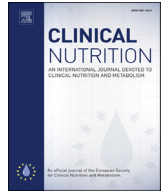




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## Randomized Control Trials

## Effects of using the MyFood decision support system on hospitalized patients' nutritional status and treatment: A randomized controlled trial

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## SUMMARY

**Background & aims:** Compliance to guidelines for disease-related malnutrition is documented as poor. The practice of using paper-based dietary recording forms with manual calculation of the patient's nutritional intake is considered cumbersome, time-consuming and unfeasible among the nurses and does often not lead to appropriate nutritional treatment. We developed the digital decision support system MyFood to deliver a solution to these challenges. MyFood is comprised of an app for patients and a website for nurses and includes functions for dietary recording, evaluation of intake compared to requirements, and a report to nurses including tailored recommendations for nutritional treatment and a nutritional care plan for documentation. The study aimed to investigate the effects of using the MyFood decision support system during hospital stay on adult patients' nutritional status, treatment and hospital length of stay. The main outcome measure was weight change.

**Methods:** The study was a parallel-arm randomized controlled trial. Patients who were allocated to the intervention group used the MyFood app during their hospital stay and the nurses were encouraged to use the MyFood system. Patients who were allocated to the control group received routine care.

**Results:** We randomly assigned 100 patients ( $51.9 \pm 14$  y) to the intervention group ( $n = 49$ ) and the control group ( $n = 51$ ) between August 2018 and February 2019. Losses to follow-up were  $n = 5$  in the intervention group and  $n = 1$  in the control group. No difference was found between the two groups with regard to weight change. Malnutrition risk at discharge was present in 77% of the patients in the intervention group and 94% in the control group ( $p = 0.019$ ). Nutritional treatment was documented for 81% of the patients in the intervention group and 57% in the control group ( $p = 0.011$ ). A nutritional care plan was created for 70% of the intervention patients compared to 16% of the control patients ( $p < 0.001$ ).

**Conclusions:** The intervention had no effect on weight change during hospital stay. A higher proportion of the patients in the control group was malnourished or at risk of malnutrition at hospital discharge compared to the patients in the intervention group. The documentation of nutritional intake, treatment and nutritional care plans was higher for the patients using the MyFood system compared to the control group. This trial was registered at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03412695).

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## 1. Introduction

Despite established guidelines [1,2] on the prevention and treatment of disease-related malnutrition, approximately 30% of hospitalized patients are malnourished or at risk of malnutrition

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[3–6] and nutritional status often deteriorates during hospital stay [7,8]. Poor nutritional status increases morbidity rates [9,10], leads to a longer length of stay [11], increases hospital costs [12,13] and may cause premature death [7,8]. A recent systematic review and meta-analysis concluded that nutritional support was associated with improved survival, lower rates of non-elective hospital readmission, higher energy and protein intake and increased body weight [14].

According to the guidelines for malnutrition [1,2], all patients should be screened for malnutrition risk on admission to hospital and thereafter weekly. For patients who are identified to be malnourished or at risk of malnutrition, a full nutritional assessment should be conducted. Following the evaluation of risk, malnutrition should be diagnosed based on changes in food intake and absorption, body weight, body mass index, muscle mass and disease burden/inflammation [15]. Furthermore, body weight, nutritional intake and symptoms should be monitored and an individual nutritional care plan should be created. Finally, all relevant information on the nutritional status and treatment should be documented in the electronic patient record and passed on to other health care professionals when the patient is transferred back to the community or another institution [16].

However, compliance with these guidelines is challenged due to poor routines for malnutrition screening and documentation of nutritional intake and treatment [17], lack of assignment of responsibility, and limited skills and knowledge on nutritional treatment among health care professionals [18]. The methods to record and evaluate the patients' dietary intake are often considered inconvenient [17]. Dietary records are most often written on paper and the nutritional assessment for malnourished patients lacks standardization. Norwegian data indicate that at the most, only 50% of malnourished or at-risk patients receive nutritional treatment [3,19].

Computerized decision support systems may have an impact on nurses' decision making [20] and aid in implementing clinical guidelines into practice [21]. In response to the apparent need for better tools and systems to follow-up the malnutrition guidelines for the large group of hospitalized patients who suffer from disease-related malnutrition, we developed the digital decision support system MyFood [22]. The MyFood system digitalizes and automates the estimation of nutritional requirements and the recording of food intake, evaluates nutritional intake compared to the requirements, and provides tailored recommendations for nutritional treatment, together with an individualized nutritional care plan. In a study investigating the potential barriers and facilitators for using the MyFood system in clinical practice, health care professionals perceived MyFood as more trustworthy, precise and motivational than the current practice they were using [23].

The present randomized controlled trial aimed to study the effects of using the MyFood system in a hospital setting. The primary outcome was change in patient body weight during the hospital stay. Secondary outcomes were change in patient body composition during the hospital stay, proportion of patients at risk of malnutrition at hospital discharge; defined as NRS 2002 score  $\geq 3$ , proportion of patients with documentation of nutritional intake compared to requirements, nutritional treatment and a nutritional care plan, and patient length of hospital stay.

## 2. Material and methods

### 2.1. Study design and participants

This study was a parallel arm randomized controlled trial conducted at a unit treating patients with hematologic diseases at a large university hospital in Norway from August 2018 to May 2019.

Patients  $\geq 18$  years admitted to the hospital department with an expected length of stay of  $\geq 3$  days were eligible for inclusion. We excluded patients with a life expectancy of  $< 6$  months, non-Norwegian speaking patients, patients with mental illness, pregnant or lactating women, and patients diagnosed with hemophilia, deep venous thrombosis or sickle cell anemia.

### 2.2. Randomization and inclusion procedure

Patients were randomly assigned to the MyFood decision support system (intervention) or to routine care (control). The unit is divided into four different wards with different nurses and some differences in diagnoses. The patients were stratified according to ward [1–4] with a 1:1 allocation to assure equal randomization. The sequence of treatment allocation was prepared using the `ralloc` command in STATA SE version 15 and random block sizes of 2, 4 and 6 by a person not involved in patient assessments. To ensure allocation concealment, we used sequentially numbered, non-transparent envelopes containing the treatment allocation information. Because the trial was an intervention involving the use of a decision support system, blinding of patients, study personnel or nurses was not feasible.

