Development and evaluation of a decision support system to prevent and treat disease-related malnutrition

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PhD Thesis

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Institute of Basic Medical Sciences
Faculty of Medicine
University of Oslo

Oslo 2019

Series of dissertations submitted to the
Faculty of Medicine, University of Oslo

ISBN 978-82-8377-661-4

Cover: Hanne Baadsgaard Utigard.
Print production: Reprosentralen, University of Oslo.

Acknowledgements

The work presented in this PhD thesis was conducted in the period from September 2016 to November 2019. Funding was supported by the South-Eastern Norway Regional Health Authority through a 3-year doctoral fellowship and from the Throne Holst Foundation at the University of Oslo (UiO). Working with this PhD project has been interesting, fun, challenging and motivating.

I would like to thank my main supervisor, Lene Frost Andersen, for giving me this opportunity. You have been my most important adviser during this period always providing constructive feedback, encouragement and support. With you as the project leader, I have felt supported throughout the whole duration of this PhD project. I am impressed by your high capacity to implement, your ability to always think clearly and 'cut through' if necessary, and to be constructive about the natural progress and next step moving forward.

I would also like to thank my co-supervisors Ingvild Paur, Cecile Varsi, and Randi Julie Tangvik. Ingvild, I have really appreciated cooperating with you. You have a high level of knowledge, a pragmatic and clear mind and an easy-going personality. A special thanks to Cecilie for valuable advice and mentoring in the field of implementation science and qualitative methods. I could not have done these parts of the project without your involvement. Randi, your clinical experience and view, combined with your pragmatic way of thinking and enthusiasm have been valuable throughout the course of this project.

Christine, your support and guidance in the project has been highly valued. You are always enthusiastic, interested and passionate about the subject and research and never hesitate to share your expertise and knowledge.

Many thanks to Dagfinn, Gard, Pål, Jarle, Marte, Rikke, Halvor, Leon, Benjamin and more at the University Centre for Information Technology (USIT), for your work with the technical development and interaction design of the MyFood system. I have learned a bit more about programming, development of web applications and technical systems, compared with when I first started.

Thanks to the former master students Johanna and Martina for invaluable help and good cooperation during the different data collection periods. Thanks also to Karoline, Mona and Kaja for practical help with data collection at the hospital.

Thanks to Jorunn for being my office mate, supporter and peer adviser during my PhD project. I have learned a lot from you and appreciate your good mood, thorough way of thinking and not forgetting, our runs around Sognsvann. Thanks to all the former and present members of the Section for Nutritional Epidemiology at the Department of Nutrition, UiO. I have had the pleasure of sharing my office with several colleagues over the period of my PhD. Thanks for all the interesting discussions and support during this process. A special thanks to Sonja, Anine and Anne for your support and sharing of knowledge and 'ups-and-downs' during the course of our period as PhD students.

Kathrine – thanks for being a good friend and our regular lunches. You inspire me by always being some steps ahead of me. Thanks to Eirik for support with computer-related issues.

I also want to thank the rest of my many great colleagues over the years at the UiO.

My gratitude to the National Advisory Unit for Disease-related Undernutrition for including me as part of the unit and providing constructive feedback during the different phases of the project. A special thanks to Hanne for your cheers, enthusiasm and constructive advice.

I would like to thank the patients and nurses included in the study. Thanks also to the health-care professionals who participated in the focus group interviews and individual interviews.

Last but not least, I want to thank Åsmund, Julie and Emilie for their love and always being there for me, and my friends, family and in-laws for their support.

Oslo, November 2019

Mari Mohn Paulsen

Table of contents

List of papers

Paper 1 Paulsen MM, Hagen MLL, Frøyen MH, Foss-Pedersen RJ, Bergsager D, Tangvik RJ, Andersen LF. A Dietary Assessment App for Hospitalized Patients at Nutritional Risk: Development and Evaluation of the MyFood app. JMIR mHealth and uHealth 2018;6(9):e175.

Paper 2 Paulsen MM, Varsi C, Paur I, Tangvik RJ, Andersen LF. Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study. JMIR Formative Research 2019;3(2):e11890.

Paper 3 Paulsen MM, Paur I, Gjestland J, Henriksen C, Varsi C, Tangvik RJ, Andersen LF. Effects of using the MyFood decision support system to prevent and treat disease-related malnutrition: A randomized controlled trial. Submitted to Clinical Nutrition, 22 August 2019. *Under revision.*

Abbreviations

ASPEN	American Society for Parenteral and Enteral Nutrition
BAPEN	British Association of Parenteral and Enteral Nutrition
BIA	Bioelectrical impedance analysis
BMI	Body mass index
CDSS	Clinical Decision Support System
CFIR	Consolidated Framework for Implementation Research
CONSORT	Consolidated Standards of Reporting Trials
CT	Computed tomography
DXA	Dual-energy X-ray absorptiometry
DIPS	Distribuert informasjons og pasientdatasystem I sykehus (the hospital distributed information and patients data system)
ECW	Extracellular water
EPR	Electronic patient record
ERIC	The Expert Recommendations for Implementing Change
ESPEN	European Society for Clinical Nutrition and Metabolism
FELANPE	Latin American Federation of Nutritional Therapy, Clinical Nutrition and Metabolism
FFM	Fat-free mass
GLIM	Global Leadership Initiative on Malnutrition
ICD-10	International Classification of Disease, 10^{th} revision
IOR	Interobserver reliability
KBS	Kostberegningssystem (food composition database and calculation system)
MNA	Mini-Nutritional Assessment
MUST	Malnutrition Universal Screening Tool
NICE	National Institute for Health and Care Excellence
NOKC	Norwegian Knowledge Centre for the Health Services
NPR	Norwegian Patient Registry
NRS 2002	Nutritional Risk Screening 2002
PENSA	Parenteral and Enteral Nutrition Society of Asia

PG-SGA-SF	Patient-Generated Subjective Global Assessment Short Form
PROM	Patent-reported outcome measures
RCT	Randomized controlled trial
REE	Resting energy expenditure
SGA	Subjective Global Assessment
SUS	System Usability Scale
TBW	Total body water
TEE	Total energy expenditure
TSD	Tjenester for sensitive data (services for sensitive data)
UiO	University of Oslo
USIT	University Centre for Information Technology

Summary

Background: About 30% of patients in hospitals are malnourished or at risk of malnutrition. Malnutrition is associated with increased morbidity, longer convalescence, prolonged length of hospital stay, higher readmission rates and premature death. Several barriers are associated with the current practice of nutritional care and treatment in hospitals and the methods are perceived to be cumbersome. Efficient systems and tools to follow up and monitor nutritional care and treatment for the large group of malnourished patients are currently lacking and little is known about the effects and implementation of such systems in clinical practice.

Aims: The aim of this PhD thesis was to develop and evaluate a decision support system to prevent and treat disease-related malnutrition in hospitalized patients. We also aimed to explore the readiness and potential barriers to and facilitators of use of such a system and to study the effects of this system in a clinical hospital setting.

Methods: A combination of quantitative and qualitative methods was used to investigate the aims. The MyFood decision support system was developed with four main functions: 1) patient registration; 2) dietary recording; 3) evaluation of intake compared with nutritional requirements; and 4) report to nurses, including recommendations for nutritional treatment and a nutrition care plan. To validate the dietary recording function in the MyFood system, 32 hospitalized patients were included and told to record their nutritional intake in the MyFood app for 2 days. Their recordings were compared with digital photographs of the meals combined with partial weighing of meal components. A qualitative study was performed to explore the current practice with nutritional care and treatment in the hospital departments, and barriers and facilitators perceived by health-care professionals for the use of the MyFood system as part of their clinical practice. Four focus groups were conducted with 20 nurses, plus individual interviews with 3 middle managers, 2 physicians and 2 registered dietitians. The Consolidated Framework for Implementation Research (CFIR) was used to develop the interview guide and analyse the results. To investigate the effects and implementation of the MyFood system in a clinical hospital setting, a randomized controlled trial (RCT) was conducted among 100 patients. The patients assigned to the intervention group were told to use the MyFood system during their hospital stay and the nurses were encouraged to follow up the patients with the system. The control group followed routine care. The patients' body weight was measured and their body composition estimated twice each week. The Nutritional

Risk Screening (NRS 2002) and the Patient-Generated Subjective Global Assessment Short Form (PG-SGA-SF) were filled in weekly by the researchers and patients, respectively. Data on nutritional treatment, nutritional documentation and the use of nutrition care plans were gathered from the electronic patient record. Data on length of stay were obtained from the hospital administration system.

Results: The MyFood decision support system was developed with an interface consisting of an app for tablet computers and a webserver. The dietary recording function in the MyFood app was found satisfactory in its estimate of the consumption of energy, protein and liquids for the majority of patients. About 70% of the patients had 80% or higher agreement between the estimated intake of energy, protein and liquids based on the MyFood app and the reference method. With regard to the intake of food and beverages, the agreement between the methods varied according to food group. Most of the patients experienced the MyFood app as easy to use and navigate, and reported to become more aware of their nutritional requirements after 2 days' use.

With regard to the current situation with nutritional care and treatment at the hospital departments, the health-care professionals expressed tension for change. The practice deviated from the guidelines for malnutrition in several areas. The MyFood system was perceived as more precise, trustworthy, motivational and fun to use compared with current practice. The use of MyFood was perceived to lead to earlier implementation of nutritional treatment and some thought it would be a time-saver. Potential barriers to the use of MyFood in clinical practice were patients from other cultural backgrounds eating types of food other than the hospital food, patients not speaking Norwegian, hygienic aspects over the use of tablet computers, concerns about the time used to follow up the system and the lack of automatic data transfer to the electronic patient record.

In the RCT, the patients allocated to the MyFood group did not differ with regard to change in body weight or body composition during their hospital stay when compared to the control group. Nutritional treatment was documented in the electronic patient records for 81% of the patients in the MyFood group and 57% in the control group ($P = 0.019$). In the MyFood group, 70% of the patients received a nutrition care plan, whereas the corresponding proportion in the control group was 16% ($P = 0.011$). Documentation of nutritional intake compared with patient requirements for energy, protein and liquids was present for 84% of the patients in the MyFood group and 4% in the control group ($P < 0.001$). Risk of malnutrition at

hospital discharge was present in 77% of the patients in the MyFood group and 94% of the patients in the control group ($P = 0.019$).

Conclusion: In this PhD thesis, a decision support system to prevent and treat disease-related malnutrition was developed, evaluated and tested as a proof-of-concept. The dietary recording function in the MyFood system was found satisfactory in its estimate of the intake of energy, protein, liquids, and food and beverage items for the majority of the patients. Several potential facilitators for use of MyFood in a clinical hospital setting were identified; however, barriers were also revealed. The use of MyFood for hospitalized patients had no effect on weight change during their hospital stay. However, the use of MyFood led to a significantly higher proportion of patients receiving nutritional treatment, a nutrition care plan and proper documentation of nutritional intake in the health record. The proportion of patients at risk of malnutrition at discharge was lower in the MyFood group compared with the control group.

1 Background

1.1 Introduction

The idea behind this PhD thesis was to create a digital system to monitor and evaluate the nutritional situation for hospitalized patients with malnutrition or at risk of malnutrition. The system should give decision support for nurses to provide optimal nutritional treatment and care for the patients. The prevalence of disease-related malnutrition in hospitalized patients is high, and the condition is associated with adverse outcomes for both patients and the health-care system. Many barriers are associated with the current practice of nutritional care and treatment, and we have identified a need for a better system to handle the process of monitoring, treating, documenting and following up malnutrition. This PhD thesis describes the development, evaluation and effects of the MyFood decision support system.

1.2 A glimpse into the history of disease-related malnutrition

The recognition of good nutrition as an important part of health and recovery dates back more than 150 years in time, but is still often a challenging and underprioritised area. Already in 1859, Florence Nightingale emphasized the important role of nutrition for patients:

‘Every careful observer of the sick will agree with this, that thousands of patients are annually starved in the midst of plenty from want of attention to the ways which alone make it possible for them to take food. I would say to the nurse, have a rule of thought about your patient’s diet. Consider and remember how much he has had and how much he ought to have today’ (1).

In 1918 the surgeon Albert F. R. Andresen stated that ‘the sooner after an operation a patient can be supplied with adequate nutrition, and the sooner the normal gastro-intestinal peristaltic can be reestablished, the better are the chances of patient recovery’ (2). Some of the first scientific papers describing hospital malnutrition were published in the 1970s. Butterworth described ‘the skeleton in the hospital closet’ by presenting evidence suggesting that malnutrition is often associated with disease in hospitalized patients (3). Bistrian described about half of surgical (4) and medical (5) patients as suffering from nutritional deficiencies. In

1999, the European Council of Europe identified the five most important barriers for effective prevention and treatment of malnutrition: 1) lack of clearly defined responsibilities; 2) lack of sufficient education; 3) lack of influence of the patients; 4) lack of co-operation among all staff groups, and; 5) lack of involvement from hospital management (6).

The European Society of Clinical Nutrition and Metabolism (ESPEN) established guidelines for nutritional screening in 2002 (7) and the American guidelines were established by the American Society for Parenteral and Enteral Nutrition (ASPEN) in 2011 (8). The first national guidelines on disease-related malnutrition in Norway were published in 2009 by the Norwegian Directorate of Health (9). A revised version is currently being prepared and is expected to be published during the second quarter of 2020.

1.3 Disease-related malnutrition

According to the ESPEN, malnutrition can be described as a nutritional deficiency resulting from an imbalance between nutritional intake and nutritional requirements and may be caused by disease or other factors such as hunger or socioeconomic factors (10). The ESPEN recommends the definition of malnutrition as described by Sobotka *et al*. (11): 'A state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease'. The same definition is used by the Norwegian Directorate of Health (9).

The terms 'undernutrition' and 'malnutrition' are often used synonymously in the literature (12). Undernutrition is often used for underfeeding or poor nutritional status in general (13). Malnutrition can include both protein and energy undernutrition, energy overnutrition and micronutrient deficiencies. The term can also be used for protein and energy deficiencies only (13, 14). In this PhD thesis, the term 'malnutrition' has been used to cover nutritional deficiency due to an imbalance between nutritional requirements and intake, as a result of disease.

Disease-related malnutrition develops in parallel with disease and is characterized by weight loss and changes in body composition, including reduced body fat and muscle mass and a relative increase in extracellular fluid volume (10). In a patient with disease-related malnutrition, the rate of weight loss and loss of lean mass are proportionally greater compared

with those in starvation alone (10). Disease-related malnutrition may occur with or without inflammation as illustrated in Figure 1.

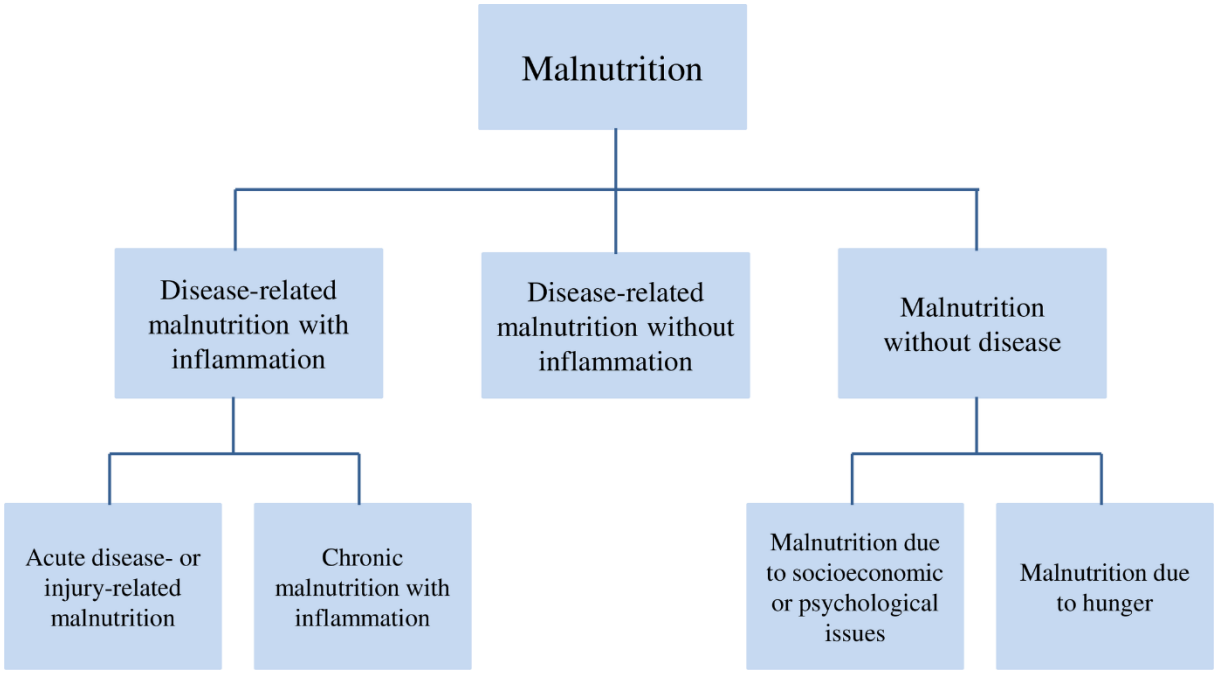

Figure 1 Aspects of malnutrition. The figure is adapted from the European Society of Clinical Nutrition and Metabolism (ESPEN) guidelines on definitions and terminology of clinical nutrition by Cederholm *et al*. (10).

Disease-related malnutrition with inflammation is often described as cachexia and may occur in organ diseases such as cancer and chronic obstructive pulmonary disease. Acute malnutrition may be due to injuries or acute disease, for example, burns or major infections (10). Disease-related malnutrition without inflammation may include, for example, dysphagia as a consequence of stroke or dementia or malabsorption as a consequence of intestinal disorders, e.g. short bowel syndrome. Malnutrition without disease may be due to hunger or socioeconomic situations, e.g. poverty or poor care (10) (Figure 1). In this PhD thesis, the primary focus is disease-related malnutrition with inflammation.

