time spent with dietetic counseling was higher than during face to face contacts (75% vs. 58% of the time) because the focus of the telephone calls was on checking nutrition-related problems. For face to face contacts compared to telephone calls, more time was spent with ONS-counseling (18% vs. 12%), and organizational issues (24% vs. 12%), for instance, checking patients' files, communication with staff to discuss the required nutritional support and ONS in institutions, or at the patients' homes, and delivery of the ONS.



**Fig. 1.** Dieticians' mean time expenditure (minutes per contact) to nutritional counseling, oral nutritional supplement counseling and organizational issues (a) in face to face contacts and (b) telephone calls. ■: Nutritional counseling. ▀: Oral nutritional supplement counseling. □: Organizational issues, i.e. arranging oral nutritional supplements and foods, and reporting to involved medical staff and nutritional assistant.

## 5. Content coverage of contacts by dieticians

According to the study protocol, dietetic counseling during all contacts (face to face contacts and telephone calls) should include (1) nutritional intake, (2) ONS intake and (3) nutrition care. In the large majority of all contacts (91%), dietetic counseling covered all three aspects as planned.

### 5.1. ONS-recommendations by the dietician

ONS was planned for all intervention patients within 5 days post-surgery. In practice, consumption of the ONS started  $3.5 \pm 1.3$  (mean  $\pm$  SD) days post-surgery; 63 patients (95%) started within the planned 5 days post-surgery and the remaining 3 patients (5%) started on day 6, due to a full agenda.

Based on inadequate oral intake from the regular diet; as the criterion for ONS prescription, ONS was recommended for a median period of 76 days (range 3–91), thus the majority of patients needed the ONS for more than 10 weeks. At 10 days post-surgery, 65 patients (98%) were in need of ONS and were therefore advised to use ONS, and at 30 days post-surgery still 58 patients (88%) needed ONS; 39 patients (59%) were still in need of ONS at 60 days post-surgery, and 28 patients (42%) could stop ONS intake within 90 days post-surgery. The remaining 11 patients (17%)

needed continuation of ONS and were transferred to a home care dietician at the end of the 3-monthly study intervention period.

### 5.2. Nutritional recommendations by the dietician

Before the start of the intervention, the energy intake, based on the 24 h recall from the previous day, was  $1281 \pm 68$  kcal/d ( $5.4 \pm 0.3$  MJ/d), and protein intake was  $55.0 \pm 2.9$  g/d. Nutritional recommendations were given with regard to choice, quantity and timing of food products and included the use of ONS, and increase the intake of energy-dense and protein-rich products both within and in between meals. One week after starting the intervention, the 24 h recall showed that energy intake had increased to  $1733 \pm 61$  kcal/d ( $7.3 \pm 0.3$  MJ/d) and protein intake to  $82.3 \pm 3.1$  g/d.

## 6. Patients' adherence to nutritional recommendations and ONS

Fifty-eight patients (88%) took the ONS for the total period as advised by the dietician. Eight patients (12%) stopped the ONS intake earlier than advised.

Forty of 66 patients kept a study diary on ONS use. Reported reasons for the absence of study diaries were: poor vision and/or difficulties with writing ( $n = 7$ ), refusal to keep a diary ( $n = 6$ ), loss of study diary ( $n = 5$ ), inability to keep a diary because of physical condition ( $n = 4$ ), no reason available ( $n = 4$ ). Adherence to the ONS as recorded by the dietician of the 26 non-diary patients was similar to the 40 diary patients in the first post-surgical period, but lower in the non-diary patient group in the second post-surgical period (0–10 days post-surgery: 78% vs. 80%; 11–90 days post-surgery: 70% vs. 87%). Results of self-reported adherence to ONS was remarkably similar compared to the dieticians' reports, i.e. 74% of the 40 patients reported to be compliant with ONS-recommendations in the first post-surgical period until 10 days post-surgery, and 75% from day 11–90 post-surgery.

For the overall group ( $n = 66$ ), the patients' adherence to nutritional recommendations as assessed by the dietician was 67% and to ONS 79% in the early post-surgical period until 10 days after inclusion. In the subsequent period from day 11 to 90, the adherence to nutritional advice was 73% and to ONS 80%.

Forty-one percent and of patients experienced problems with using ONS in the first post-surgical period until 10 days post-surgery, 43% of the patients from 11 to 30 days post-surgery, and 24% from 31 to 90 days post-surgery, such as aversion against the taste of the ONS, experiencing high satiation by the ONS, physical constraints, and delivery failure of the supplement.

## 7. Discussion

Especially in elderly hip fracture patients, it is important to prevent loss of muscle mass because impaired recovery and loss of lean mass can result in loss of functional capacity and loss of independency.<sup>7,23</sup> ESPEN guidelines<sup>18</sup> recommend standard use of ONS in elderly patients after hip fracture surgery in order to reduce complications. Nevertheless, oral nutritional supplementation is not yet common in Dutch health care practice. The present process evaluation of an integrated nutritional intervention program comprising dietary counseling and ONS showed that overall the applied intervention was feasible in the present Dutch health care system, with regard to number and duration of contacts.