The patients were asked for participation in the study by a project nurse or project worker  $\leq 2$  days after hospital admission.

### 2.3. The MyFood system

The MyFood digital decision support system is developed for use among hospitalized patients who are malnourished or at risk of malnutrition. The system includes the following four functions:

- 1 *Patient registration* included anthropometry (weight and height), nutrition-related symptoms (nausea, difficulty swallowing, chewing problems, ulcers in mouth/throat, diarrhea and constipation), fever, nutritional route (normal oral intake, tube feeding, parenteral nutrition) and self-reported allergies/intolerances.
- 2 *Dietary recording function* included pictures and nutritional content of all dishes, foods, beverages and medical nutrition products available at the hospital. Snack products, fast food and several other dishes, foods and beverages were also included.
- 3 *Automatic evaluation of recorded nutritional intake*, including oral nutritional support, tube feeding and parenteral nutrition, was compared to individual requirements for energy, protein and fluids.
- 4 *Report to health care professionals* included an overview of the patients' nutritional intake compared to individual requirements, recommendations for nutritional treatment tailored to the individual patient and a template for a nutritional care plan. Data about the patient's food intake and symptoms were used to tailor the output using algorithms and a knowledge base incorporated in the system. The knowledge base was built upon guidelines for prevention and treatment of malnutrition from the Norwegian Directorate of Health [2,16,51]. The template for the nutritional care plan contained information about the patient's nutrition-related symptoms, nutritional requirements and intake. The nurse had to complete the plan with the aim for the patient's nutritional treatment and the specific treatment that was planned and/or initiated. The nutritional care plan could be copied and pasted by the nurse into the patients' electronic record.

The user interface of the MyFood decision support system consisted of an app including functions 1–3 and a website including function 4. MyFood was used both by the patient (the

app) and the health care professional (the app and the website). The development and evaluation of the MyFood app have been reported elsewhere [22]. Figure 1 illustrates the dietary recording and evaluation functions in the MyFood app.

Encrypted data from the MyFood app were sent to “Services for sensitive data” (TSD) (Fig. 2) as described earlier [22].

To gain access to the MyFood website the nurses completed an access form that was used to create a list of approved persons in the TSD server. Log-in to the website was done through a common log-in solution for public services in Norway [25] and authentication was sent to the TSD server [26] to verify access to the website. Patient reports on the website were retrieved by the nurses using the patient’s Norwegian Patient Register (NPR) number.

#### 2.4. Procedures for the intervention group

The patients in the intervention group were given a demonstration of the MyFood app by a project worker. The demonstration included how to navigate and record in the app, and the opportunity to see an overview of their daily nutritional intake compared to their requirement for energy, protein and fluids. The patients were instructed to use the MyFood app to record their daily dietary intake during their entire hospital stay. During the data collection period, project workers were available at the department every weekday. Additionally, a project phone was available at all times to answer any questions from the health care professionals or patients.

#### 2.5. Training of nurses

Information and training were provided to the nurses through group sessions or one-on-one demonstrations, which strived to reach all nurses working in the department. The nurses were given a demonstration on website login and use. The nurses were told to check the reports for their patients daily, assist their patients in recording their dietary intake if needed and record parenteral or

tube feeding in the app if given. Written information about the trial and the expected follow-up by the nurses was sent by e-mail to all employees at the department before the start of the study and to all the nurses during the data collection period. In addition, one informational meeting was held for the physicians at the department and one for the registered dietitians at the hospital.

#### 2.6. Pilot

A small pilot study was performed in May 2018 to test the technical solution of the MyFood system, the feasibility of the study and the measurement methods. Five patients fulfilling the inclusion criteria were included and used the MyFood app for five days. Access to the MyFood website was given to the nurses responsible for the included patients. The experiences from the pilot study were included in the planning of the main study.

#### 2.7. Outcomes and characteristics

##### 2.7.1. Baseline characteristics

Information about age, diagnosis and cause of hospital admission was retrieved from the hospital administration system. Data about education, technology experience and comorbidity were collected from the questionnaires that patients completed at baseline.

##### 2.7.2. Body weight

Body weight in kg was measured each morning and evening and written on a whiteboard in the patient room, as part of an established routine at the hospital department. The body weight was measured by a nurse or the patients themselves to the nearest 0.1 kg on digital portable floor scales that were present in all the patient rooms. A project worker weighed the patient in cases of doubt or if the weight was missing, otherwise the morning weight was used at baseline and thereafter weekly.

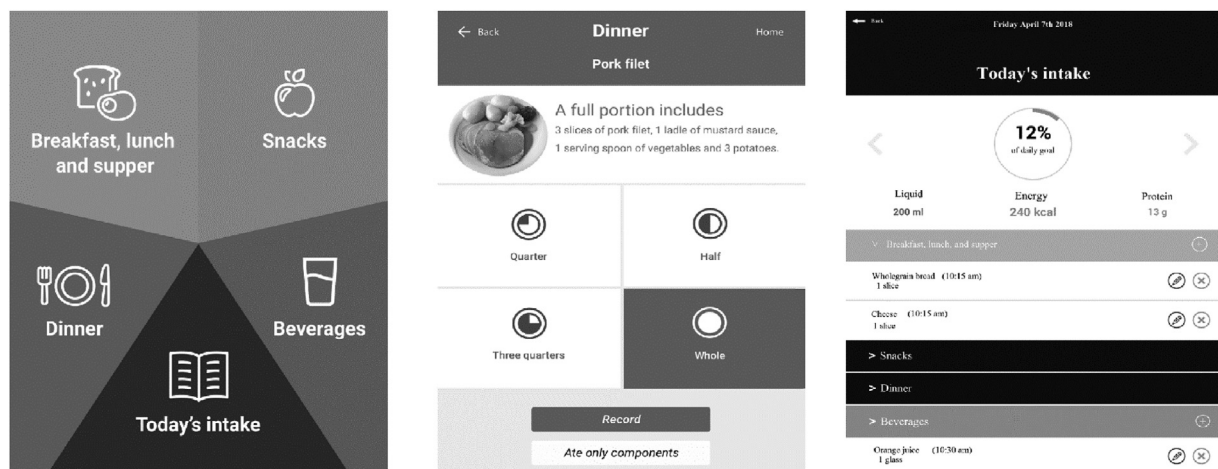


Fig. 1. Dietary recording and evaluation in the MyFood app.