1.4 Nutritional diagnosis

The use of diagnoses for patients who are malnourished or at risk of malnutrition is important. A precise description of the problem improves the chances of proper treatment and systematic monitoring. Besides, the use of nutritional diagnoses will provide increased economic incentives for the hospitals because it may involve higher incomes.

The Global Leadership Initiative on Malnutrition (GLIM) suggested a new set of international criteria for the diagnosis of disease-related malnutrition in 2018 (15). The GLIM included the four largest nutrition societies in the world: the ASPEN, the ESPEN, the Latin American Federation of Nutritional Therapy, Clinical Nutrition and Metabolism (FELANPE) and the Parenteral and Enteral Nutrition Society of Asia (PENSA). The GLIM recommends a two-step approach to diagnose malnutrition by first performing nutritional screening using any validated screening tool, and second performing a nutritional assessment including both phenotypical and etiological criteria. The phenotypical criteria include non-volitional weight loss, a low body mass index (BMI) and a reduced muscle mass. The etiological criteria include reduced food intake or assimilation, and disease burden/inflammation. A malnutrition diagnosis requires at least one phenotypical criterion and one etiological criterion (15).

The Norwegian guidelines for prevention and treatment of malnutrition from the Directorate of Health recommend using the international classification of diagnosis in the *International Statistical Classification of Diseases and Related Health Problems*, 10th Revision (ICD-10) (9). The ICD-10 has three main diagnosis codes for malnutrition; E46: unspecified protein-energy malnutrition, which should be given to patients at risk of malnutrition, E44: mild-to-moderate malnutrition; and E43: severe malnutrition (16). The Norwegian adaptation of the ICD-10, includes specifications for E46, E44 and E43, including an evaluation of the score from a nutritional screening tool, weight loss, BMI and energy intake (9, 16).

1.5 Prevalence and consequences of disease-related malnutrition

Approximately 30% of hospitalized patients are malnourished or at risk of malnutrition, both internationally (17-19) and in Norway (20, 21). The term ‘risk of malnutrition’ includes both patients who are malnourished and those at risk of malnutrition, as illustrated in Figure 2.

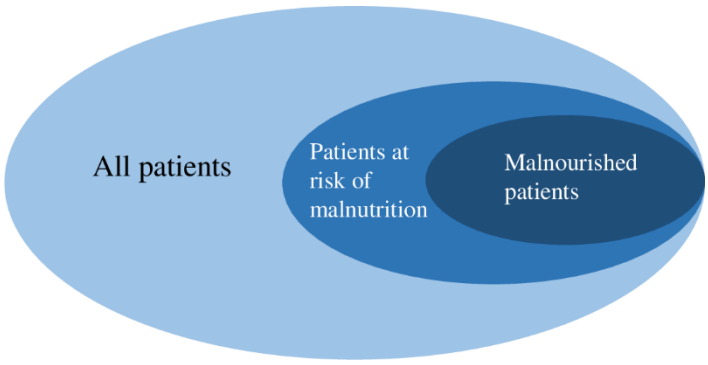

Figure 2 The relationship between malnutrition and risk of malnutrition. The figure is adapted from an illustration made by Ingvild Paur.

The prevalence of disease-related malnutrition in hospitals today is described as between 20% and 50%, depending on the definitions used to categorize nutritional status (17). Nutritional status can be defined as the extent to which an individual's physiological need for nutrients has recently been met (22). A recent systematic review and meta-analysis of the prevalence of malnutrition risk in older European adults found that different screening tools revealed varying results for this prevalence (23). The risk of malnutrition also varies with the disease. A high prevalence of malnutrition is found in patients with cancer, infections, pulmonary diseases, and gastroenterological diseases (21, 24, 25) and patients with multiple comorbidities (23). The prevalence of malnutrition risk is found to increase with a higher age among older adults aged >65 years (23).

Predisposing factors such as increased age, chronic illness and socioeconomic factors increase the risk of weight loss and declining nutritional status during a hospital stay (26, 27). Factors such as loss of appetite, inactivity, depression, inflammation and the effects on energy and protein metabolism caused by the disease may all contribute to the loss (28).

Disease-related malnutrition is associated with increased morbidity and shorter survival among patients (9, 17, 29-32), significantly longer length of hospital stay (33-35), longer convalescence (17), increased risk of poor wound healing and infections (36), higher readmission rates (33) and reduced health-related quality of life (37).

In 2018, the British Association of Parenteral and Enteral Nutrition (BAPEN) estimated the cost of malnutrition to be about 15% (£23.5 billion and ~£370 per capita) of the total health and care costs in the UK, and that managing malnutrition with nutritional support is highly cost-effective (38). In 2010, a cost-benefit analysis demonstrated that reducing the length of stay by 1 day for patients at risk of malnutrition could save the Norwegian hospitals approximately NOK800 million annually (39).

1.6 Prevention and treatment of disease-related malnutrition

1.6.1 Nutritional guidelines

In addition to the guidelines for malnutrition from the ESPEN (7) and ASPEN (8), country-specific guidelines are developed in many countries, e.g. the National Institute for Health and Care Excellence (NICE) guidelines in the UK (40) and the recently published guidelines for prevention and treatment of malnutrition from the National Board of Health and Welfare (Socialstyrelsen) in Sweden (41). The Norwegian guidelines are relatively in line with international guidelines and state that all patients who are hospitalized should be screened for risk of malnutrition on admission, and thereafter weekly. Exceptions from this are patients aged <18 years, patients with terminal conditions, patients who have undergone bariatric surgery, and pregnant and lactating women (9). Those patients who are identified as malnourished or at risk of malnutrition should have an individual nutrition care plan that documents nutritional status, nutritional requirements, dietary intake and nutritional treatment. Finally, this information should be documented in the electronic patient record and communicated to the next level of care (9).

1.6.2 Action plan for patient safety

Disease-related malnutrition was included as part of the Norwegian patient safety program in 2015 (42) as one of 16 focus areas considered to have the most potential for reducing patient harm (43). A nutrition expert group was established and three action plans for patient safety related to malnutrition were developed; one for hospitals; one for nursing homes; and one for home-based care (44). This happened in parallel with the planning and conduction of this PhD project and has influenced the work. As of 2019, the work initiated in the patient safety program has been continued and incorporated within the Department of Quality Improvement and Patient Safety within the Norwegian Directorate of Health. In line with the Norwegian guidelines described above (9), the most important tasks to prevent and treat malnutrition are described in the action plan, as illustrated in Figure 3.

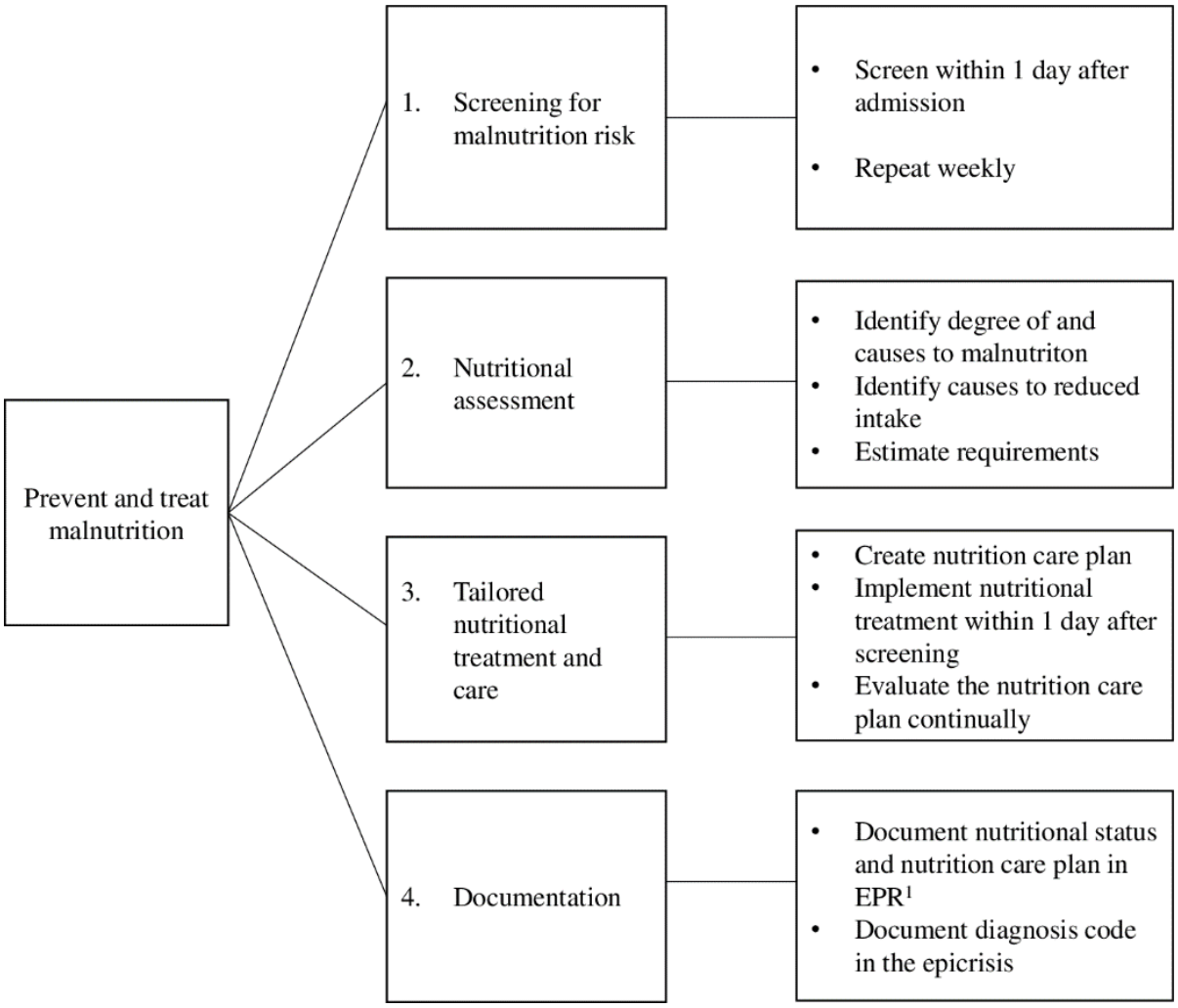

Figure 3 The most important tasks to prevent and treat disease-related malnutrition. Adapted from the Norwegian Directorate of Health (43). [1]EPR, electronic patient record

The action plan includes process indicators and result indicators that should be monitored and measured locally in each hospital (45). The four steps in the action plan are based on important principles and are described in more detail and elaborated according to existing research below.

1.6.3 Screening for risk of malnutrition

As described above, the first step in the prevention and treatment of disease-related malnutrition should be screening for risk of malnutrition (7, 8, 43, 46). The screening process identifies both patients who are already malnourished and patients who are at risk of malnutrition. The screening should be performed on hospital admission to be able to implement measures or treatment before the condition gets worse, as the treatment of malnutrition is challenging. There is a wide range of tools that may be used to screen for the

risk of malnutrition in the hospital setting (47). Some of the most commonly used tools are shown in Table 1.

Table 1 Selected screening tools recommended for use in the hospital sector

Screening tool	**Fators assessed by the sceening tool**						
	Weigth loss	BMI[1] (kg/m^2)	Food intake	Symptoms	Severity of disease	Activity/mobility	Other
NRS[2] 2002	X	X	X		X		
MUST[3]	X	X			X		
PG-SGA[4]	X		X	X		X	
MNA[5]	X	X	X		X	X	X

[1]BMI, body mass index. [2]NRS, Nutrition Risk Screening (48). [3]MUST, Malnutrition Universal Screening Tool (49). [4]PG-SGA, Patient-Generated Subjective Global Assessment (50). [5]MNA, Mini Nutritional Assessment (51)

The ESPEN recommends the use of Nutritional Risk Screening 2002 (NRS 2002) for hospitalized patients, the Malnutrition Universal Screening Tool (MUST) for adults in the community and the Mini Nutritional Assessment (MNA) for elderly people (7). The current Norwegian guidelines recommend using NRS 2002, MUST or MNA in hospitals (9). The Patient-Generated Subjective Global Assessment (PG-SGA) has been specifically developed for cancer patients (50, 52). Contrary to most of the screening tools named above, the PG-SGA can be used for screening, diagnosis and assessment (52).

1.6.4 Nutritional assessment

The nutritional assessment seeks to extend the process initiated in the screening (27). The nutritional assessment is a thorough evaluation of the patient's nutritional status (53) and also factors that may affect the nutritional intake and estimation of the patients' nutritional requirements (43, 46). The assessment determines to what extent a patient's nutritional requirements have been covered during a period (53). There is no universally accepted definition of what components and measures the nutritional assessment should include (54). The ESPEN defines nutritional assessment as the assessment of body weight, body height, BMI, body composition and biochemical indices (10). A recent review of the nutritional management of medical inpatients by Reber *et al*. (27) defined nutritional assessment in the light of the GLIM criteria (15). According to this definition, the nutritional assessment should include an assessment of the phenotypical criteria: weight loss, BMI, decreased muscle mass, and the etiological criteria: decreased food intake and/or assimilation and disease burden/inflammation. Nutritional assessment should be performed in all patients who are identified as malnourished or at risk of malnutrition according to international and national

guidelines (8, 10, 43). In the action plan for malnutrition by the Norwegian patient safety program (see Figure 3), the nutritional assessment includes the identification of the extent of the patient's malnutrition, the identification of which factors may affect the nutritional intake and the estimation of nutritional requirements (43). To sum up, there are several definitions of what should be included in the nutritional assessment. In this PhD thesis, nutritional assessment included the assessment of body weight, body composition, nutritional requirements and nutritional intake. These measurements and estimations are described in more detail below.

Anthropometric measures

The ESPEN guidelines recommend that body weight should be measured and recorded one to three times each week for hospitalized patients, except for patients with terminal conditions in late palliative phases (10). The Norwegian guidelines for malnutrition do not explicitly define how often weight should be measured, but the assessment of body weight is included in the nutritional screening, which should be performed on admission and thereafter weekly for hospitalized patients (9). According to the Norwegian guidelines for nutrition in health and care services from the Directorate of Health, height should be measured using a stadiometer or similar device attached to the wall. Self-reported height may be used as an alternative (46).

Body composition

A measurement of a patient's body composition can be used in the nutritional assessment because the body composition reflects the nutritional intake, losses and gains over time (55). These data may also be valuable as a snapshot to provide information about, for example, a patient's muscle mass. BMI and weight change are often inaccurate measures of alterations in body composition (55). More precise methods, such as bioelectrical impedance analysis (BIA), dual-energy X-ray absorptiometry (DXA), ultrasound and computed tomography (CT) can be used to assess the body composition. However, these methods might be time-consuming and costly and associated with different advantages and challenges (56, 57).

BIA is a rapid, non-invasive technique that measures the resistance in different tissues in the body and makes it possible to predict extracellular water (ECW) and total body water (TBW), and thereby estimate skeletal muscle mass, fat mass and fat-free mass (FFM). Low muscle

mass has been found to be a predictor of poor morbidity and mortality (58) and BIA may be used as a tool in the nutritional assessment (59).

Nutritional requirements

To evaluate whether the nutritional intake for a patient is sufficient, it is necessary to know the patient's nutritional requirements. Human energy requirements depend on the basal energy expenditure, diet-induced thermogenesis, physical activity level and metabolic stresses of different disease conditions (28, 36, 60). The 'gold standard' for estimating energy requirements is the use of indirect calorimetry (27). Through the use of indirect calorimetry, the energy expenditure can be estimated by comparing the volumes of inhaled oxygen and exhaled carbon dioxide per minute (61). However, indirect calorimetry requires specialized equipment that is seldom or never present in hospitals. Predictive equations, e.g. the Mifflin's formula (62) or the Harris–Benedict formula (63) are other alternatives (27). Roughly estimated weight-based formulae may also be used (27), and a common rule of thumb for hospitalized patients is 25–35 kcal/kg body weight per day (10). However, individual adjustments will often be necessary (9, 10, 40, 43).

Protein requirements are in general 0.8–1.5 g/kg body weight per day for both healthy adults and hospitalized patients and this corresponds to 10-20 E% (40, 60, 64). The guidelines for malnutrition from the Norwegian Directorate of Health recommend 1.2 g/kg body weight per day (9, 46).

With regard to liquids, the recommendation for the general population is not stringent, but rather that the sensation of thirst should be a guide (60). In addition to water derived from foods, 1–1.5 litres are the Nordic Nutrition Recommendations (60). For hospitalized patients, 30 ml/kg body weight per day is the commonly used 'rule of thumb' recommendation (46).

Nutritional intake

Nutritional intake should be recorded and evaluated to make a comparison of the patient's intake with individual requirements (9, 43). In the screening for risk of malnutrition, rough measurements are usually performed, e.g. categorization of food intake as a percentage of normal intake: 0-25%, 25–50%, 50–75%, and 75–100%. A more comprehensive evaluation of

intake should be performed for patients who are classified as being at risk of malnutrition, however, the assessment of dietary intake might be a demanding and time-consuming task.

The use of dietary recording or 24-hour recalls is a necessary prerequisite to deciding the nutritional treatment, to document the effects of treatment, and to establish a foundation for dialogue with the patient about food habits (46). Causes of reduced nutritional intake should also be identified. Potential causes may be, for example, the side effects of medications or medical treatment, reduced level of function, or nutritional content or portion sizes of the food served (46).

1.6.5 Nutritional treatment and care

According to the Norwegian Patient's Rights Act, all patients in Norwegian hospitals have the right to receive treatment and care according to their requirements (65). This includes the right to sufficient, safe and nutritionally adequate food (46, 66). For malnourished patients, the right to receive adequate nutritional care is thus regulated by law.