Adherence figures with ONS in studies in elderly hip fracture and orthopedic patients range from 15 to 100%.<sup>24–27</sup> Generally speaking, a short intervention period in combination with small amounts of ONS<sup>24,25,27</sup> does not always lead to better adherence

compared to studies with a longer period of ONS use and larger amounts of ONS (more than one can a day).<sup>27,28</sup> In some studies a fixed amount of ONS was used.<sup>24,25,27</sup> In our study we used variable amounts of ONS, based on individual requirements of patients. This individual approach may be one reason for patients to consume the ONS over a longer period of time and in a larger amount, and with a relatively high adherence (79–80% over two periods as assessed by dietitians and 74–75% as reported by patients). Also continuity of care with respect to personnel and type of advice in our intervention, may have contributed to the high adherence to ONS and to nutritional advice. Furthermore, personal coaching of patients by the dietician with frequent personal contacts (face to face or telephone) may have played a role.

The present process evaluation indicates that implementation of the nutritional intervention for elderly hip fracture patients is feasible, though not easy to achieve in a complex health care setting. Dietary intake in hip fracture patients usually fails to meet requirements not only during hospital admission,<sup>29,30</sup> but also for a prolonged period thereafter. Even in our study almost all patients (98%) needed additional ONS during hospital admission and the majority (59%) of intervention patients needed additional ONS for a >2 months period. This finding shows that even relatively uncomplicated hip fracture patients fail to meet nutritional requirements and usually need ONS in the period after hospital discharge in addition to their normal dietary intake. Our individually tailored approach aimed at improving regular food intake, proved to be a suitable way to meet patient's nutritional requirements and to safeguard dietary intake in this vulnerable post-surgical period. Of note, the content as well as the number, the types and frequency of contacts can be adjusted to the individual patient's needs.

### 7.1. Study limitations

Several limitations of our study should be considered. First, the intervention was executed amongst elderly hip fracture patients in a study setting. Care should be taken when extrapolating data to cognitively impaired patients, patients who are bedridden before hip fracture, and patients with underlying disease. In these patients implementation of the intervention might be more difficult, especially more telephone calls may have to be replaced by face to face contacts.

Second, study execution and data collection were executed by the same person (study dietician). Participants might have given socially accepted answers causing biased data.

Third, continuity of in the context of our study dietetic care was guaranteed, since a study dietician took care of a proper follow up of the patient after discharge from the hospital. However, in practice hip fracture patients will often meet different dietitians in the hospital, rehabilitation centre and at home, which may substantially affect successful implementation. Also, limited possibilities in nutritional services in institutions, e.g. absence or limited presence of a nutritional assistant, limited possibilities to deliver the ONS, and limited possibilities in offering and timing of specific foods with high nutritional value to the patient, were met by the study dietitians, which are likely to hamper successful implementation in routine health care.

Fourth, communication on medical and nutritional issues between institutions, e.g. from hospital to rehabilitation centre, was not standardized, which may lead to discontinuity in nutritional care. The study dietitians noted that in present usual care insufficient attention was usually paid to nutritional care. Especially in the integrated care trajectory, diagnosing nutrition-related problems, facilitating nutritional support and follow up of treatment and transfer of nutrition-related therapies are not yet

common practice and seem to be a major problem in the present integrated nutritional care trajectory.

Finally, the intervention was expected to be cost-effective, as results of retrospective cost analysis of published trials suggested potential savings between 5792 and 12,342 Euro per patient as a consequence of reduced complication rates. The cost of the intervention as estimated a priori amounted to 1000 euro, including both the dietary supplement and additional labor costs by a dietician; the estimated reduction in length of stay (–16.8 days) would lead to savings of ca. 5660 Euro minus intervention costs = 4660 euro. A formal cost-effectiveness study of our trial will follow.

## 8. Conclusions

Based on the results of the present process evaluation, we conclude that the implementation of the integrated nutritional intervention in elderly hip fracture patients is feasible with regard to number, duration and content of contacts. Based on the dietitians' judgment nutritional support for hip fracture patients is needed for a prolonged period after surgery, and the ONS was needed for more than two months in the majority of hip fracture patients, in order to meet their nutritional requirements.

Further studies are needed to elaborate the factors influencing the continuity of the nutritional intervention in the context of usual health care in the settings of hospital and rehabilitation centre and in the home setting, as well as effects and costs.

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This was an investigator-initiated study. Both funding sources (Organization for Health Research and Development ZonMw and Framework Programme) had no role in the study design, collection, analysis, and interpretation of data, in the writing of the report, or in the decision to submit the paper for publication.

### Statement of authorship

Author contributions to the manuscript are as follows: PD and NR were responsible for the study design. JB was responsible for data collection, data analysis and writing the manuscript. PR, MP, TW and PD participated in interpretation of data, writing and revising the manuscript. CW, SH, JA, BM participated in writing the manuscript. All authors read and approved the final manuscript.

### Conflict of interest

The authors declare no conflict of interest.

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