Fig. 2. Data flow in the MyFood decision support system. <sup>1</sup>TSD: Services for sensitive data.

### 2.7.3. Body composition

Bioelectrical impedance analysis (BIA) was measured by a project worker or a dedicated research assistant nurse at baseline, two times per week, and at discharge using the whole-body BIA Seca 525 Body Composition Analyzer (Hamburg, Germany). BIA measures body composition indirectly by passing an alternating current through the body. By measuring BIA with the Seca 525 we were able to detect any imbalances in the patients' hydration status. Information about the patients' hydration status provided relevant information regarding the validity of the weight measurements. The BIA measurements were taken with the patient in a supine position by placing a pair of skin electrodes on each hand and foot using a skin prep gel (Nuprep) and connecting the electrodes to a measuring mat placed above the patient's knees. The BIA measurements generated values for total body water (TBW), extracellular water (ECW), fat mass (FM), fat-free mass (FFM), fat mass index (FMI), fat free mass index (FFMI), skeletal muscle mass (SMM) and phase angle (PhA), which is a biomarker of cellular integrity [27]. The relationship between ECW and TBW was used as a measure of the patients' hydration status.

Height in cm was either measured by measuring tape or self-reported. Body mass index (BMI) was calculated at baseline and once per week using the following formula:  $BMI (kg/m^2) = \text{body weight (kg)} / \text{height}^2 (m^2)$ .

### 2.7.4. Malnutrition risk screening

Malnutrition risk screening was performed by a project worker for all included patients at baseline and thereafter weekly and at discharge using the validated Nutritional Risk Screening (NRS 2002) form [1,28] translated to Norwegian. An NRS 2002 score  $\geq 3$  points indicates the risk of malnutrition. Both nutritional status and the degree of the disease are scored from 0 to 3 points related to severity. Patients  $\geq 70$  years get an extra point related to age.

The Patient-Generated Subjective Global Assessment Short Form (PG-SGA SF) [29] can be used both as a screening and an assessment tool and was used for assessment in the current study. The PG-SGA SF includes questions about weight change, food intake, symptoms that affect food intake, and activity level and function. The included patients completed the Norwegian translation of the PG-SGA SF (18-004 v05.01.18) [30] at baseline and thereafter weekly, and finally, at discharge.

### 2.7.5. Nutritional treatment, nutritional care plans and documentation

Data on the documentation of dietary intake and nutritional treatment during the patient's hospital stay and the creation of a nutritional care plan were retrieved from the electronic patient records of patients in both the intervention and control groups. Documentation of food intake in the electronic patient records was coded into the following categories: 1) general information about intake (e.g., ate little), 2) information about what was eaten (e.g., ate cornflakes for breakfast), 3) information about the amount eaten (e.g., consumed 1000 kcal) and 4) information about the amount consumed compared to the requirements (e.g., consumed 80% of energy needs). Nutritional treatment was defined as nutrition support in the form of one or several measures: Food fortification, use of oral nutritional supplements, interventions related to meal frequency, tube feeding or parenteral nutrition.

### 2.7.6. Length of stay

Data on the length of stay were collected from the hospital database.

### 2.7.7. Compliance

Patient compliance for use of the MyFood app was defined as the number of days recorded in the app divided by the patient length of stay. Compliance by the nurses was assessed by using technical logs from the MyFood system, which recorded sign-up for access and log-in to the MyFood website.

### 2.8. Sample size

The sample size estimation was performed using weight change during the hospital stay as the primary outcome. A clinically relevant difference was defined as a 1 kg difference in weight change between the intervention and control groups during the hospital stay. With an estimated standard deviation of 1.5 kg, a minimum of 37 patients were required in each group, a total of 74 patients, considering a significance level of 5% and a power of 80%. To allow for possible dropouts and missing data, and to be able to study secondary endpoints, we included 100 patients in total.

### 2.9. Ethics

The study was performed in accordance with the Helsinki declaration and was approved by the Norwegian Committee for Medical Research Ethics (2016/1464) and the data protection authority at the hospital. Informed verbal and written consent was collected from all participating patients. The study was registered at the National Institutes of Health Clinical Trials ([www.clinicaltrials.gov/](http://www.clinicaltrials.gov/); Identifier: NCT03412695).

### 2.10. Statistics

Analyses were performed based on the intention-to-treat principle, which included all patients randomized to the intervention or control groups unless they withdrew consent or were lost to follow-up. Continuous data are described with means and standard deviations (SD) or standard error (SE) for normally distributed data and median (25–75th percentile) for nonnormally distributed data. Differences between the intervention and control groups were statistically tested by the independent samples t-test or Mann–Whitney U test. Categorical data are described with the number of patients and proportions and were tested with the Pearson chi-square test or Fisher's exact test. The repeated measurements for weight during follow-up were analyzed using a linear mixed model with a random intercept. The dependent variable was weekly weight measurements. Treatment modality and baseline weight together with an interaction term between follow-up time points and treatment modality were included as fixed main effects. The same linear mixed model analysis was performed for the repeated phase angle measurements.

All statistical tests were performed in the statistical software package IBM SPSS Statistics 24 using a two-sided significance level at 5%.

## 3. Results

### 3.1. Characteristics of the participants

In total, 314 patients were screened for eligibility in the period between August 22, 2018 and February 13, 2019, of whom 100 patients were randomized to the MyFood intervention group ( $n = 49$ ) or the control group ( $n = 51$ ). The data collection period lasted until May 31, 2019. Figure 3 shows the flow diagram for the inclusion and follow-up of patients in the trial. No adverse or unintended effects were reported in the trial.