The screening for malnutrition and assessment of nutritional status should be followed by the development of an individualized nutrition care plan for those patients who are identified as being malnourished or at risk (27, 47). The development of a nutrition care plan should be based on the nutritional assessment (7, 9) and should ideally be developed by an interdisciplinary team, together with the patient and his or her next-of-kin (10). According to the action plan for malnutrition in the Norwegian patient safety program, the nutrition care plan should as a minimum include the following (43):

- Documentation of nutritional status, including the results from the screening and assessment. Special concerns that are related to the type of diet, food texture, help with the meal situation, etc. should also be reported here
- The patient's nutritional requirements
- Status of the patient's nutritional intake
- Nutritional treatment or measures, tailored to the patient
- Goals for the nutritional treatment

In the literature, the terms ‘nutritional treatment’, ‘therapy’, ‘support’, and ‘intervention’ are often used interchangeably for the action of performing one or several measures to improve the patient’s nutritional situation. In this PhD thesis, the term ‘nutritional treatment’ was used to describe nutrition-related measures.

Adequate nutritional treatment for patients at nutritional risk aims to prevent any further decline in the patient’s nutritional status and may have a positive influence on disease outcomes (47). The ESPEN guidelines recommend that oral nutrition should be the first choice before considering other types of nutritional treatment. This may include both fortifications with energy- and protein-dense food or beverages and commercial fortification solutions or oral nutritional supplements (28). Tube feeding or parenteral nutrition can be considered if oral nutrition is not possible, safe or sufficient. Enteral nutrition is preferred over parenteral nutrition, because it is more physiological, and leads to increased maintenance of gastrointestinal health and a lower risk of infections and complications (28). According to the Norwegian Directorate of Health, nutritional treatment should be performed stepwise in a systematic manner, as shown in Figure 4 (9).

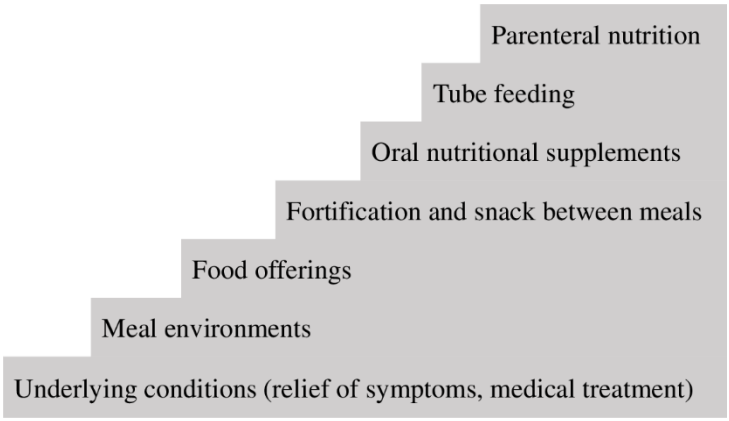

Figure 4 The nutritional stairs. Adapted from the Norwegian Directorate of Health (9).

An early focus and relatively simple measures may often be enough to prevent or delay more invasive and expensive treatments such as tube feeding or parenteral nutrition. Therefore, the focus should first be on intervention at the lowest level, and then gradually move up the stairs. In some circumstances, consideration should be given to starting at a higher treatment level (9). Patients who struggle to meet their nutritional requirements through hospital food alone should, in addition, or as a substitute, be provided with oral nutritional supplements, tube feeding or parenteral nutrition (9, 67). It is important to monitor nutritional care continually, specifically concerning nutritional intake and weight change (27, 43).

Two meta-analyses by Bally *et al*. (68) and Feinberg *et al*. (69) found an increased body weight and higher consumption of energy and protein after nutritional support for hospitalized patients. However, no effects were seen on mortality, morbidity, complications, and non-elective readmissions. A Cochrane review by Baldwin *et al*. (70) investigated the effects of supportive interventions for improving dietary intake in adults who were malnourished or at risk of malnutrition. Improved weight and lower relative risk for all-cause mortality were seen in patients receiving nutritional intervention compared with the control groups. The evidence was, however, rated as low to moderate (70). A recently updated systematic review and meta-analysis including almost 7000 patients found that receiving nutritional support was associated with significantly lower rates of mortality, a reduction in nonelective hospital readmissions, a higher intake of energy and protein, and increased weight (71). However, no effects were observed for length of hospital stay, rates of infections and functional outcome (71). It has been argued that the lack of consistent evidence of the effects of nutritional support is a consequence of too many studies performed with low statistical power and methodological issues and that more high-quality randomized controlled trials (RCT) are needed (27). A recent Swiss multicentre study, including more than 2000 hospitalized patients, showed that individualized nutritional support improved clinical outcomes and increased the intake of energy and protein for hospitalized patients (72). A multicentre study, conducted among 622 older hospitalized adults in the USA, found that the use of a specialized oral nutritional supplement during hospitalization and post-discharge increased the weight and reduced the 90-day mortality compared with placebo (73). However, no effect was seen on the primary outcome comprised by the 90-day postdischarge incidence of death and non-elective readmission (73). In summary, the results from systematic reviews, meta-analysis and large RCTs the recent years have demonstrated that individualized nutritional intervention and treatment are important to improve patient and health-care outcomes.

1.6.6 Documentation and transfer of information to the next level of care

According to international and Norwegian guidelines for malnutrition, documentation is an important part of the nutritional care process (7, 9). Furthermore, documentation of the screening for risk of malnutrition, nutritional status, nutritional requirements, nutritional intake, treatment, goals, and outcomes should, according to ESPEN, be documented in the electronic patient record in the same way as any other part of medical and nursing treatment is

documented (10, 74). The screening for malnutrition risk, the nutritional assessment and the nutrition care plan should, according to the Norwegian Directorate of Health, also be documented in the epicrisis and transferred to the next level of care (9, 43, 44). Adequate documentation is crucial for ensuring that all health-care professionals involved in the treatment and care of the patient have sufficient information to provide appropriate treatment. The medical record is a legal document and 'if it is not documented, it did not happen' (74).

1.7 Nutritional routines, barriers and solutions

1.7.1 The current situation with nutritional care and treatment in the hospital setting

Nutritional care for the patient has traditionally been the nurse's responsibility and nutrition is described as an important nurse task (75). Today it is emphasized that the nutritional treatment and care should be an interdisciplinary task (9, 10). As the nurses represent the largest group of health-care professionals in the hospital and also see the patients most often, they are, however, often assigned the primary responsibility for identifying the need for and to implement nutritional treatment (76).

A recent review by Swiss and American researchers of nutritional management in hospitalized patients revealed that, despite guidelines and initiatives, malnutrition is still often unrecognized as a diagnosis, under-reported and remains untreated (27). Norwegian data indicated that only 12% of patients at risk of malnutrition had a nutrition care plan documented in the electronic record (77) and that only 50% or less of patients who were malnourished or at risk of malnutrition received nutritional treatment (20, 78).

1.7.2 Barriers

A review by Souza *et al*. (79) described the lack of incorporation of screening and nutritional therapy tools for hospitalized patients into routine care as being a major barrier for appropriate nutritional care and treatment. Scandinavian data indicate that the main barriers to appropriate nutritional care include the absence of both routines and assignment of responsibility (76). As described above, the day-to-day responsibility for nutritional care is often assigned to the nurse. However, the nurses often experience a lack of skills, resources

and knowledge about nutritional treatment and follow-up (77, 80). A Norwegian study by Eide *et al.* (76), investigating barriers to nutritional care for older hospitalized patients identified that the methods for recording and assessing dietary intake are considered impracticable by nurses. The Norwegian Directorate of eHealth states that most of the current tools and systems in the health-care sector are cumbersome and deficient, and do not lead to efficient utilization of expertise (81).

1.7.3 Solutions

Internationally, a few methods that aim to be simpler and easier to use than traditional practices have been developed. For example, a dietary assessment method called 'rate-a-plate' has been developed in the Netherlands, and is used in the nutritional follow-up of patients at risk of malnutrition. It is also part of the 'Safety Programme for Older Patients Admitted to Hospital' of the Dutch government (82). The rate-a-plate method is filled in by nurses or nutritionists and, by using a scoring system, patients may be roughly categorized into low, moderate or sufficient intake (82). In Iceland, a plate diagram sheet is developed to provide an easy-to-use tool to monitor patients' nutritional intake, by selecting the proportion of the meal that is consumed, i.e. 0%, 25%, 50% or 100% (83). A similar tool was developed in Indonesia, but as well as the selection of proportion of consumed meal, the tool included pictures of six different portion sizes for the three food groups: staple foods, animal protein and non-animal protein (84).

In 2015, the Norwegian Knowledge Centre for the Health Services (NOKC) published a report stating that electronic tools providing recommendations and notifications based on individual patient information are among the measures with documented effect in getting health-care professionals to change their clinical practice and follow the clinical recommendations (85). The NOKC concluded that there is a huge need to implement nutrition as a more central part of patient treatment, and calls for the implementation of actions that can provide attention, increase knowledge, give better nutritional treatment and reduce the number of incidences related to malnutrition in Norwegian hospitals (86).

1.8 The use of technology in nutritional assessment, care and treatment

There has been a long history of technological innovation in the design and development of dietary assessment tools (87). Technology has been introduced as an attempt to reduce the costs, limit the measurement errors and make the recordings simpler for the respondent and the receiver. Over the last few decades, there have also been major technological advances in the possibilities for processing data (87). The internet has provided opportunities for automated dietary recording by linking dietary assessment systems to food and nutrition databases (88). New technology-based dietary assessment methods are increasingly used in intervention studies for weight control or healthy eating to provide tailored feedback to the user (89, 90). Technology-based tools are described as having a large potential for personalized nutrition and improved diet and lifestyle on a widespread level (91). A recent review by Trtovac and Lee (92) concluded that computerized tools and apps may contribute to reducing health-care professionals' workload and time spent assessing patients for malnutrition.

Digital health and care, eHealth, may be defined as 'health services and information delivered or enhanced through the internet and related technologies' (93). The term includes information and data sharing between patients and health-care professionals, hospitals, health service providers and health information networks (94). In Norway, the Directorate for eHealth has developed a national strategy and action plan for eHealth (81). According to the Norwegian government, the increasing life expectancy and the rising need for healthcare should be met with more effective solutions and greater use of technology and digitalization (81, 95). One of the objectives in the 'Health&Care21strategy' from the Norwegian government is to increase the degree of innovation in health, care and welfare services, e.g. through implementation, research and evaluations of new technology (96). According to the Directorate of eHealth, it is crucial to utilize the possibilities of digital technology in a better way to be able to reach the government's ambitions for better quality, increased patient safety and improved utilization of competence and resources (81).

The development and use of eHealth tools are increasing (97, 98). A recent report from the Research Council in Norway concluded that a substantial amount of eHealth tools for use by health-care providers and patients has been developed, within both somatic and psychiatric

health (99). Several different types of eHealth interventions exist and clinical decision support systems (CDSS) are one example. CDSS can be defined as systems that use individual patient characteristics to generate recommendations to aid the health-care professionals' decision making (100). CDSS can be categorized into knowledge-based systems and non-knowledge-based systems (101). Knowledge-based systems often include a knowledge base containing a set of rules based on specific assumptions. These rules often take the form of 'IF-THEN' rules. The system combines the rule from the knowledge base with patient data (101). With regard to nutrition, this would mean, for example, 'IF the patient has nausea, THEN recommendations for treatment or relief of nausea will appear'. Non-knowledge-based CDSS often use artificial intelligence, in the form of machine learning, which makes the system able to learn from previous experiences or to find patterns in the clinical data (101). Patient-oriented CDSS also exist and could have huge potential; however, the literature for this emerging field is scarce (102).

Even though the use of technology and CDSS in healthcare has increased in general, the use of such systems for nutritional care and treatment among hospitalized patients has been limited both internationally and in Norway. A few eHealth initiatives about malnutrition are described in the literature. The app 'NutriDia', which includes decision support for cancer patients living at home was developed and evaluated in Denmark (103). NutriDia included modules for registration of diet, weight, nutrition impact symptoms and physical activity. The patients could send information from the app to health-care professionals and the health-care professionals could use this information to prepare meetings with the patient in rehabilitation centres or general practice (103). In Norway, the app 'Appetitus' was developed to inspire older adults living at home to eat healthily (104, 105). Appetitus was developed specifically for elderly patients and included photographs of appetizing meals. This app was developed to be easy for older adults to use, and therefore the level of detail and precision in the dietary recording was low (104). To our knowledge, no CDSS for the performance of the nutritional care pathway in malnourished hospitalized patients has been developed nationally or internationally.

Fitting digital solutions to health problems or diseases could be complicated. As the development and use of eHealth increase, it is important to ensure that the systems are usable, effective, and fit for purpose (106). Usability has been identified as an important aspect in the development of eHealth systems (107). Zhang and Walji (108) suggested that a system is

usable if it is easy to learn, easy to use and error-tolerant. Challenges related to usability for CDSS can involve clinical and technological issues (101). Usability can be evaluated based on surveys; however, qualitative methods may be even more useful (106).

1.9 Evaluation of dietary assessment methods

Although several potential advantages could be associated with the use of new technology in dietary assessment, the measurement errors associated with traditional dietary assessment methods will probably not disappear (109). Cade (88) described that, despite the large possibilities for new technologies to measure dietary intake, several challenges still remain with the estimation of portion sizes, the technological readiness of the user and the size of the nutritional database in the tool.

It is well known that self-reported data are often associated with measurement errors and that the use of such methods is challenging (87). The ability to estimate portion sizes and the memory of intake are common challenges when using self-administrated methods for dietary recording (110). It is therefore crucially important to evaluate new dietary assessment methods in order to understand their potential to replace, improve or complement traditional methods (111). Evaluation includes the terms ‘reliability’ and ‘validity’ (112). Reliability relates to the reproducibility of a method, examples include consistency over time through the measurement of test–retest reliability and consistency across several researchers measured by interobserver reliability (IOR) (113). Validity relates to the extent to which a method can measure what it is intended to measure. To evaluate the validity of a method, the reliability of the method has to be taken into account. However, a method can have high reliability but a low validity (113). When validating a dietary assessment method, it is usually recommended to compare the results from one dietary assessment method with those from another method designed to measure the same thing (114). The errors of the comparison method should preferably be independent of those of the method being evaluated (115).

1.10 Effects and implementation of eHealth interventions

Several advantages of eHealth tools have been described and Noar and Harrington (116) summarize these advantages to include convenient use, having a wide appeal and providing

individualized tailoring, flexibility and automation. Different eHealth interventions have been found to be effective in the prevention and treatment of various diseases (97, 117), and have the potential to improve the quality of care and treatment and to reduce health-care costs (97). However, the field is still young and several aspects about, for example, long-term effects and economic aspects need to be considered before eHealth tools that have proven to be effective in studies can be implemented into routine clinical care (99). In the recent years, an increasing number of clinical trials have been conducted to study CDSS ability to improve patient outcomes and care (118-120). A recent systematic review by Varghese *et al*. (120) concluded that the use of CDSS often is associated with positive effects on patient outcomes. Cautions about eHealth tools might be that they are not necessarily appropriate for all subgroups of the population, e.g. those with limited computer skills or older people. Also, concerns related to privacy and data safety need to be carefully considered in the development, testing and dissemination of eHealth applications (116).

In science, the most common research approach has traditionally been to follow a step-wise pathway from basic science to the development of treatment, then on to clinical efficacy and/or effectiveness research, and finally to implementation research (121-123). This linear model has been criticized because it often leads to a considerable time lag between research findings and implementation into routine care (122). It is widely reported that it takes 17 years, on average, to implement evidence generated through research into routine clinical care (124). Also, we cannot necessarily assume that what works in an efficacy trial is effective in a real-world setting. To succeed with eHealth interventions, it is necessary to focus on the change process associated with the implementation of digital solutions (81).

1.10.1 The assessment of barriers and facilitators

To succeed with implementation, it is recommended that the readiness and potential barriers and facilitators are assessed in advance (97, 125). Such factors are also referred to as ‘determinants’, ‘barriers and enablers’, or ‘disincentives and incentives’ (126, 127). A theoretical framework, e.g. the Consolidated Framework for Implementation Research (CFIR) (128) can assist in the manoeuvring of the process. The CFIR is a compilation of 39 constructs, divided into 5 domains, that may be used to identify the most relevant barriers to and facilitators of implementation (128). Figure 5 illustrates the CFIR framework. The CFIR

is widely used for the identification of barriers and facilitators (129-132) and is often classified as a determinant framework (133, 134).

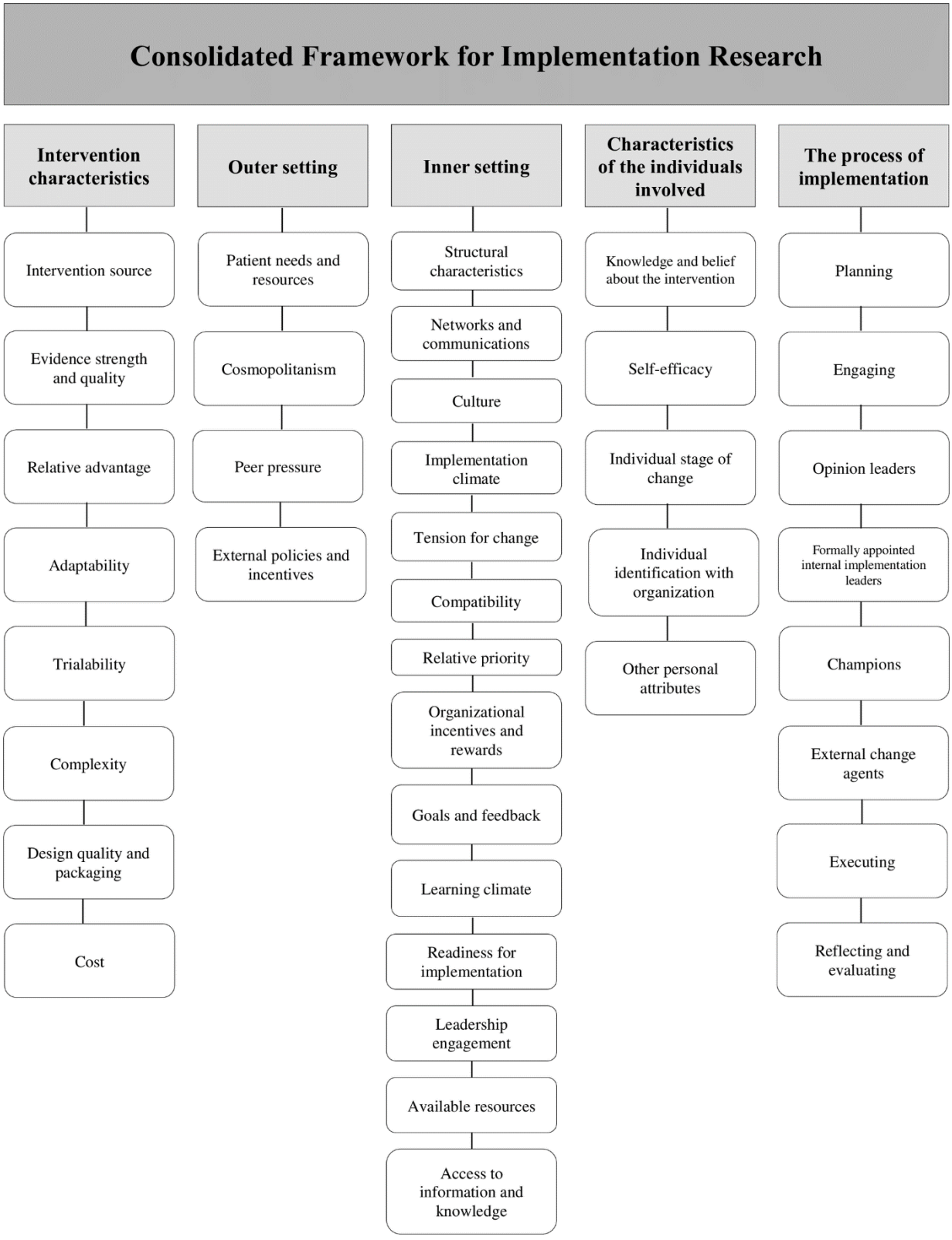

Figure 5 The Consolidated Framework for Implementation Research (CFIR) (128).

1.10.2 Making an implementation plan

Despite promising effects, a considerable number of eHealth interventions have failed during implementation into clinical practice (98). The implementation of eHealth interventions into a specific context is often challenging and does not necessarily lead to the expected effects (135). To increase the opportunities for successful implementation of an intervention to the setting of interest, it is often recommended to make an implementation plan. An implementation plan can include information about the specific actions that will be necessary to conduct in the implementation process, including implementation strategies, information about who will be responsible, the timeline and the expected outcomes (136).

In recent years, there has been a growing awareness of the importance of using implementation strategies. According to Proctor *et al*. (137), implementation strategies constitute the 'how to' aspect when the purpose is to change practice related to health-care. Such strategies can, hence, be used to overcome barriers and make the implementation more effective (137). The Expert Recommendations for Implementing Change (ERIC) project has published a compilation of 73 implementation strategies and definitions, divided into nine thematic clusters (138, 139). Figure 6 illustrates these clusters with examples of strategies within each cluster.

Thematic cluster	Example of strategy
Evaluative and iterative strategies	• Assess for readiness and identify barriers and facilitators • Audit and provide feedback (collect performance data and give it to clinicians to monitor, evaluate and modify behavior)
Provide interactive assistance	• Provide clinical supervision • Provide local technical assistance
Adapt and tailor to context	• Promote adaptability (identify how a clinical innovation can be tailored to meet local needs) • Tailor strategies (to address the identified barriers and facilitators)
Develop stakeholder interrelationships	• Identify and prepare champions[1] • Recruit, designate and train for leadership • Use an implementation advisor
Train and educate stakeholders	• Conduct educational meetings • Develop educational materials • Conduct ongoing training
Support clinicians	• Remind clinicians • Create new clinical teams
Engage consumers	• Prepare patients/consumers to be active participants • Intervene with patients/consumers to enhance uptake
Utilize financial strategies	• Fund and contract for the clinical innovation • Access new funding
Change infrastructure	• Change physical structure and equipment • Mandate change (have leadership declare the priority of the innovation and their determination to have it implemented)

Figure 6 Thematic clusters of implementation strategies with examples of strategies in each cluster. Adapted from Powell and Waltz (138, 139).
[1]Champions: 'Individuals who dedicate themselves to supporting, marketing and driving through an implementation, overcoming resistance to the intervention that may provoke in the organization' (125).

There is limited evidence on how to systematically choose implementation strategies, so there should be consideration of which strategies and activities that would be most suitable and effective in the specific context (136, 140). For the development of effective implementation strategies, knowledge about the potential barriers and facilitators is important. Strategies to target specific barriers or facilitators can be either 'top-down', e.g. distribute educational material or 'bottom-up', e.g. organize clinician implementation team meetings (136). Tailored implementation strategies will improve implementation success (141).

To sum up, our knowledge about the large challenge of disease-related malnutrition in the hospital setting indicates a need for a better system for nurses to monitor, follow-up and treat malnutrition. This system should be evaluated, the potential barriers to and facilitators of the system should be assessed, a plan for implementation should be created and the potential effects on patient outcomes should be explored.

2 Aim and objectives

This PhD thesis aimed to develop, evaluate and study the effects of a decision support system to prevent and treat disease-related malnutrition in a hospital setting as a proof-of-concept.

Objectives

- Develop a decision support system for dietary assessment and nutritional treatment of hospitalized patients at risk of malnutrition (Paper 1).

- Evaluate the dietary recording function in the MyFood app and the patients' experiences with use of the app (Paper 1):

    i. The MyFood app's ability to estimate patients' intake of energy, protein and liquids.

    ii. The MyFood app's ability to estimate patients' intake within food groups.

    iii. The patients' experiences of using the MyFood app to record their nutritional intake.

- Investigate the current situation, readiness and perceived barriers to and facilitators of the use of the MyFood decision support system in clinical practice (Paper 2):

    i. Explore current practice with malnutrition risk screening, dietary assessment, nutritional treatment and care in the hospital.

    ii. Explore readiness and investigate the perceived barriers to and facilitators of the use of the MyFood decision support system in clinical practice among nurses, physicians, registered dietitians and hospital middle managers.

- Investigate effect outcomes of using the MyFood decision support system for hospitalized patients in a randomized controlled trial (Paper 3):

    i. Study the effect on weight change during the hospital stay, as the primary outcome.

    ii. Study the effects on body composition, documentation of nutritional intake in the electronic patient record, nutritional treatment, development of nutrition care plans, malnutrition risk score and length of hospital stay, as secondary outcomes.

3 Methods

In this PhD thesis, the MyFood decision support system was developed, evaluated and tested as a proof-of-concept. The MyFood project consisted of five phases: 1) development of the MyFood decision support system; 2) evaluation of the dietary recording function in the MyFood app; 3) assessment of the readiness and potential barriers to and facilitators of use, 4) creation of an implementation plan including implementation strategies, and; 5) effect study. The different parts of the project, the timeline and the related papers are illustrated in Figure 7.

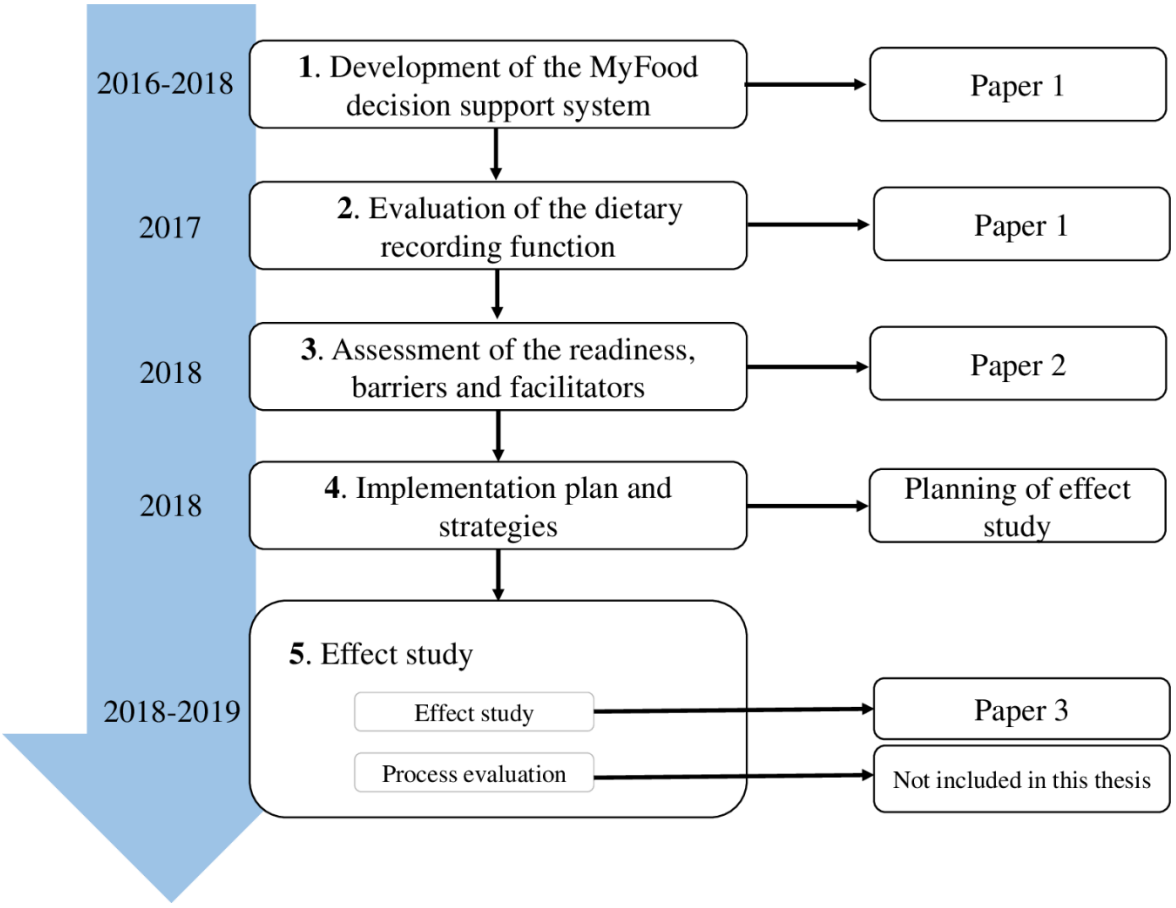

Figure 7 The different phases of the MyFood project.

This method section first describes the development of the MyFood decision support system. Second, the design, sample and data collection methods will be outlined, before the data analysis will be described. Finally, ethical statements will be defined.

3.1 The MyFood decision support system

The MyFood decision support system was intended for use in a hospital setting to monitor and evaluate patients' nutritional intake and provide decision support to nurses for nutritional care and treatment. Researchers with nutrition as the academic background were in charge of the content related to nutritional assessment, care and treatment. This was based on the guidelines and the action plan for malnutrition from the Norwegian Directorate of Health (9, 43, 46). The technical development of the MyFood decision support system was performed by professionals in web application development and computer programming.

The interface of the MyFood decision support system consisted of an app for tablet computers and a computerized webserver, and included the following four functions:

1. Registration of patient information
2. Dietary recording function
3. Evaluation of nutritional intake compared with individual requirements
4. Report to nurses, including guideline-based recommendations for nutritional treatment and a draft for an individual nutrition care plan

Functions 1–3 were included in the MyFood app, whereas function 4 was present on the MyFood webserver. The different functions are described in detail below and print screens are shown in Appendix 1. In this PhD thesis, the short-form MyFood system is used for the MyFood decision support system.

3.1.1 Registration of patient information (function 1)

Before a patient or a nurse could use the MyFood app to record dietary intake, patient information had to be registered. The data stored in the MyFood app locally on each tablet computer were deleted every night at 03:00, and the app had to be set up each morning for patient identification and use. Patient registration included anthropometry (weight and height), nutrition-related symptoms (nausea, difficulty swallowing, diarrhoea, etc.), presence of fever, nutritional situation (normal oral intake, tube feeding or parenteral nutrition) and allergies/intolerances. The Norwegian Patient Registry (NPR) number was used as the patient ID.

The information about anthropometry, age and fever was used to estimate the patient's daily requirements for energy, protein and liquids based on recommendations from the Norwegian manual for diet and nutritional care (*Kosthåndboken*) (46). The following calculations were used to estimate individual requirements:

- energy: 30 kcal/kg body weight
- protein: 1.2 g/kg body weight
- liquids: 30 ml/kg body weight (minimum 1500 ml)

In addition, the following criteria were used:

- If BMI <20 kg/m^2, energy requirements were increased by 10%.
- If BMI >25 kg/m^2, energy, protein and liquid requirements were calculated based on BMI = 25 kg/m^2.
- If aged between 18 and 30 years, energy requirements were increased by 10%.
- If aged >70 years, energy requirements were reduced by 10%.
- If fever was present, energy and liquid requirements were increased by 10% for each degree (°C) of elevated temperature.

3.1.2 Dietary recording function and evaluation of nutritional intake (functions 2 and 3)

The dietary recording function was developed by including pictures and the nutritional content of all dishes, foods, beverages and medical nutritional products served by the food services at the hospital. In addition, a wide selection of medical nutrition products, groceries, fast food products and other dishes and beverages were included. In total this amounted to approximately 600 food items. The nutritional content of the hospital dishes was retrieved from the hospital nutrition database (Aivo, Norway) and the hospital's definition of what constituted a full portion. The nutritional content of the food and beverage products (e.g. bread, spreads, milk, fruit) was retrieved from an in-house dietary calculation system at the University of Oslo (UiO) (KBS version 7.0), based on the Norwegian food composition table (142), and from manufacturers. Information about the nutritional content of oral nutritional supplements and artificial nutrition was retrieved from the manufacturers. Nutritional

information in the MyFood app was given for the intake of energy (kcal), protein (g) and liquids (ml).

The MyFood app was developed with the possibility for recording the content of a meal manually. In such cases, the patient or a nurse could write what was consumed and provide information about the nutritional content of the meal manually.

Several algorithms were included in the MyFood app, as described above, for the calculation of individual patient requirements. The patient's intake compared with individual requirements was available under the 'Today's intake' option, and illustrated as the intake as a percentage of requirements of energy, protein and liquids, as shown in Figure 8. Appendix 1 shows an extended version of screen shots from the MyFood app and the MyFood webserver.

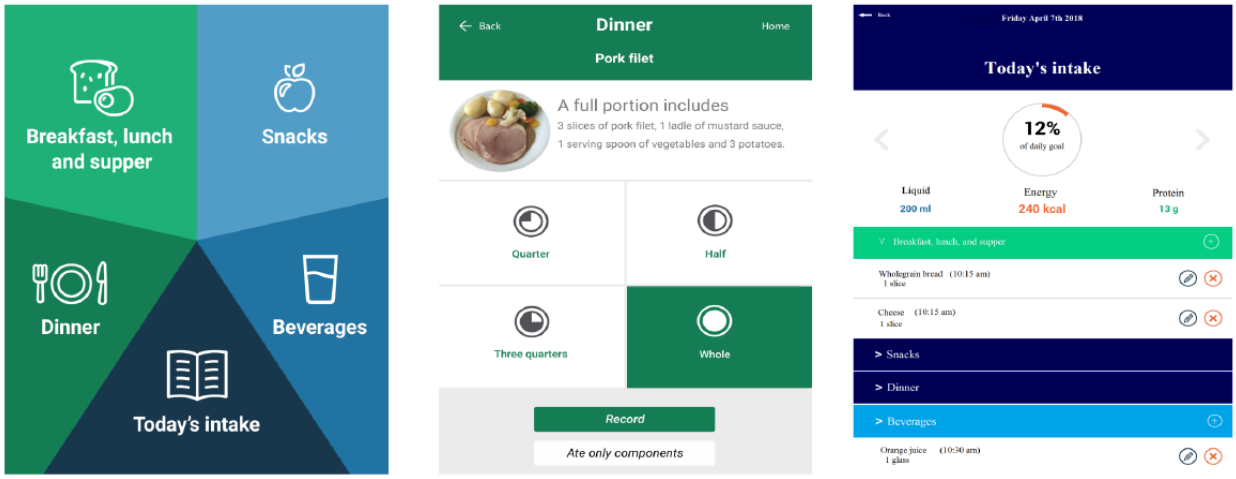

Figure 8 Screen shots of the MyFood app. From left: 1) Main menu of the dietary recording function; 2) Selection of portion size; 3) Evaluation of intake compared to requirements for energy, protein and liquids.

3.1.3 Report, recommendations and nutrition care plan (function 4)

The fourth function included a report to nurses and was developed on a webserver. The reports for the individual patients included an overview of the patient's nutritional intake compared with individual requirements, guideline-based individualized recommendations for nutritional treatment and a draft for a nutrition care plan tailored to the individual patient.

To generate tailored feedback and decision support to nurses for individual patients, a rule matrix was developed in the MyFood webserver. This is an example of a knowledge-based CDSS using IF-THEN rules, as described in section 1.8. The rule matrix used the information

recorded in the MyFood app about the patient's intake of energy, protein, and liquids, nutrition-related symptoms, nutritional situation, and any allergies or intolerances. By using different assumptions in the matrix that could or could not be fulfilled, e.g. the presence of nausea, the use of tube feeding and energy intake the previous day <50% of requirements, guideline-based recommendations and feedback were generated. By using such a rule matrix, including a range of assumptions, decision support could be provided to nurses including patient reports, alerts, guideline-based recommendations for nutritional treatment and support related to the nutritional diagnosis. These functions are in line with the most common facilities provided for other clinical decision support systems (143). Refeeding syndrome is a severe disruption in the electrolyte or fluid balance that may arise in malnourished individuals after a period of inadequate nutrition if the startup of feeding begins too rapidly (64). Information and cautionary advice about this were included in the report function.