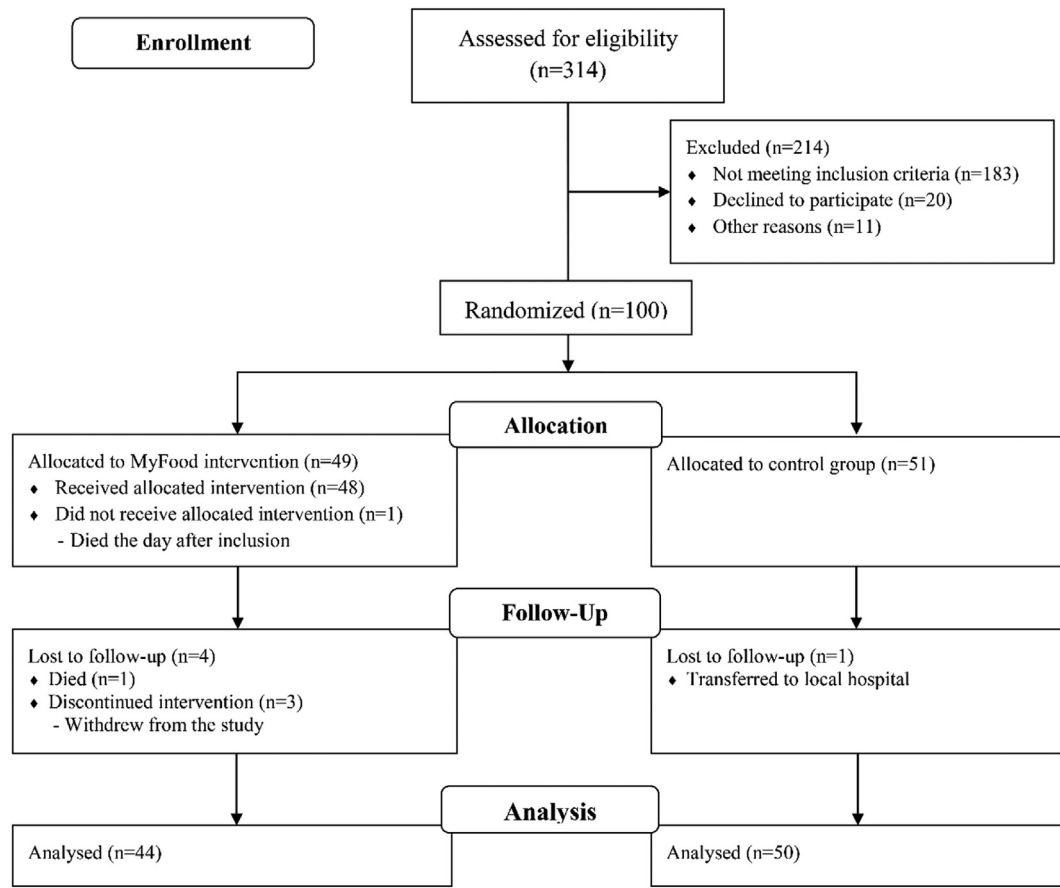


Fig. 3. Consolidated Standards of Reporting Trials (CONSORT) flow diagram for patients' allocation into the intervention and control groups.

The baseline characteristics of the study participants were similar between groups, except for sex, where the proportion of males was significantly higher in the intervention group than the control group (Table 1).

The mean age of participants was 51.9 years and the mean BMI was 25.5 kg/m<sup>2</sup>. The most common diagnosis was leukemia. Approximately half of the patients were admitted to hospital for treatment with bone marrow transplantation, whereas 20% were hospitalized with newly discovered cancer. Just below half of the patients included in the study were malnourished or at risk of malnutrition on admission, defined as NRS 2002 score  $\geq 3$ .

### 3.2. Changes in body weight during the hospital stay

No significant differences in body weight change from hospital admission to discharge were found between the intervention and control groups. The mean weight loss was 2.4 kg in the intervention group and 2.7 kg in the control group (Table 2).

Only 10 patients in each group were normally hydrated, defined as ECW/TBW within the normal reference area [31]. Approximately half of the patients had a shift in hydration status from baseline to discharge; defined as either moving from normal to overhydrated or dehydrated or the opposite. The large shifts in hydration status affected the weight analyses, and thus the analyses were also performed for the subgroup of patients with normal hydration status (Table 2).

The change in mean body weight in the intervention group and the control group during the hospital stay is illustrated in Fig. 4.

To take into account the weekly repeated measurements for the included patients a mixed model analysis was performed. No significant differences in mean adjusted body weight between the intervention and control groups were found at any time point, except a borderline significant difference at week 5 with a 2 kg higher mean body weight in the intervention group than in the control group (Table 3).

### 3.3. Change in patients' body composition during the hospital stay

No significant differences in body composition change from hospital admission to discharge were found between the intervention and control groups (Supplementary table S-1).

The phase angle decreased in both groups during the hospital stay, with a tendency toward a larger decrease in the control group than in the intervention group (Fig. 5).

To take into account the weekly repeated measurements for the included patients a mixed model analysis was performed. A significantly higher phase angle was found for the patients in the intervention group at 4 weeks of hospital stay (Table 4). Borderline significantly higher phase angles were found in the intervention group at the 2 and 3 weeks of hospital stay compared to the control group.

### 3.4. Malnutrition risk

Both groups had a deterioration in NRS 2002 score during the hospital stay. The proportion of patients with an NRS 2002 score  $\geq 3$  increased from 45% at hospital admission to 77% at hospital

**Table 1**  
Baseline characteristics of the patients included in the study.

Variables	MyFood (n = 49)	Control (n = 51)
<b>Gender, male*</b>	35 (71%)	25 (49%)
<b>Age (years)</b>	50 (15)	53 (14)
<b>Mean body mass index (kg/m<sup>2</sup>)</b>	25.6 (3.9)	25.5 (4.4)
Underweight, <18.5	0 (0%)	2 (4%)
Normal weight, 18.5–24.9	22 (45%)	21 (41%)
Overweight, 25–29.9	24 (49%)	21 (41%)
Obese, ≥30	3 (6%)	7 (14%)
<b>Education</b>		
Primary and secondary school	6 (12%)	6 (10%)
Comprehensive school/high school	15 (31%)	15 (29%)
College/university 1–4 years	16 (33%)	17 (33%)
College/university >4 years	12 (25%)	14 (28%)
<b>Earlier experiences with apps and smartphones/tablets</b>		
None/little	5 (10%)	2 (4%)
Some (use sometimes)	14 (29%)	13 (26%)
A lot (use often/daily)	30 (61%)	36 (71%)
<b>Diagnosis</b>		
Leukemia	34 (69%)	31 (61%)
Other type of cancer in blood/bone marrow/lymph	12 (25%)	14 (28%)
Systemic sclerosis	1 (2%)	2 (4%)
Anemia	2 (4%)	4 (8%)
<b>Cause of admission</b>		
Newly discovered cancer	10 (20%)	11 (22%)
Chemotherapy	6 (12%)	10 (20%)
Bone marrow transplantation	24 (49%)	23 (45%)
Complications	5 (10%)	6 (12%)
Other	4 (8%)	1 (2%)
<b>Comorbidity</b>		
None	38 (78%)	32 (63%)
Heart	2 (4%)	2 (4%)
Lung	1 (2%)	0 (0%)
Diabetes	2 (4%)	4 (8%)
Muscular/skeletal	3 (6%)	7 (14%)
Cancer, other type	1 (2%)	2 (4%)
Other	1 (2%)	3 (6%)
Several comorbidities	0 (0%)	1 (2%)
<b>NRS<sup>a</sup> 2002 score ≥3</b>	22 (45%)	24 (47%)
<b>PG-SGA SF<sup>b</sup> score</b>	6 (6)	4 (4)