The generation of a tailored nutrition care plan was automatically developed in the MyFood webserver by using the information recorded in the app to provide data on potential factors that affect the food intake, the patient's nutritional requirements and the patient's nutritional intake compared to the requirements. The goal for the nutritional treatment and the specific treatment measures to be implemented had to be filled into the nutrition care plan manually by the nurse. The nutrition care plan could be copied and pasted by the nurse into the patient's electronic records.

3.1.4 Technical development and data flow

The MyFood system was developed in cooperation with the University Centre for Information Technology (USIT) at the UiO. App developers, programmers and interaction designers were involved in the process and USIT was responsible for the technical solution. A web form (144) was used for data flow in the app and data were sent to and stored in 'Services for sensitive data' (Tjenester for sensitive data, TSD) (145), both hosted by USIT. Information registered in the MyFood app and the recordings of dietary intake were sent encrypted through the web form to secure storage in TSD, as illustrated in Figure 9.

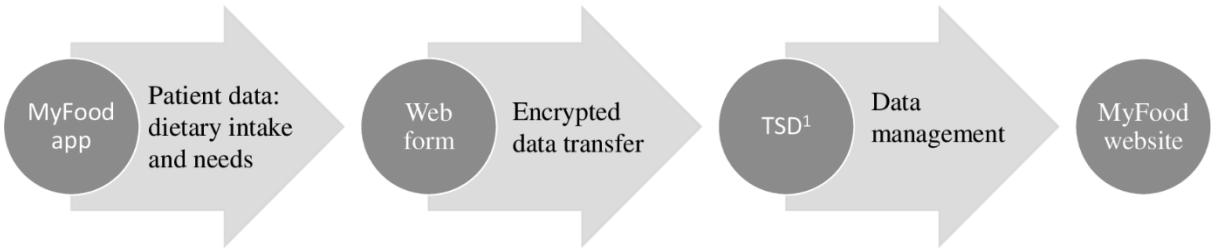

Figure 9 Data flow in the MyFood system. [1]TSD: Services for sensitive data

The TSD system is a high-security private cloud eInfrastructure to process and store sensitive research data. It is included in NorStore, the Norwegian national infrastructure for handling and storing scientific data (146). An analysis of potential risks associated with the use of TSD as part of the MyFood system in the hospital setting was conducted by the privacy protection officer at the hospital.

Data recorded in the MyFood app were stored locally on the tablet computer and were visible until 03:00 the following day. This allowed the user to keep track of their dietary intake compared with their requirements each day in the 'Today's intake' option (see Figure 8). The patients and nurses were also able to add or edit dietary recordings during the day. All data recorded in the MyFood app were continuously sent to TSD. In cases of technical problems or loss of internet connection, the data were stored temporarily in an encrypted format before being sent to TSD when the tablet resumed an internet connection.

To control the sensitive data stored on the tablet computers, the Mobile Device Management System, AirWatch, was used during the data collection periods. If a tablet disappeared, it could be reset remotely so it was impossible to use until reopened via Air-Watch.

To gain access to the MyFood webserver, nurses had to complete an access form, which was used to create a list of approved people in the TSD server. Log-in to the webserver was done through a common log-in solution to public services in Norway (147) and authentication was sent to the TSD server (145) to verify access to the webserver. Patient reports on the webserver were retrieved by the nurses by using the patient's NPR number.

3.1.5 Stakeholder involvement

Different stakeholders, such as patients, nurses, registered dietitians and hospital management, have been involved during the entire process with the development and

evaluation of the MyFood system. Before technical development began, paper-based sketches of the MyFood app's user interface were developed. Usability was explored with three nurses and three patients at the university hospital. By performing a usability test at an early stage, issues related to the usability of a system can be fixed before the system goes into production (101). A usability test often involves making the participant complete typical tasks while the researcher observes, listens and takes notes with a minimum of interruption (101). In the present PhD thesis, an interaction designer conducted the usability testing and the PhD candidate participated as an observer. After the first usability test was conducted, a prototype of the MyFood app was developed. Another round of usability testing was performed among four patients and two nurses. The patients and the nurses were given tasks related to recording of food intake and registration of patient information. The observations of the patients' and the nurses' use of the system and their feedback were used to adapt the design and the content of the MyFood app before the initiation of the evaluation study (Paper 1).

The responses we received from the patients answering a short questionnaire in the evaluation study in Paper 1, as described in section 3.2.1, were used to do some modifications and adjustments in the MyFood app before the RCT was initiated (Paper 3).

The webserver, including the report function of the MyFood system, was developed in cooperation with registered dietitians and nurses. When the prototype was developed, usability testing was performed by the PhD candidate among three nurses and three registered dietitians. The health-care professionals were given tasks and were observed with minimal interruption. Afterwards, they were encouraged to give feedback on the content, design and usability of the system. The results from the usability test and the nurses' responses were used to modify the system.

3.2 Design

The clinical setting for this PhD project was a large university hospital in Norway. The study sample consisted of patients and health-care professionals, as shown in Table 2. A combination of quantitative and qualitative methods was used to evaluate and study the effects and implementation of the MyFood system. The design and methods used in the three sub-studies are described in sections 3.2.1, 3.2.2 and 3.2.3.

Table 2 Study sample in the three papers

	Paper 1	**Paper 2**	**Paper 3**
Population	Patients	Health-care professionals	Patients
Setting	2 hospital departments University hospital, Norway	2 hospital departments University hospital, Norway	1 haematological department University hospital, Norway
Eligibility criteria	Age ≥18 years Expected stay ≥2 days	Working at the hospital departments of interest	Age ≥18 years Expected stay ≥3 days
Exclusion criteria	Pregnancy, infectious infections, mental illness, to critically ill, unable to read Norwegian, no intake of nutrition orally		Life expectancy <6 months, pregnancy, breastfeeding, mental illness, sickle cell anemia, DVT[1], haemophilia, unable to read Norwegian
Eligible for inclusion/ invited, n	45	28 in total: Nurses: 21. Physicians: 2 Managers: 3. Dietitians: 2.	120
Included in study, n	32	27 in total: Nurses: 20. Physicians: 2. Managers: 3. Dietitians: 2.	100
Included in analysis, n	32	27	94
Age, mean (range)	52 (17-77)	30 (25-42)	52 (18-77)
Sex, male (%)	22 (69)	2 (7)	60 (60)
Method	Quantitative	Qualitative	Quantitative

[1]DVT, deep venous thrombosis

3.2.1 Evaluation of the dietary recording function in the MyFood app

Digital photography, combined with a partial weighing of meal components, was used to evaluate the accuracy of the dietary recording function in the MyFood app (Paper 1). Eligibility and exclusion criteria in the evaluation study are shown in Table 2 and the flow chart for inclusion of patients to the study is illustrated in Appendix 2.

The included patients received a tablet computer and were asked to record their consumption of food and beverages for breakfast, lunch and dinner for 2 days. To evaluate the accuracy of the recordings in the MyFood app, we photographed the patients' meals before and after consumption, combined with a partial weighing of the meal components. The patients were asked about the type of food or beverage item if this information could not be obtained from the photographs, e.g. whole fat versus low-fat milk, butter versus margarine. In cases of doubt, the patients were also asked if they had provided themselves with food several times.

After recording their food consumption in the MyFood app for 2 days, the patients completed a form including questions about the ease of use, navigation and perceived value, and whether

they needed to acquire new knowledge to use the app. The content of the form was adapted from the System Usability Scale (SUS) (148). The SUS is a usability test containing 10 questions based on the Likert 5-point scale. The scale provides a rapid measurement of the perceived usability of a digital system (148).

3.2.2 Assessment of readiness and the perceived barriers to and facilitators of use

To be able to plan the effect study (Paper 3) in a proper way, the current situation with nutritional care and treatment at the hospital departments was assessed in advance. In addition, the health-care professionals' readiness and their perceived barriers to and facilitators of the use of the MyFood system in clinical practice were explored (Paper 2). According to Draper (149), qualitative research can be used to 'explore experiences and what these phenomena mean to individuals, and hence a qualitative design was considered most feasible.

As the MyFood system was developed primarily for providing decision support to nurses, nurses constituted the majority of the interviewees. Focus groups were held with the nurses as such group discussions are applicable to exploring common experiences, attitudes or views in an environment where many people interact (150). Group interactions are an important part of the method and are suitable for exploring health-care professionals' views and attitudes (151). The participants in the focus groups were recruited by the middle manager at the department, based on nurses' working day shifts on the days the focus groups were to be conducted.

To be able to illuminate aspects from other groups of health-care professionals, a few individual interviews were conducted in addition, with middle managers, physicians and registered dietitians. The main purpose of an individual interview within research is to understand the views from the perspective of the interviewee (152). The physicians were recruited from a list of physicians working at the department, provided by the department manager. The physicians were contacted by email in order from the top of the list. The first physicians who were asked provided consent to participate. The registered dietitians and the middle managers were far fewer than the physicians and they were also recruited by direct contact by email.

Semi-structured interview guides for the focus group discussions and the individual interviews were developed in advance. The CFIR framework (128), shown in Figure 5, was used to guide the process of developing the interview guides. The interview guide included topics such as the organization of the department and the practice related to nutritional care. A demonstration of the MyFood system was given and the interviewees were asked to discuss aspects like the design and functionality and the potential advantages and barriers related to use of the system. The focus groups, 4 in total, were conducted in a meeting room at the hospital departments, and the individual interviews, 7 in total, were performed in the office of the physicians and dietitians who were interviewed. The first focus group was used as a pilot to evaluate the interview guide. No fundamental changes were made to the guide after conduction of the first group, so the results from this focus group were included in the analysis. The interview guide was similar for the different groups of health-care professionals; however, some adjustments were made to adapt the content and make it relevant to each profession. The formulation and order of the questions varied somewhat, and this was related to the dynamic development in each focus group and individual interview. The focus group lasted from 45 min to 55 min and the individual interviews from 30 min to 50 min. The focus group discussions and the individual interviews were audio-taped and thereafter transcribed verbatim.

The creation of an implementation plan and use of implementation strategies

The data collected in the qualitative study (Paper 2) were used to create a plan for the implementation of the MyFood system into the hospital department in the RCT (Paper 3). The implementation plan included implementation strategies derived from the ERIC project, as illustrated in Figure 6. The strategies that were identified as most relevant to the context in this PhD thesis are shown in Table 3.

Table 3 Implementation strategies used in the different phases of the MyFood project. Proposed by Powell and Waltz (125, 139)

Phase	Description	Strategy	Method
1	Assess current situation, readiness, barriers and faciliators (Paper 2)	Assess for readiness and identify barriers and facilitators	• Focus groups and interviews with HCP[1]
2	Preparation, training and performance	**Adapt and tailor to context**	
		• Tailor strategies	• Tailor to context based on results from Paper 2
		• Promote adaptability	• Provide support for nurses' access to the MyFood website. Research nurse available
		Train and educate stakeholders	
		• Conduct educational meetings	• Education at the department at 7 time points
		• Develop educational material	• Written material to HCP[1] and patients about MyFood and the clinical trial
		• Distribute educational materials	• By email and brochures
		Develop stakeholder interrelationships	
		• Recruit, designate and train for leadership	• Include leaders in the planning of the trial • Provide responsibility to leaders for the distribution of information and involvement in the trial
		• Identify and prepare champions	• Employ research nurse as a super-user and a 'champion' • Play an active part in motivating and engage the nurses
		• Use an implementation advisor	• A supervisor plays this role
3	During the MyFood RCT[2]	**Develop stakeholder interrelationships**	
		• Organize clinician implementation team meetings	• Discussion of different aspects, challenges etc
		• Identify early adopters	• Encourage early adopters to promote the MyFood study and positively influence others
		Train and educate stakeholders	
		• Conduct ongoing training	• Continuous training in group or one-to-one
		• Provide ongoing consultation	• Availability of study personnel every weekday A project phone available at all times
		Support clinicians	
		• Remind clinicians	• Inform and remind nurses. Encouraging managers to remind of the project and the expected follow-up
		Provide interactive assistance	
		• Provide local technical assistance	• Support nurses with access and log-in • Be a link between the hospital and USIT[3] in the case of technical problems • MyFood assistance for patients and nurses
		• Provide clinical supervision	• Train the research nurse to teach and support the other nurses at the department
		Engage consumers	
		• Involve patients/consumers and family members	• Encourage patients to use the MyFood app daily Next of kin are welcome to contribute
		• Intervene with patients/consumers to enhance uptake and adherence	• Provide support to patients
		• Prepare patients to be active participants	• Provide verbal and written information. Patients will be encouraged to ask if they have questions

[1]HCP, Health-care professionals. [2]RCT, randomized controlled trial. [3]USIT, University Center for Information Technology

3.2.3 Effect study

The effect study (Paper 3) was a parallel-arm, RCT. The setting and the sample are shown in Table 2. The sample consisted primarily of cancer patients, but also included patients with scleroderma and anaemia.

Patients who confirmed verbal and written consent were randomly assigned either to use the MyFood system (intervention) or to routine care (control), as illustrated in the flowchart in Appendix 3. 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 webserver to follow-up on the nutritional care and treatment of the patients. The nurses were trained in how to follow up the intervention patients using the MyFood system. Figure 10 illustrates the design of the effect study.

The primary outcome measure was body weight change during the hospital stay, as shown in Table 4. The patients' were weighed every morning and evening using digital scales available in each patient room, as part of an established routine at the hospital department. Twice weekly, a project worker noted the morning weight on a form. Secondary outcomes were change in body composition, malnutrition risk score, the implementation of nutritional treatment, the creation of nutrition care plans and hospital length of stay (Table 4).

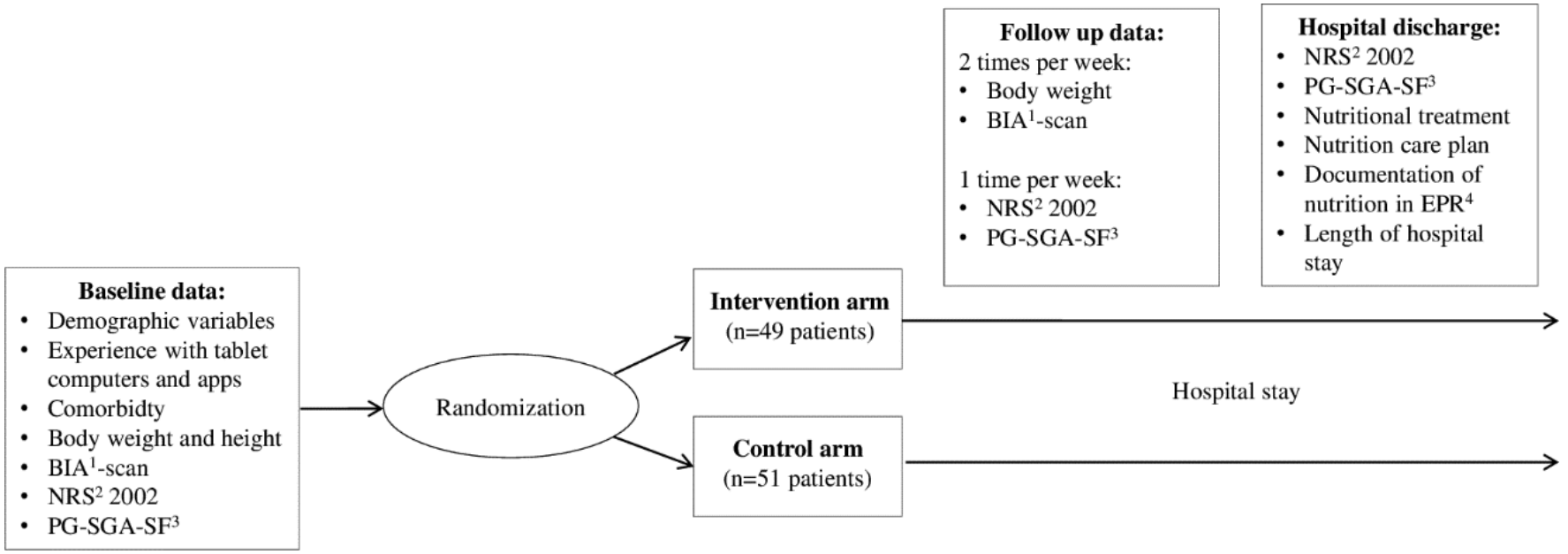

Figure 10 Study design and data collection in the effect study.
[1]BIA, bioelectrical impedance analysis. [2]NRS, Nutrition Risk Screening. [3]PG-SGA-SF, Patient-Generated Subjective Global Assessment Short Form. [4]EPR, electronic patient record.

Table 4 Outcome variables collected in the effect study (Paper 3)

	Method	**Interpretation**
Primary outcome		
Body weight	Measurement by scale	Weight change from hospital admission to discharge
Secondary outcomes		
Body composition	Seca 525 Body Composition Analyzer	Change from hospital admission to discharge
FFM[1]		
FFMI[2] (kg/m^2)		
FM[3]		
FMI[4] (kg/m^2)		
SMM[5]		
PhA[6]		
ECW[7]		
TBW[8]		
ECW/TBW[9]		
Risk of malnutrition		
NRS[10] 2002 score	NRS[10] 2002 form. Includes questions about nutritional status: weight loss, food intake; and about the severity of disease	Score ≥3 indicates risk of malnutrition
PG-SGA-SF[11] score	PG-SGA-SF[11] form. Includes questions about body weight, food intake, symptoms affecting food intake, activity level/function	Score 2-3: need for nutritional education, 4-8: need for nutritional, intervention, ≥9 critical need for nutritional intervention
Nutritional treatment	Data retrieved from the EPR[12]	Food enrichment, ONS[13], meal frequency, tube feeding, parenteral nutrition
Nutrition care plan	Data retrieved from the EPR[12]	Information about nutritional requirements and intake, recommended nutritional treatment and treatment goal
Documentation in EPR[12]	Data retrieved from the EPR[12]	Nutritional intake compared to individual requirements
Length of stay	Data retrieved from the hospital administration system	Number of days from hospital admission to discharge

[1]FFM, fat-free mass. [2]FFMI, fat-free mass index. [3]FM, fat mass. [4]FMI, fat mass index. [5]SMM, skeletal muscle mass. [6]PhA, phase angle. [7]ECW, extracellular water. [8]TBW, total body water. [9]ECW/TBW, ratio of extracellular water divided by total body water. NRS[10], Nutritional Risk Score. [11]PG-SGA-SF, Patient-Generated Subjective Global Assessment Short-Form. [12]EPR, electronic patient record. [13]ONS, oral nutritional supplements.