Data are presented as the number of participants (%) or the mean (SD).

\* $p < 0.05$ .

<sup>a</sup> NRS: Nutritional Risk Score.

<sup>b</sup> PG-SGA SF: Patient-Generated Subjective Global Assessment Short Form.

**Table 2**  
Unadjusted values for change in body weight through hospital stay for patients in the intervention group and the control group.

	n	MyFood			n	Control			$p^a$
		Baseline	Discharge	Change		Baseline	Discharge	Change	
<b>All patients</b>									
Weight, kg (SD)	44	79.6 (12.6)	77.2 (11.6)	−2.4 (3.5)	50	77.4 (16.1)	74.7 (16.2)	−2.7 (2.8)	0.716
Weight change, % (SD)	44			−2.8 (4.2)	50			−3.5 (3.3)	0.420
<b>Normally hydrated patients</b>									
Weight, kg (SD)	10	75.1 (10.3)	73.1 (9.7)	−2.0 (2.4)	10	68.5 (13.0)	65.5 (11.8)	−3.1 (2.3)	0.329
Weight change, % (SD)	10			−2.6 (2.9)	10			−4.2 (3.2)	0.236

<sup>a</sup> Independent samples t-test.

discharge in the intervention group, and from 47% to 94% in the control group (Table 5). At hospital discharge, a significantly higher proportion of the patients in the intervention group was not at risk of malnutrition compared to the control group, as indicated by an NRS 2002 score <3 (23% vs. 6%,  $p = 0.019$ ) (Table 5). This was due to a significantly higher score for impaired nutritional status in the NRS 2002 form in the control group compared to the intervention group (2.1 vs 1.5 points,  $p = 0.014$ ).

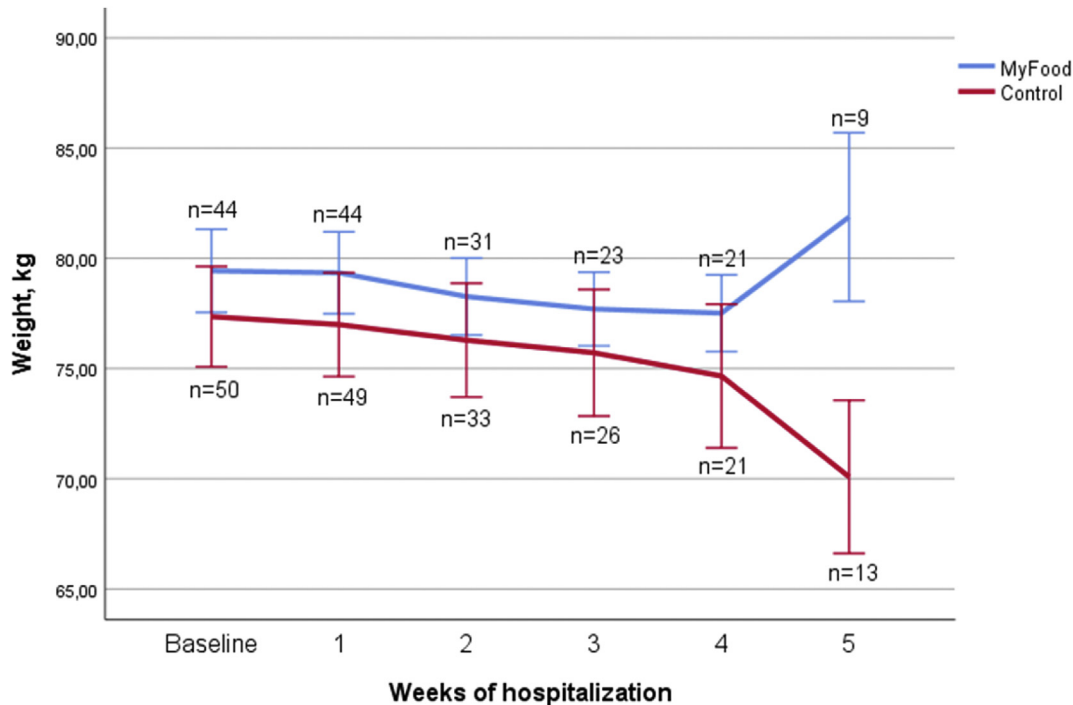
No difference in PG-SGA SF score was found between the groups at hospital discharge, but a borderline significant difference was observed for self-reported food intake where 32% of the patients in

the intervention group and 16% of the patients in the control group reported their food intake as “normal or higher” (Table 5).

### 3.5. Nutritional treatment

The documentation of nutritional treatment was significantly better for the patients in the intervention group than for the patients in the control group (Fig. 6).

Eighty-four percent of the patients in the intervention group and 4% of the patients in the control group had documentation of nutritional intake compared to individual requirements in the



**Fig. 4.** Unadjusted values for change in mean body weight for patients in the intervention group and the control group. Data for  $\geq 6$  weeks are not shown due to few participants. Error bars:  $\pm 1$  SE.