Data about compliance with the MyFood system were collected from both the patients and the nurses. The patient compliance was retrieved by comparing the number of days of nutritional intake recorded in the MyFood app dividing by the patient's hospital length of stay. Information about the nurses' compliance was gathered from the technical logs of the MyFood system, i.e. the number of nurses who used the system and how often.

3.3 Data analysis

3.3.1 Quantitative parts (Papers 1 and 3)

The statistical analyses were performed using the IBM SPSS statistical software version 24. All tests were two-sided and the significance level was set to $P < 0.05$. Continuous data are described with mean and standard deviation (SD) or standard error (SE) for normally distributed data and median (25–75th percentile) for non-normally distributed data. Categorical data are described together with the number of patients and the proportions.

When several researchers are involved in data collection in validation studies, it is important to ensure that the IOR is high. By assessing the IOR, we can check that the collected data do not depend on who conducted the observation (153). As the data collection in the evaluation study in the present PhD thesis (Paper 1) was performed by two researchers, the processing of data files and comparison of the agreement between the methods were first performed independently and then compared to secure an acceptable IOR.

The food composition database KBS at the Department of Nutrition, UiO, was used to analyse the nutritional content of the estimated food intake using the photograph method. The estimated intake from the patients' recordings in the MyFood app was collected from TSD. This task involved manual handling of four different forms: information about the amount of each food or beverage item, the content of energy, protein and liquids in the recorded intake, and information about the food items that were deleted in the MyFood app. Statistical analysis in the evaluation study (Paper 1) included both the group and the individual level. To analyse the agreement between patients' recordings of dietary intake in the MyFood system, and the estimated intake from the photograph method on the group level, Wilcoxon's signed ranks test was used, due to non-normally distributed variables. The primary objective was to investigate the ability of the MyFood app to estimate individual patient's dietary intake, hence

multiple scatter plots of estimated energy, protein and liquid consumption were generated for each patient. Similar scatterplots were created for the intake of selected food groups. An overview of the proportion of patients with ≥80% and ≥90% agreement between the MyFood recordings and the estimation from the photograph method was therefore created. The agreement between the methods was assessed in total, and divided into breakfast, lunch and dinner meals for recording days 1 and 2, separately. Omissions were calculated as items observed in a meal photograph, but not recorded in the MyFood app.

The statistical analysis in the RCT (Paper 3) was 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. The trial was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (154).

The independent samples Student's *t*-test or Mann–Whitney U-test were used to test differences between the intervention and control groups with regard to the primary and secondary outcomes for continual data, according to the distribution of the data. The categorical data were tested using Pearson's chi-square test or Fisher's exact test. The repeated measurements for weight during follow-up were analysed using a linear mixed model with a random intercept (Paper 3).

3.3.2 Qualitative methods (Paper 2)

NVivo version 11 (QSR International) was used for the qualitative analysis. Thematic analysis was used to analyse the transcripts, and the notes from the focus group and individual interviews with the health-care professionals. Thematic analysis is a method that can be used to identify, analyse, describe, organize and report themes from transcribed material (155). A deductive approach to the analysis was used in a stepwise manner, as described by Braun and Clarke (155) (Table 5).

Table 5 Stepwise analysis (155) of the transcripts from focus groups and individual interviews with health-care professionals

Step	Task	Purpose
1	Read through all transcripts and take notes	Get an overview
2	Create intial codes by the use of CFIR[1]	Organize the quotes
3	Search for themes	Sort and evaluate codes
4	Review	Re-evaluate and reconsider

[1]CFIR, Consolidated Framework for Implementation Research

By using these steps, codes were created, sorted and evaluated based on the CFIR domains and constructs. As described in section 1.10.1, the CFIR is a compilation of 39 constructs divided into 5 domains: 1) characteristics of the intervention; 2) outer setting; 3) inner setting; 4) characteristics of the individuals involved, and; 5) the process of implementation (128) (Figure 5).

The stepwise analysis was performed in several rounds. The sorting and evaluation were discussed and reviewed together with a co-author. After the thematic analysis, 22 of the CFIR constructs were included in the analysis.

We used the results from the qualitative analysis to develop an implementation plan and guide a process evaluation that we performed in parallel with the RCT.

3.4 Ethical statements

The project was conducted in accordance with the declaration of Helsinki. The data collection periods were approved by the Norwegian Regional ethical committee (2016/1464), the Data protection officer at the hospital and the Chief Information Security Officer at the UiO. Informed verbal and written consent were collected from all participating patients and for all groups of health-care professionals who participated in the focus groups and individual interviews. The randomized controlled trial was registered on the US National Library of Medicine (www.ClinicalTrials.gov; ID: NCT03412695). The ethical considerations are discussed in more detail in section 5.2.

4 Results

4.1 Summary of findings

An overview of the most important results in this PhD thesis is shown in Figure 11 and described in sections 4.2, 4.3 and 4.4. In summary, the results from the three papers include the development of a decision support system for prevention and treatment of malnutrition, the evaluation of the dietary recording function of the system, identification of the perceived barriers to and facilitators of the use of the MyFood system, and the effects of using MyFood on patient outcomes and nutritional treatment and care (Figure 11).

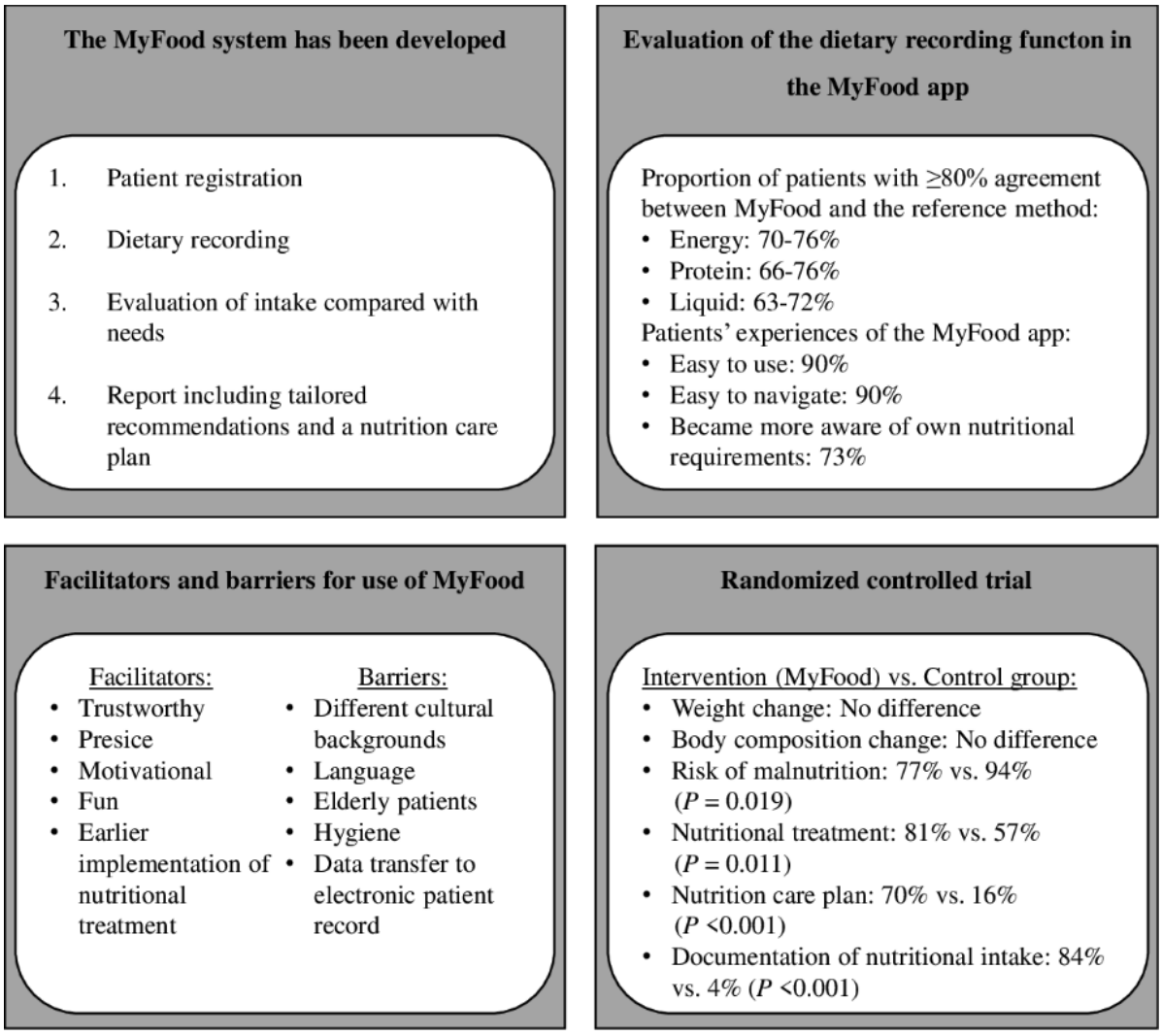

Figure 11 Overview of main findings from Papers 1, 2 and 3

4.2 Development and evaluation of the MyFood app

The MyFood system was developed as described in section 3.1 (Paper 1). On the group level, there was no clear pattern of skewness or systematic differences for the 32 included patients between the MyFood app and the reference method for the estimated intake of energy, protein and liquids, as shown in Figure 12.

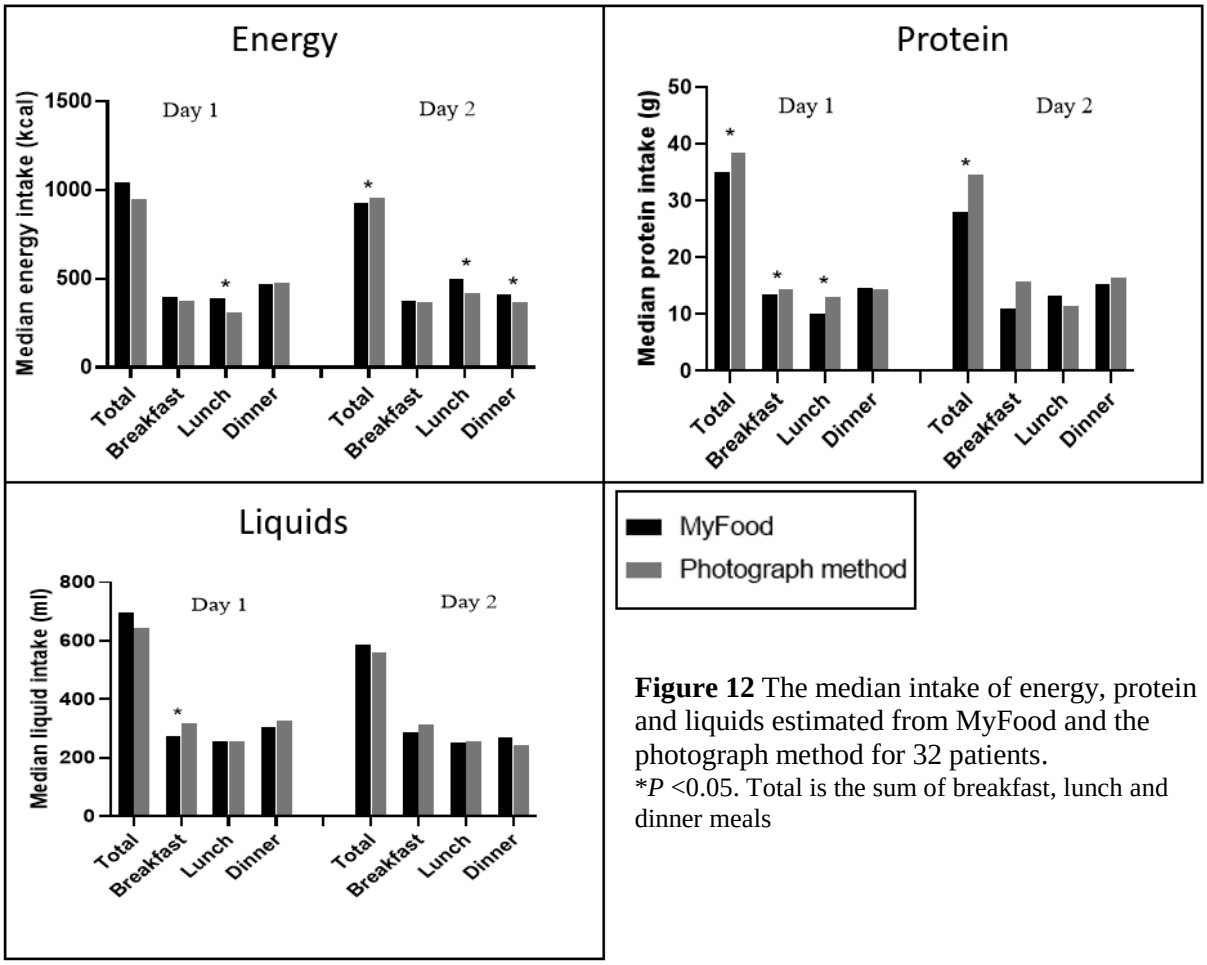

Figure 12 The median intake of energy, protein and liquids estimated from MyFood and the photograph method for 32 patients.
*P <0.05. Total is the sum of breakfast, lunch and dinner meals

On day 1, the median energy intake from the lunch meal estimated by the MyFood app was significantly higher than estimated by the reference method. This was also observed on day 2. In addition, on day 2, the median total energy intake was estimated significantly lower in the MyFood app than in the reference method, whereas for dinner the median estimated intake in MyFood was significantly higher. For protein, several significant differences were observed on day 1, including a lower estimated intake in MyFood compared with the reference method for total intake, breakfast and lunch. On day 2, the total intake was also significantly lower in MyFood than in the reference method. Estimated liquid consumption had fewer significant

differences between the methods. Only for breakfast day 1 did the MyFood app show a significantly lower intake than the reference method.

When analysing the results at the individual level, approximately 50% of the patients had ≥90% agreement across the methods for energy, protein and liquids, on both recording days (Figure 13).

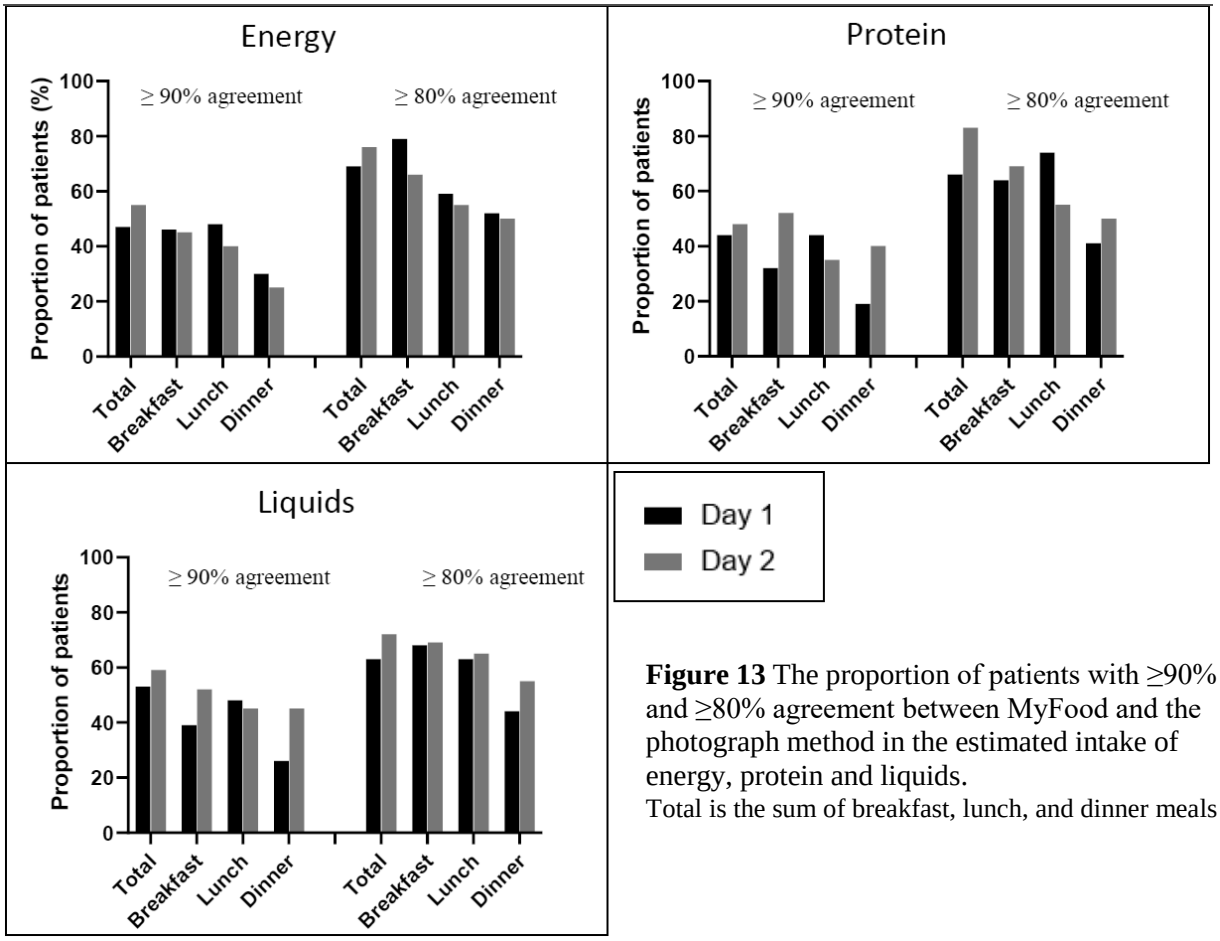

Figure 13 The proportion of patients with ≥90% and ≥80% agreement between MyFood and the photograph method in the estimated intake of energy, protein and liquids.
Total is the sum of breakfast, lunch, and dinner meals

The proportion of patients with ≥80 or ≥90% agreement between the methods for the total estimated intake of energy, protein and liquids increased from day 1 to day 2 (Figure 13). The agreement between the methods for the estimated nutritional intake for breakfast and lunch was in general higher than for dinner.