**Table 3**  
Adjusted mean body weight (kg) at each week of hospital stay.

	n	MyFood	n	Control	Mean difference <sup>a</sup>	p
<b>Weight</b>						
1 week	44	78.0	49	77.9	0.1 (-0.9, 1.0)	0.972
2 weeks	31	76.6	33	76.8	-0.2 (-1.0, 1.0)	0.788
3 weeks	23	76.5	26	76.3	0.2 (-1.1, 1.6)	0.723
4 weeks	21	76.3	21	75.6	0.6 (-0.8, 2.0)	0.374
5 weeks	9	76.2	13	74.2	2.0 (0.0, 4.1)	0.054

<sup>a</sup> Mean difference (95% CI) analyzed using linear mixed models for repeated measurements adjusted for baseline differences and missing data.

electronic record ( $p < 0.001$ ). In the intervention group, 70% of the patients had documentation of a nutritional care plan in the electronic patient record compared to 16% of the patients in the control group ( $p < 0.001$ ) (see Fig. 6).

### 3.6. Length of stay

The median length of stay was 21 (25–75 percentile, 9–30) and 19 (25–75 percentile, 8–31) days in the MyFood intervention group and the control group, respectively ( $p = 0.836$ ). One extreme outlier in the intervention group had a length of stay of 120 days. The minimum length of stay was 3 days.

### 3.7. Compliance

Patient compliance was high for the use of the MyFood app. On average, the compliance was 92.6% (min 72.7%, max 100%). The majority of the patients recorded their food intake in the app themselves. One patient did not record his food intake at all due to unfamiliarity with the use of apps and tablet computers. In this case, the patient wrote down his dietary intake on a sheet of paper, which a nurse transferred to the MyFood app. Three patients needed some help from the nurses with the recordings to be able to

find the correct food item. One patient needed assistance because of sensitivity to light from the screen due to use of medications.

Eighty-six of about 120 nurses signed up for access to the MyFood website. Sixty nurses had at some time logged into the MyFood website to check patient reports, create nutritional care plans or see recommendations for tailored nutritional treatment. This means that approximately 30 nurses did not sign up for access to the website and only about half of the nurses at the department used the MyFood website one or several times. For the nurses who used the MyFood website, the median number of log-ins was 3 days (min 1 day, max 18 days).

## 4. Discussion

In the present study, we found no significant differences in weight change during hospital stay between the intervention and control groups. At week 4 of the hospital stay, patients in the intervention group had a significantly higher phase angle than patients in the control group, indicating a reduced nutritional status [32] in the control group compared to the intervention group at this point of hospital stay. Both groups deteriorated with regard to risk of malnutrition, defined by NRS 2002, during the hospital stay. However, a significantly higher proportion of the patients in the intervention group had an NRS 2002 score  $< 3$  at discharge, indicating that a higher proportion of the patients in the control group was malnourished or at risk of malnutrition at hospital discharge. Nutritional treatment and dietary intake compared to individual requirements were significantly more often documented in the electronic patient record for patients in the intervention group than for patients in the control group, and a higher proportion of the patients in the intervention group received a nutritional care plan.

Both the intervention and the control group lost weight during their hospital stay. This is not surprising, as it is reported that most patients lose weight during their hospital stay [33]. The population in the present study had a relatively long length of stay and diseases

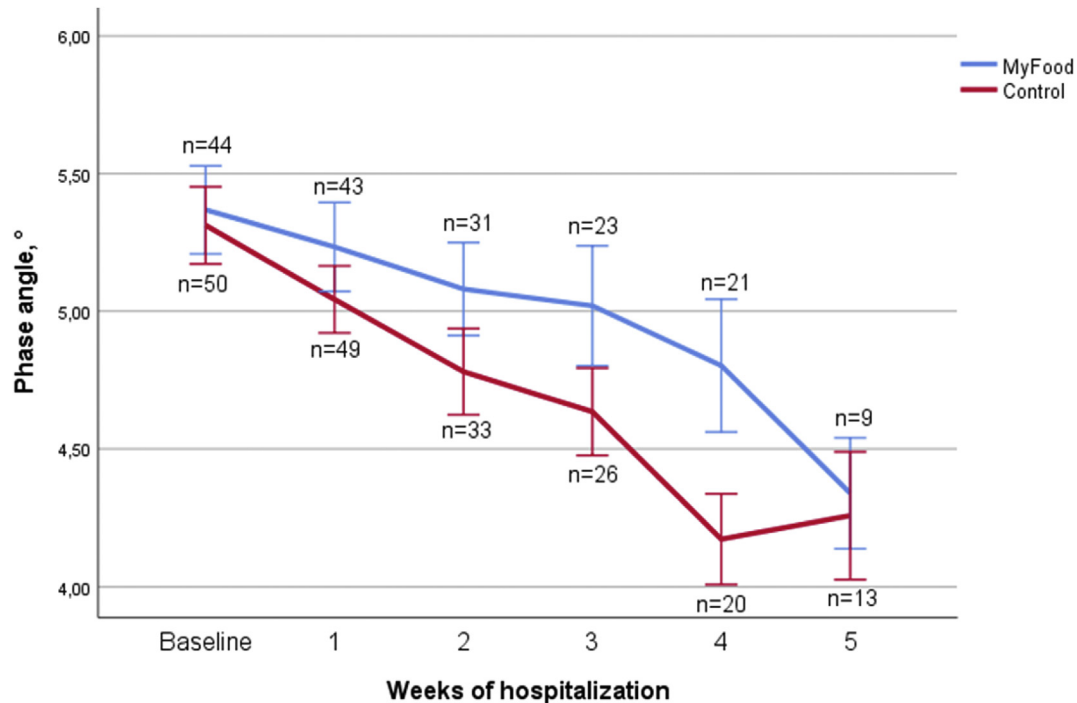


Fig. 5. Unadjusted mean values for the change in phase angle during the hospital stay for patients in the intervention group and the control group. Data for  $\geq 6$  weeks are not shown due to few participants. Error bars:  $\pm 1$  SE.

**Table 4**  
Adjusted mean phase angle ( $^{\circ}$ ) at each week of hospital stay.

	n	MyFood	n	Control	Mean difference <sup>a</sup>	p
<b>Phase angle</b>						
1 week	43	5.2	49	5.1	0.1 (-0.1, 0.4)	0.388
2 weeks	31	5.1	33	4.8	0.3 (0.0, 0.6)	0.055
3 weeks	23	4.9	26	4.6	0.3 (0.0, 0.6)	0.055
4 weeks	21	4.7	20	4.3	0.4 (0.1, 0.8)	<b>0.013</b>
5 weeks	9	4.8	13	4.5	0.2 (-0.2, 0.7)	0.286

Bold numbers indicate significant values.

<sup>a</sup> Mean difference (95% CI) analyzed using linear mixed models for repeated measurements adjusted for baseline differences and missing data.

associated with a high rate of nutritional challenges. Despite no difference between groups in body weight change through the hospital stay, we observed a tendency towards a positive effect of

the MyFood intervention among the patients with the longest length of stay, indicating that the system may have larger effects when used over a longer period of time. Due to a smaller number of patients with a length of stay  $>4$  weeks, these results are uncertain and need to be confirmed in follow-up studies. A recent study with more than 2000 patients in Swiss hospitals found differences in complications and mortality, even though there were no differences in weight change between the intervention group, which received individualized nutritional support, and the control group [34]. Two systematic reviews identified a small effect of nutritional support on weight change among hospitalized patients [35,36]. A Danish app for decision support among cancer patients living at home found that patients using the app maintained weight, but the study had no control group [37].

Fluid imbalances, edemas or ascites in patients often influence body weight measurements [38]. Increased extracellular water is a

**Table 5**  
Malnutrition risk scores and assessment.

	MyFood			Control			p <sup>c</sup>
	Admission (n = 49)	Discharge (n = 43) <sup>a</sup>	Change	Admission (n = 51)	Discharge (n = 49) <sup>b</sup>	Change	
NRS <sup>d</sup> 2002, mean (SD)	2.9 (1.3)	3.9 (1.5)	1.1 (1.7)	2.9 (1.2)	4.5 (1.2)	1.7 (1.6)	0.124
NRS <sup>d</sup> 2002 score $\geq 3$ , n (%)	22 (45%)	33 (77%)		24 (47%)	46 (94%)		<b>0.019</b>
PG-SGA SF <sup>e</sup> , mean (SD)	6 (6)	10 (6)	5 (8)	4 (4)	12 (6)	7 (6)	0.104
PG-SGA SF <sup>e</sup> food intake, n (%)							0.071
As normal or higher <sup>f</sup>	28 (57%)	14 (32%)		32 (63%)	8 (16%)		
Less than normal <sup>f</sup>	21 (43%)	30 (68%)		19 (37%)	42 (84%)		

Bold numbers indicates statistically significant values.

<sup>a</sup> Missing screening forms at discharge for 1 patient.

<sup>b</sup> Missing screening forms at discharge for 1 patient.

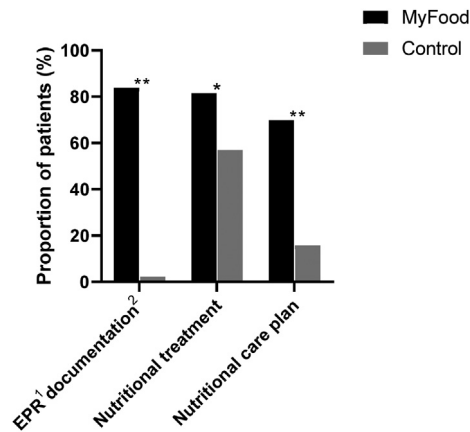
<sup>c</sup> For continuous variables (mean NRS 2002 and mean PG-SGA SF) the reported p values represent the difference between the intervention group and the control group for change in score from admission to discharge. For categorical variables (NRS 2002  $\geq 3$  and PG-SGA SF food intake) the reported p-values represent differences between groups at hospital discharge. Continual data are tested with the independent samples t-test. Categorical data are tested with the chi-square test.

<sup>d</sup> NRS: Nutritional Risk Screening.

<sup>e</sup> PG-SGA SF: Patient-Generated Subjective Global Assessment Short Form.

<sup>f</sup> Food intake indicated by the patient in the PG-SGA SF form.





**Fig. 6.** Comparison of documentation of the nutritional intake, nutritional treatment and nutritional care plans between the intervention and control groups. \* $p < 0.05$ . \*\* $p < 0.001$ , tested with chi-square test. <sup>1</sup>Electronic patient record. <sup>2</sup>Documentation of intake compared to requirements.

common feature of severe illness and systemic inflammation and this complicates the interpretation of changes in body weight during treatment [38] and is often considered a contraindication for the use of BIA [32]. Fluid imbalances were highly prevalent in our study population with only approximately 20% of the patients having a normal fluid balance at both hospital admission and discharge. The sample size estimation did not take into account the large proportion of patients with fluid imbalances. As the number of normally hydrated patients was equal in the intervention and the control group, we may anticipate that this affected the results in a similar manner in both groups. Thus, the results related to body weight change and body composition should be interpreted with caution, and other measures of nutritional status may be more relevant.

There is no “gold standard” recommended for the identification of malnutrition [32], indicating that several parameters should be considered. The phase angle is a useful, independent indicator to assess the risk of malnutrition among hospitalized patients [39,40] and may be used as a more objective measure of nutritional status [41]. The phase angle provides information about hydration status, body cell mass and cell integrity without requiring the assumption of constant tissue hydration and may be used as a prognostic parameter in various diseases [42]. The phase angle is not reliant on any of the predictive equations otherwise applied by BIA to determine other measures of body composition that depend on assumptions of normal fluid distribution [32]. A recent study found comparable values in patients with or without fluid retention when studying the correlation between phase angle and subjective global assessment (SGA) [32]. Although no significant difference between the groups in phase angle change through hospital stay was found in the present study, a higher phase angle was observed in the intervention group at week 4 of hospital stay. However, due to a small number of patients included in the analysis at week 4, this result is uncertain and should be confirmed in follow-up studies.