At the group level, the median reported intake of bread and cereals was higher and reported intake of fruit was lower, when using the MyFood app compared with the reference method. The median reported intake of bread and cereals on day 1 was 110 g in the MyFood app recordings and 93 g for the reference method (P <0.001). On day 2, the corresponding values were 83 g and 72 g (P <0.001). The median reported fruit consumption was underestimated in

the MyFood app compared with the reference method with 30 g versus 91 g on day 1 (P = 0.04) and 13 g versus 63 g (P = 0.09) on day 2. Otherwise, there were no significant differences between the methods with regard to food and beverage items.

At the individual level, eggs was the food item with the highest agreement between the methods, whereas fruit and vegetables had the lowest agreement. The reported consumption of bread and cereals was in most cases estimated to be higher in the MyFood app than in the reference method. A tendency to a lower estimated intake of spreads in the MyFood app compared with the reference method was seen with increasing intake. There was a tendency to an increased agreement between the methods from the first to the second recording day. The most common food items that the patients omitted were butter and margarine, and meal condiments. The results from the validation study led to some revisions in the food composition database underlying the system and prompting of questions, before the MyFood system was implemented in the RCT (Paper 3).

The patients reported that the dietary recording function in the MyFood app was easy to use (90%), easy to navigate (97%), that they managed to report their nutritional intake accurately (87%) and they became more aware of their nutritional requirements (71%). Most of the patients disagreed with the claim that they had to acquire new knowledge to use the MyFood app (87%).

4.3 Readiness and perceived barriers and facilitators

The qualitative study (Paper 2) showed that the current practice for nutritional care and treatment deviated from the guidelines for preventing and treating malnutrition, and that tension for change was present. Several advantages and possibilities for the use of the MyFood system were highlighted and several perceived barriers and challenges were also identified, as shown in Figures 11 and 14.

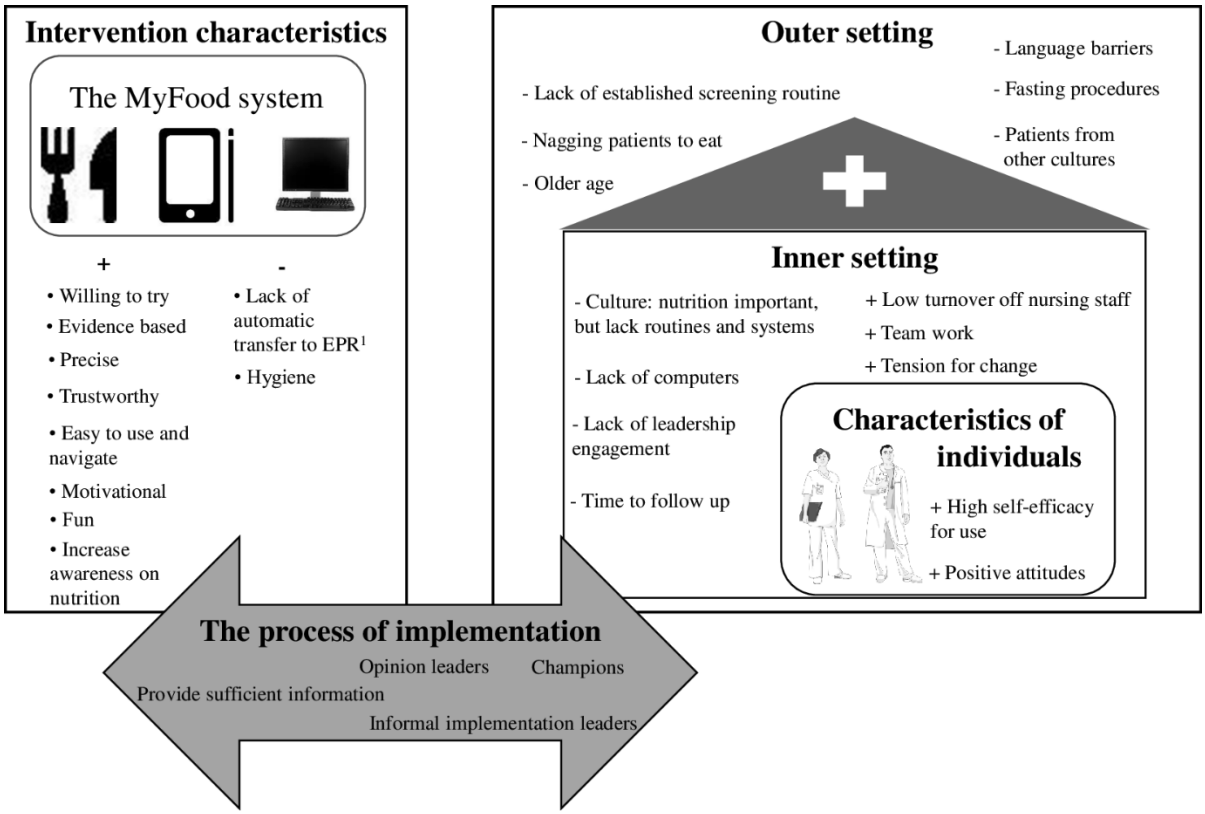

Figure 14 Results from focus groups and individual interviews with health-care professionals divided into the 5 domains of the Consolidated Framework for Implementation Research (CFIR): intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation. The figure includes pictures from colourbox.com and free images from Servier Medical Art (Creative Commons Attribution License, creativecommons.org/licences/by/3.0).
[1]EPR, Electronic Patient Record. + indicates facilitators. - indicates barriers.

The CFIR constructs are divided into the five CFIR domains as shown in Figure 5. The results are described related to the CFIR constructs typed in bold below and placed in their respective CFIR domain as shown in Figure 14. The first domain was concerned with the intervention characteristics. The health-care professionals acknowledged that the nutritional recommendations from the Directorate of Health were accepted and known, which relate to the **evidence strength and quality** construct. **Relative advantages** included the perception of the MyFood system as being more trustworthy, precise, fun and motivational to use than the current practice, and that use of MyFood could increase awareness of nutrition and precede nutritional treatment: '*This would be a lot easier and it would mean less guesswork. … Many patients would think it was fun. … and so would a lot of us nurses'* [nurse]. Concerning the **trialability** construct, nurses, middle managers, physicians and registered dietitians expressed in general a positive attitude to being part of the MyFood study, and said that they were used to clinical trials going on at their department. The MyFood system was not perceived as having a high **complexity**, but was regarded as easy to use and navigate, and also as having a

neat, understandable and user-friendly design (**design, quality and packaging**). **Adaptability** relates to 'the degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs' (128). The lack of automated transfer of information to the electronic patient record was perceived as a potential barrier: *'It would have been great if it was connected to DIPS* [electronic patient record], *but I understand that it might be too early for that'* [nurse]. Hygienic aspects of the use of tablets by patients with infections were also perceived as a possible barrier.

In the domain of the outer setting, the **patient needs and resources** were illuminated. We revealed that screening for risk of malnutrition was not an established routine. The health-care professionals experienced continually having to nag patients about eating more. Perceived barriers to use of the MyFood system were fasting due to procedures, transmission to other hospitals, older patients not familiar with apps and tablet computers, language barriers, and patients from other cultures who might eat different types of foods than the hospital food.

In the domain of the inner setting, relevant information about the **structure** of the included departments was revealed and the turnover of nurse personnel was described as low. Related to the **network and communication** construct, the nurses were assigned the main responsibility for the patients' nutrition. The cooperation among the groups of health-care professionals was described as good, but some said that a different focus of what the most important aspects were could be conflicting and therefore confusing for patients who received inconsistent advice. A lack of **culture** for screening for malnutrition risk was present. **Tension for change** with regard to screening for malnutrition risk, dietary assessment and nutritional treatment was revealed: *'We could get very much better'* [middle manager]. The nurses expressed a tendency for waiting too long before starting nutritional treatment: *'Maybe you let it go too far before we start pushing that food, you know'* [nurse]. They perceived the current practice as inconvenient and the use of paper-based dietary recording forms as time-consuming and based on too much guesswork. **Leadership engagement** and **available resources** constitute the **readiness for implementation** construct. The management was not described as prioritizing nutrition and nutrition did not have any particular focus. The limited availability of computers and the limited time for follow-up were perceived as potential barriers to use of the MyFood system by the nurses. However, time was also seen as a potential facilitator, due to a belief that the MyFood system would make the work with nutritional monitoring and documentation more time-efficient.

The fourth domain involves individuals' characteristics. Results were revealed for the constructs **knowledge and beliefs about the intervention** and **self-efficacy**. There were positive attitudes and beliefs about the MyFood system's advantages as a tool for use in the departments and nurses perceived that they would be able to use the MyFood system.

The fifth domain involves the **process.** As this study was conducted before the RCT (Paper 3), these results were primarily relevant to the planning, through the development of an implementation plan as described in section 3.2.2. Due to a large number of nurses working either full or part-time at the department, the importance of reaching all employees with information was emphasized: '… *if you haven't received information and don't know why we are doing it, then no one cares*' [nurse]. The identification and involvement of **opinion leaders**, **champions** and **informal implementation leaders** are all included in the **engaging** construct. Some nurses said that the physicians may be filling the role of opinion leaders, although, others meant that authorities within the group of nurses also could fill this role. Champions could be nurses trained extensively about the MyFood system or nurses responsible for information and training.

4.4 Effects of the MyFood system in a clinical hospital setting

In the period from August 2018 to February 2019, 314 patients were screened for eligibility for the MyFood RCT. Of these, 120 patients were considered eligible and 100 patients provided informed consent to participate in the study. These 100 patients were randomized to the MyFood group (n=49) or the control group (n=51), as shown in Appendix 3.

The patients in the MyFood group reduced their body weight by −2.4 kg (−2.8%) during the hospital stay, whereas the corresponding number for the control group was −2.7 kg (−3.5%) (P = 0.716). A tendency towards larger weight loss in the control group compared with the MyFood group, was observed when the length of the hospital stay increased. Both groups reduced body fat, skeletal muscle mass and phase angle during their hospital stay, but no difference was found between the groups in body composition change. As for weight, there was a tendency to a larger decrease in the phase angle with increasing hospital length of stay for the control group, compared to the MyFood group. Imbalances in the hydration status were present for 80% of the patients during the hospital stay.

Based on screening with the NRS 2002 form, the risk of malnutrition at hospital discharge was present in 77% of the patients in the MyFood group and 94% of the patients in the control group ($P = 0.019$). The PG-SGA-SF score at discharge was 10 for the intervention group and 12 for the control group ($P = 0.302$), indicating a critical need for nutritional intervention in both groups. In the PG-SGA-SF, 68% of the patients in the intervention group and 84% of the patients in the control group reported a food intake representing less than normal at hospital discharge ($P = 0.071$).

The proportion of patients with nutritional treatment documented in their electronic record was 81% in the MyFood group and 57% in the control group ($P = 0.011$). The proportion of patients receiving a nutrition care plan was 70% in the MyFood group and 16% in the control group ($P <0.001$). Documentation of dietary intake compared with individual requirements was present in the electronic record for 84% of the patients in the MyFood group compared with 4% of patients in the control group ($P <0.001$).

No difference was found between the MyFood group and the control group for length of hospital stay.

The compliance with use of the MyFood app was high. On average, the nutritional intake was recorded on 93% of the days during the hospital stay. Compliance related to the use of the MyFood webserver was lower. About a third of the nurses did not sign up for use of the MyFood webserver, and about half used the report function and the functionalities for nutritional treatment and care once or several times during the trial.

5 Discussion

In this PhD thesis, a digital decision support system to monitor and follow up nutritional care and treatment in hospitalized patients at risk of malnutrition was developed, evaluated and tested.

Methodological considerations are discussed in section 5.1, ethical considerations are discussed in section 5.2, a discussion of the results is found in section 5.3, and the implications for clinical practice are discussed in section 5.4.

5.1 Methodological considerations

5.1.1 Development of the MyFood system

The dietary recording function

Traditionally, dietary records are considered to be an open-ended method that can be used to obtain detailed information about food and nutritional intake over a specific period (156). Therefore, a limitation could be that the dietary recording function in the MyFood app did not provide pictures and nutritional content for all possible types of foods and beverages that may be consumed by the patients. The patients were told to record something similar if they could not find exactly what they had consumed. This was experienced as confusing for some patients. It was possible to manually record foods or beverages which were not included in the dietary recording function. This opportunity was used by some nurses in the recording of glucose solution for intravenous infusion, and by a few patients who ate other types of foods and dishes than what was served at the hospital. However, manual coding and entry of such items require, in general, considerable effort (156), moreover, it may introduce inaccuracy. The food database in the MyFood system should, therefore, be as complete as possible. More limitations of the dietary recording function will be discussed in the discussion of the results, section 5.3.1.

Assessment of the patient's nutritional requirement

To be able to evaluate if the patient's nutritional intake is adequate, an accurate estimate of the patient's nutritional requirements is necessary. As described in section 1.6.4, indirect calorimetry is the gold standard for estimating individual energy requirements; however, its use is often unfeasible in clinical practice. The most commonly used prediction equations in clinical practice are Mifflin's formula, the Harris–Benedict equation, Owen's equation and the equation of the WHO/Food and Agricultural Organization of the UN (FAO) (157). The energy requirements in the MyFood system were calculated based on a low activity level because the study involved hospitalized patients. In the development of the MyFood app, we used algorithms based on the Norwegian Directorate of Health's recommendations for sedentary or bedridden adults (9, 46). To estimate patients' energy requirements, 30 kcal/kg per day was used as the rule of thumb, in addition to adjustments for age, BMI and fever, as described in section 3.1.1. Due to individual variations, a potential source of error in the MyFood system may be the use of standardized algorithms to estimate the patient's requirements.

The ESPEN guidelines and the NICE guidelines recommend using 25-30 kcal/kg per day to estimate patients' energy requirements, anticipating that the total energy expenditure (TEE) will be comparable with that of healthy controls (28, 40, 64, 158). According to the ESPEN guidelines for nutrition in cancer, such rough estimates will often overestimate TEE in obese and underestimate TEE in severely malnourished patients (64). In the study population in the present PhD thesis, a large part of the participants was at risk of malnutrition which means that the estimated energy requirements for some patients with low body weight may be estimated too low in the MyFood system. This may have led to erroneous feedback of nutritional intake compared with individual requirements. To avoid excess and unrealistic requirements for overweight or obese patients (BMI >25 kg/m^2), based on the standard rule-of-thumb algorithms, the recommended intake of energy, protein and liquids for these patients was calculated based on a BMI of 25 kg/m^2. According to the ASPEN and the feedM.E. Global Study Group, ideal or adjusted body weight should be used to estimate the requirements of obese or emaciated adults (26, 159). The Swedish guidelines for prevention and treatment of malnutrition also recommend calculating the energy and protein requirements for overweight and obese patients based on a BMI of 25 kg/m^2 with an extra 25% of the excess weight (41). No specific recommendations about this are included in the

Norwegian guidelines. A Danish intervention study about the effects of individualized meal servings in hospitals also used estimated energy requirements for overweight patients, based on a BMI of 25 kg/m^2 (160). A systematic review of the literature for the most common predictive equations found that Mifflin's formula is the most accurate for obese adults (157). Still, Mifflin's formula has lower accuracy in obese than in non-obese people, and therefore an obesity-specific equation has been proposed (161). In the further development of the MyFood system we could consider evaluating whether Mifflin's formula or other equations provide more accurate estimates for hospitalized patients, both obese and normal-weight individuals. However, even though predictive equations might be useful to estimate resting energy expenditure (REE) at a group level, Purcel *et al*. concluded that such equations are inaccurate at the individual level for cancer patients (162). This means that the use of predictive equations in the MyFood system probably not will lead to more accurate estimations of requirements for the individual hospitalized patient than the use of 30 kcal/kg body weight per day.

According to Frankenfield *et al*. (157), predictive equations are generally less precise in the estimation of energy requirements for older adults than for others; however, the data are limited, especially for those aged >80 years. The heterogeneity in requirements for older adults might be even larger than for the general population, due to increased differences in body composition and function (157). The ESPEN guidelines on clinical nutrition and hydration in geriatrics recommend that nutritional and hydration care should be individualized to older patients due to the heterogeneity in this patient group (158). In the qualitative study described in Paper 2, the nurses reported that they perceived the MyFood system to be more trustworthy and precise than the current paper-based dietary recording forms. It is important to emphasize to the nurses and patients that the system can provide an estimate of the patient's nutritional intake compared with individual requirements, but not necessarily the exact truth.

The algorithm for the estimation of patient protein requirements in the MyFood app was 1.2 g/kg per day based on the recommendations from the Norwegian Directorate of Health (9, 46). This is in line with the ESPEN guidelines on nutrition in cancer and the NICE guidelines that recommend a protein intake in the range of 0.8–1.5 g/kg per day (40, 64). It is important to be aware that many older adults require higher levels of protein than younger adults (10, 163). As with energy, individual adjustments for protein requirements may be necessary for

some patients. In MyFood we could potentially include an adjustment for patients over a specified age, e.g. 1.5 g/kg per day for patients aged ≥70 years. In addition, surgery, trauma and inflammation are frequently associated with increased needs for protein (164, 165). As with energy requirements, inaccuracies in the estimation of protein requirements may affect the feedback to patients and nurses in the MyFood system.

The estimated liquid requirements were also based on the recommendations from the Norwegian Directorate of Health (9, 46). The Norwegian guidelines are in line with the NICE guidelines, which recommend an intake of 30–35 ml fluid/kg per day for patients who are malnourished or at risk of malnutrition (40).