The documentation of dietary intake in the electronic patient records and the creation of individualized nutritional care plans were significantly better in the intervention group than in the control group in the present study. The MyFood intervention also had a significant effect on the proportion of patients with documented nutritional treatment in the electronic patient record. Other studies have shown that the documentation of nutritional treatment in hospital practice is often unsatisfactory and limited

[43,44]. Causes for this lack of documentation have been described to be barriers related to a short hospital stay, resource demands and discrepancies in nutritional knowledge and skills among health care professionals [17,43]. It is well described that nutritional treatment for malnourished patients is a low-risk, cost-effective strategy to improve the quality of hospital care and key clinical outcomes [45]. Studies performed in Norwegian hospitals have shown that a low proportion of patients at risk of malnutrition receive nutritional treatment [3,19,46]. A clear demand and a high potential for quality improvement in nutritional treatment for hospitalized patients have been reported [46]. A study investigating the effects of a computerized decision support system on care planning for pressure ulcers and malnutrition in Norwegian nursing homes found that the implementation of the system resulted in more complete and comprehensive documentation of malnutrition-related nursing assessments and interventions [47]. This corresponds to the results in the current study regarding improved documentation of dietary intake and nutritional treatment for the intervention group. Electronic systems for nutritional care have been shown to be time-effective compared to paper-based methods for documentation [48]. Based on the results in the current study the MyFood decision support system may be a driver to improve the implementation of the guidelines on malnutrition.

Patients' compliance with the intervention was much higher than the nurses' compliance. This was surprising, as the MyFood decision support system originally was meant to be a tool providing decision support for nurses. A study investigating the potential barriers and facilitators for the use of the MyFood system in a hospital setting found that MyFood was perceived as more motivational to use compared to the current practice with paper-based dietary recording forms [23]. Furthermore, hospital staff meant that the system could potentially lead to increased patient empowerment with regard to their nutritional situation [23]. Future research should focus on how the MyFood intervention can be implemented among both nurses and patients and in the hospital organization. It may also be beneficial to include some of the recommendations for nutritional support into the MyFood app to empower motivated patients with regard to their nutritional situation and treatment.

## 5. Strengths and weaknesses

The randomized controlled design and the involvement of patients, nurses and registered dietitians in the planning phase are important strengths of this study. Significantly more men belonged to the intervention group than the control group. We do not consider it likely that this sex difference influenced the results.

The same nurses could potentially be involved in the care of both patients in the intervention and control groups. This may have led to a contamination effect in which components of the MyFood intervention were transferred to patients in the control group. The presence of researchers at the department in the data collection period and the training of nurses in the MyFood system may have increased the focus on nutritional treatment during the study period, thus leading to improved nutritional treatment for all patients involved during the data collection period.

The patients in the control group did not record their dietary intake as part of this study because we believed that such recordings possibly could interfere with the intervention. Ideally, we should have obtained information about the food intake in both groups to be able to study the potential effects of the MyFood intervention on the intake of energy, proteins and fluids in the patients.

Body weight was measured at scales present in the patients' rooms at the hospital. A challenge arose if the patient changed

rooms during their hospital stay or if the scale was replaced, as the scales at the department were not calibrated. Conditions were not standardized for the BIA measurements and patients were measured at different time points during the day when appropriate for the patient and in-between other medical treatment at the hospital, and this may have influenced the results. However, fasting and bedrest were demonstrated to be unnecessary to obtain reliable measurements of phase angle in a study in hospitalized patients in the United Kingdom [32].

A challenge in our data was the different follow-up times for the patients included in the trial. The patients were included at hospital admission and followed through their hospital stay. This meant that some patients were followed for only 3 days, whereas others were followed for several months. The change in weight during hospital stay could, hence, mean the weight change in 3 days, a week or 3 months. To take this into account, an analysis of repeated measurements was performed using a mixed-model analysis (Tables 3 and 4). Using these analyses, we could test differences between the groups at different time points. This meant that fewer participants were incorporated in the analysis after several weeks than the analysis after 1 week of hospital stay, hence, these analyses were underpowered according to the sample size estimation.

Malnutrition or risk of malnutrition was not an inclusion criterion and less than half of the patients were at risk of malnutrition at baseline, defined as an NRS 2002 score  $\geq 3$ . We might have seen other results if only patients with an NRS score  $\geq 3$  were included. However, only five of the participants (3 in the intervention group, 2 in the control group) were not malnourished or at risk of malnutrition at any time point during their hospital stay. We found a large deterioration in the NRS 2002 scores during the hospital stay in both groups. Almost half of the patients, i.e. 49% in the MyFood group and 45% in the control group were admitted to hospital to undergo bone marrow transplantation. The completion of a bone marrow transplantation should, by definition, give a score of 3 points for the severity of the disease according to the NRS 2002 form [1]. Hence, an increase in the NRS 2002 score for disease severity was expected for a large proportion of patients in our study population and the group of patients in this study was at particularly high risk of malnutrition compared to the general hospital population. The distribution of bone marrow transplants was equal between the intervention and control group and the difference in NRS 2002 score at discharge was due to a significant difference in score for nutritional status between the groups.

This study was performed at a single unit at one university hospital. The results may therefore not necessarily be generalizable to other patient groups and hospitals. The majority of the patients in the present study received chemotherapy which is associated with weight loss [49], and the results may have been different in other types of hospital units. The patients in our sample were relatively young, with a mean age of 52 years and a maximum age of 77 years. Therefore, we do not know if an older age is a barrier for use of the dietary recording function in the MyFood app. Our study population had a relatively high level of education (Table 1), compared to the general Norwegian population [50]. Our relatively young and well-educated study sample implies that our results are not necessarily transferable to the general hospital population. We excluded patients with cognitive deficits and psychiatric illnesses, so we do not know whether MyFood can be used in these patient groups either. The effects of the MyFood decision support system should be studied in other patient groups and hospitals in follow-up studies.

In conclusion, this randomized controlled trial found no effect of the MyFood intervention on weight change, body composition or length of the hospital stay. However, the proportion of patients with an NRS 2002 score  $< 3$  at discharge was significantly higher in

the intervention group than the control group, indicating less degree of malnutrition risk in the patients following the MyFood intervention. Also, the use of MyFood significantly increased the proportion of patients receiving nutritional treatment and an individualized nutritional care plan, compared to the control group.

### Statement of authorship

The authors' responsibilities were as follows – MMP, LFA, IP, CH, RJT and CV designed research; MMP and JG conducted research; MMP and JG analyzed data and performed statistical analysis; MMP wrote the paper; LFA had the primary responsibility for the final content. All of the authors provided critical revision of the manuscript for important intellectual content and read and approved the final manuscript.

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### Conflicts of interest

The authors have no conflicts of interest to declare.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.clnu.2020.03.012>.

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