For only one patient, the possibility for manual registration of nutritional requirements in the MyFood app was used. For this patient, manual calculations were necessary because of an amputated leg. For patients with an amputation, the calculation of nutritional requirements must be performed manually. In the effect study (Paper 3), we used the procedure described by Osterkamp and recommended in the tutorial for the MNA screening form (166, 167). The researchers performed the calculation and the nurses registered the adjusted values for the patient in the MyFood app.

Calculations of micronutrient consumption were not included in the current version of the MyFood system, because the monitoring of energy, protein and liquids was considered most important in the first place. A deficiency of vitamins, minerals, or trace elements may lead to micronutrient abnormalities. Malnutrition is associated with a risk of micronutrient deficiency (168). A deficiency in one or several micronutrients may lead to impaired wound healing and increased susceptibility to infections (10). For example, vitamin D deficiency may be seen in cancer patients and low vitamin D status has been associated with muscle wasting (64, 169). It may be relevant to include an evaluation of micronutrient intake in further development of the MyFood system.

Report and tailored recommendations for nutritional treatment

To create the report function in the MyFood system, we developed a rule matrix in TSD, as described in section 3.1.3. The use of information recorded in the MyFood app to tailor the nutritional recommendations for each patient requires accurate recordings. Inaccurate or wrong recordings in the MyFood app will potentially lead to erroneous reports and

recommendations on the webserver, as discussed above. Even though the MyFood system tailored the feedback for the individual patient, the recommendations were relatively general. The MyFood system did not, for example, take into account the patient's diagnosis or special food preferences. The intention of the MyFood system was not to replace the health-care professional, but to provide a system that enabled the health-care professional to follow the guidelines for malnutrition by the use of decision support. We have emphasized on the MyFood webserver that the report is based on recordings in the app and, if in doubt about the recorded food intake, there should be discussions with the patient. For patients with a complex nutritional situation or when the use of MyFood does not lead to the expected results, referral to a registered dietitian will be necessary.

Within the specific time frame of this PhD project, it was not feasible to establish an automatic transfer of information from the MyFood system to the electronic patient record. This lack of communication between the electronic systems was reported to be a potential barrier for use by the nurses in Paper 2. The Norwegian government has ambitions for increased digitalization of the health-care sector (170). However, a challenge is that several, non-compatible solutions have been implemented. This means that health-care professionals have to log-in to different technical solutions for the documentation and follow-up of their patients. This may lead to double documentation of health information and take time away from patient contact. Ideally, the MyFood webserver should automatically transfer information to the hospital's electronic patient record system. The future potential development and use of the MyFood system in hospitals and other health-care sectors, make it expedient not to latch on to one specific electronic patient record system, because this varies between hospitals and sectors. Hopefully, the future will bring more integrated solutions with one electronic record for each patient, independent of health-care level. This will provide availability of all patient information, regardless of where the patient is treated. In Trøndelag in Norway, such a solution is under development (171) as a first step towards the target of the Norwegian Ministry of Health and Care Services set out in the white paper 'One citizen – one health record' (172).

The success of a decision support system is related to the system's adoption by its potential users, and whether the system is used as intended in clinical practice. Usability testing during the development of a decision support system has been associated with an increased adoption rate among health-care professionals (173). Usability testing of the MyFood system was

incorporated into the development process, as described in section 3.1.5. The patients' experiences with use of the MyFood app described in Paper 1 were also included in the development process.

5.1.2 Study sample

The study sample in this PhD thesis consisted of hospitalized patients and health-care professionals. As the overall aim was to evaluate the MyFood system as a proof-of-concept, the departments included in the project were chosen because of a particularly high prevalence of malnutrition.

The evaluation study

The evaluation study (Paper 1) included hospitalized patients from two departments at a large university hospital in Norway. A possible limitation is the inclusion of only 32 patients. The number of patients needed was based on power calculations where we considered a difference of 50 kcal between estimated nutritional intake in the MyFood app and the photograph method as a clinically relevant difference on group level. As the standard deviation of this difference was unknown, we considered that the detection of a difference between the methods of 1 SD would be relevant based on recommendations by Altman (174) and discussions with a biostatistician. Validation studies not using biomarkers have in general included from seven to several thousand patients (175, 176). We were most interested in the ability of the MyFood app to measure the absolute nutritional intake of individual patients, and less concerned about the effects at the group level. This contrasts with most validation studies that look at the average intake and capability to rank individuals. We considered it likely that the individual results from the 32 patients in Paper 1 would give a good indication of how accurately the dietary recording function in the MyFood app could capture individual patients' intake. A limitation of the study was that only 24 patients completed 2 days of dietary recording in the MyFood app, whereas the remaining 8 patients completed 1 day of recording. The reasons for not completing 2 days of recording for these patients were hospital discharge or the need to fast for a procedure. However, this represented a total of 55 recording days. As we were interested in the ability of the dietary recording function in the MyFood app to estimate absolute intake and not the 'usual' intake of the patients, this was probably of less concern.

The internal validity of a study refers to the extent to which the results can be generalized to the rest of the study population (115). In the evaluation study (Paper 1), only patients who consumed nutrition orally were included. The results may not necessarily represent patients who received tube feeding or parenteral nutrition. Patients with the highest disease severity or those who received tube feeding or parenteral nutrition could be less able to perform accurate recordings on the MyFood app. 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 as indicated among the health-care professionals in Paper 2. Other studies about the use of tablet computers among elderly people have found that they are often positive about new technology, capable of using it and eager to learn (177-179).

The external validity refers to the extent to which the results can be generalized to people outside the study population (115). The dietary recording function in the MyFood app was validated among patients at two specific departments in one university hospital. We do not know how our results can translate to other patient groups at other somatic hospital departments. We excluded patients with cognitive deficits and psychiatric illnesses, so we do not know whether MyFood can be used in these patient groups either. Future studies should evaluate MyFood for a more general hospital population.

The qualitative study

To secure the anonymity of the health-care professionals in the qualitative study (Paper 2), the names of the hospital and departments are not mentioned.

The sample size in a qualitative study is determined differently from a quantitative study. For focus groups, the accepted rule of thumb is three to four groups for each type of category or individual of interest (180). There is no rule regarding how many participants should be included in each focus group, but smaller groups with five or six participants usually lead to more interaction (181). In the present PhD thesis, four focus groups consisting of four to seven nurses were conducted (Paper 2). This number served the purpose of the study well, and generally, there was a good interaction between the participants. Some nurses were more dominant and talked more, but all participants were included in the discussion. The nurses have the day-to-day responsibility for the nutritional care of the patient and, hence, this was considered the most important group to include in the study. To obtain additional information,

individual interviews were also performed with interviewees from other central groups of health-care professionals. These interviews included three middle managers, two physicians and three registered dietitians.

After conducting the focus groups and interviews, it had to be decided whether saturation had been reached. Saturation can be defined as 'the point where you have heard the range of ideas and are not getting any new information' (180). During the conducting of the last focus group, a sensation of reaching saturation was identified because the range of views and aspects from the interviewees were repetitive and we did not obtain any new information. Malterud *et al*. (182) have proposed the term 'information power' as being more relevant than saturation to decide the sample size in qualitative studies. To evaluate whether the information power in a sample is satisfactory, it is necessary to look at the study aim, the specificity of the sample, the use of theory, the quality of dialogue and the strategy used for the analysis. The more information about the research question the sample contains, the lower the number of participants needed (182). The less we know about what we are interested in, the larger the chance of obtaining random and scarce data from our sample (183). The health-care professionals in our qualitative study had characteristics that were highly relevant to the study aim, and the aims of the study were relatively precise. The transcripts were analysed using a deductive approach with thematic analysis in a stepwise manner. The analysis involved coding based on the domains and constructs of the CFIR framework (128), which constituted the theoretical foundation. Based on the criteria of information power, we considered that the sample size for the focus groups with the nurses was most probably sufficient. The views of the other groups of health-care professionals were not necessarily completely covered, but was used to provide additional value to the data material.

The interviewees were relatively young, with a mean age of 30 years. This reflected the age distribution at the departments well, especially with regard to the nurses and the registered dietitians. The mean age among the physicians and the middle managers was higher. One could imagine that younger age would be associated with increased acceptance of eHealth interventions; however, the acceptance of eHealth did not differ across age quartiles in a web-based questionnaire survey of almost 300 German health-care professionals (117). Our participants were primarily women, with less than 30% being men. Being a man was associated with higher acceptance of eHealth interventions than for female health-care professionals in the German survey (117). Patients and next-of-kin were not included in Paper

2. The inclusion of patient and next-of-kin perspectives could have enriched the study by providing insights about their perceived use of the MyFood app during the hospital stay and their experiences related to the current situation with nutritional monitoring, care and treatment at the hospital.

In qualitative research, the terms ‘credibility’, ‘confirmability’ and ‘transferability’ are most often used rather than ‘validity’, ‘reliability’ and ‘generalizability’ which are commonly used in quantitative research (184). These terms are discussed in section 5.1.5.

The effect study

In the RCT (Paper 3), 100 hospitalized patients at a hematological department in a university hospital in Norway were included. Due to the scarcity of literature on the effects of similar trials, results from studies investigating effects of different forms of nutritional intervention for hospitalized patients, such as the systematic review by Bally *et al*. (68) and the Cochrane review by Feinberg *et al*. (69), were the foundation for determining the clinically relevant difference and the expected standard deviation used in the sample size estimation. Several intervention studies on hospitalized patients at risk of malnutrition have investigated the effects of oral nutritional supplements. To our knowledge, no RCTs have previously investigated the effect of a decision support system on the prevention and treatment of disease-related malnutrition, and hence no directly comparable studies were available. We could have performed a pilot study to obtain the data required for the sample size estimation. However, only five patients were included in a small pilot to test the feasibility of the methods, as described in Paper 3. Due to time constraints and this study being the first proof-of-concept study, we based the sample size analysis on data from the scientific literature and defined a clinically relevant difference between the groups as 1 kg with a SD of 1.5 kg. Considering av power of 80% and a significance level of 5%, a minimum of 74 patients in total were required. To be able to allow for possible drop-outs or missing data, a sample of 100 patients were included.

Of the patients who fulfilled the inclusion criteria, 83% provided consent to participate in the RCT (Paper 3). The patients were, in general, positive about participating in a study using a digital tool and many expressed interest in their nutritional situation. The internal validity of the study was considered to be high, as the inclusion of new participants lasted for 7 months, and we assumed that the patients included in our study represented the general population at

that hospital department. With regard to the external validity, only one hospital and one department treating specific diseases were included, hence, we do not know if the effects we found are transferable to other hospitals or patient groups. Approximately half of the patients were treated with stem-cell transplantation. Stem-cell transplantation has been an exclusion criterion in other studies, e.g. in a large Swiss multicentre study investigating the effects of individualized nutrition support (72), probably because of the severe effects that this treatment usually has on nutritional status. By including a hospital department with less severity of disease, we could have obtained other results. Future studies should consider examining the effects of the MyFood system in a general hospital population, as previously stated.

5.1.3 Statistical methods

In the evaluation study (Paper 1), statistical tests were used to compare the estimated intake from the MyFood app and the photograph method at the group level. We used the non-parametric Wilcoxon's signed rank test, due to the non-normality of the data distribution and the fact that this was not corrected by log transformation of the data. Non-parametric tests are, in general, less powerful in their ability to detect absolute differences (e.g. obtain statistically significant *P* values) than parametric tests (185). However, they are considered to be affected less by extreme observations and are hence more robust. The use of rank methods is also useful in small data sets (185), as was the case in our study.

Our primary interest was to evaluate the ability of the MyFood app to measure the patients' nutritional intake at the individual level. The choice of method was therefore somewhat atypical for our study. To obtain an overview of the agreement between the recordings in MyFood and the photograph method for each of the 32 individual patients, we created individual drop plots. These drop plots did not, however, provide any statistical test. We also performed Bland–Altman plots, a method that may identify systematic under- or overestimation of nutritional intake and can be used to analyse results at both the group and the individual level (186). However, a normal distribution of the data is an assumption for the use of these plots (186). In our data, several of the differences between the methods were not normally distributed. The Bland–Altman plots were not, therefore, presented in Paper 1.

In the RCT (Paper 3), an intention-to-treat analysis was performed according to the CONSORT guidelines (154). The primary outcome was analysed by an independent sample

Student's *t*-test, to test whether a difference existed in weight change between the MyFood group and the control group during the hospital stay. 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. 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. Due to measurements of weight and body composition twice weekly, an average of weekly measurements was used in the analysis.

5.1.4 Evaluation of the dietary recording function in the MyFood app

As described in section 1.9, it is recommended to validate a dietary assessment method by comparing the results with another method that is considered superior (114) and holds errors independent of those of the method being evaluated (115). The photograph method was chosen as the reference method and this represented a partly objective method with independent errors of those in the dietary recording function in the MyFood app, which was considered to be a strength of the evaluation study in Paper 1. However, the judgement of the amount of food and beverage items from photographs is to some degree subjective. The method would have given a higher degree of objectivity if all meal components had been weighed. This was not considered to be feasible due to the circumstances of patients in the hospital setting, and we did not want to mess up the plate when many patients already experienced challenges with loss of appetite due to disease or treatment. The photograph method has been validated against weighed records among 19 free-living healthy adults for the evening meal (187) and 60 test meals in a university cafeteria in the USA (188). However, the photograph method has to our knowledge not been validated in a hospital setting.

When using observation as a validation method, it is usually recommended to perform the observations unobtrusive (189). To make the observations using digital photography feasible in the hospital departments, some communication with the patients was necessary. As

described in section 3.2.1, the patients were asked about the type of food item in cases of doubt, when this information was impossible to obtain from the photographs. We also had to make appointments for the timing of meals, and ask them not to throw away potential food waste before the meal trays had been photographed.

Other alternatives than the photograph method were also considered. Direct observation has been described as the 'gold standard' to validate a dietary assessment method (190). Direct observation of meals is usually performed by researchers observing the meal and noting the type and amount consumed (153). Due to impracticalities in the use of direct observation in the hospital setting and ethical considerations about the constant presence and observation of patients, who were often quite ill and had impaired general conditions, it was not considered a suitable method. Biochemical markers are, according to Rothman (115), the optimal standard for evaluation of dietary assessment methods, although a major disadvantage is that markers exist only for a small selection of nutrients. Biomarkers are also influenced by different absorption and metabolism, short-term biological variation and measurement errors in the laboratory (115). In the present PhD thesis, we were interested in the MyFood app's ability to estimate patients' intake of energy, protein and liquids, in addition to food and beverages. We could have used recovery biomarkers to validate patients' intake of energy and protein. By using doubly labelled water and urinary nitrogen, we could have obtained information about patients' absolute intake of energy and protein (114). However, the use of recovery biomarkers was considered unfeasible due to the need of collecting several 24-hour urine samples in ill hospitalized patients. These methods are also quite expensive, especially the use of doubly labelled water. Another potential method was 24-hour recalls. A 24-hour recall is an in-depth interview about the respondent's dietary intake over the last day, performed by a trained interviewer. Possible sources of error using 24-hour recalls are the requirement of memory and the quantification of portion sizes (114), hence, the same potential errors as the dietary recording function in the MyFood app.

Other validation studies of methods to assess dietary intake for hospitalized patients have used different methods. The 'rate-a-plate' method was validated for Dutch hospitalized patients aged ≥55 years during two phases of dietary recording for 3 or 2 days, respectively. The reference method was dietary recording using a combination of standardized portion sizes and weighing of meal components. Digital photography was also used to get an overview of leftovers on the plate after completion of the meal (82). A plate diagram sheet to record the

proportion of a meal consumed, i.e. 0%, 25%, 50%, 75%, 100%, was validated among hospitalized patients in Iceland, using weighed food records as the reference method (83).

We evaluated the agreement between the recordings in the MyFood app and the photograph method for only the three main meals: breakfast, lunch and dinner. We did not consider it feasible to observe the intake over the entire day, both for practical reasons with data collection and with respect to ethical concerns for the patient having a researcher in close quarters for the entire day and night. By excluding snack meals, the evening meal, beverage consumption between meals and other possible consumption during the day, we were unable to evaluate the dietary recording function in the MyFood app's ability to capture the patient's total intake. Energy consumption in total for breakfast, lunch and dinner was found to constitute 85% of the patients' total intake in a similar hospital population (191), so it is likely that most of the patients' total intake was captured with the dietary recording function in the MyFood app. However, it may be reasonable to assume that the precision of the recording of, for example, snack meals is less accurate because it may be easier to forget than the main meals. The patients included in our evaluation study knew that their meal trays were about to be photographed before and after consumption, and compared with their recordings in the MyFood app. This may have made their recordings more precise and acted as a reminder to record the meals in the app. The presence of disease and fatigue among the included patients may have affected the precision of their recordings. However, as the target users of the MyFood system are hospitalized patients, the system should be usable for this population.

Two project workers divided the days between them with regard to photographing the meals, including partial weighing of food components and taking notes. Both project workers estimated the amount and nutritional content of the food consumed. Training of the project workers was performed before data collection at the hospital to secure as high interobserver reliability (IOR) between the observers as possible. In the evaluation study (Paper 1), we found an IOR of 0.97 for energy, 0.98 for protein and 0.98 for liquid after correction for obvious typing errors. This indicated an acceptable standardization and improved the internal validity of the study.

5.1.5 The use of qualitative methods

Research in the field of nutrition and dietetics is primarily dominated by quantitative approaches (192). Qualitative methods are relevant for research that seeks to explore how and

why people behave and interact in certain ways (193). The type of evidence produced by most qualitative research is not empirically generalizable, which means that the findings cannot be used to presume the characteristics of a wider population (194). However, qualitative research can be theoretically generalizable, which means that the findings can be used to develop concepts, make suggestions and understand circumstances that are relevant to other settings and other groups of individuals (149). In the qualitative study in the present PhD thesis (Paper 2), we could use the information from the health-care professionals to obtain a better understanding of how they perceived using the MyFood system in their clinical practice and their attitudes towards such a tool.

Sometimes it is reasonable to divide the participants in a qualitative study into groups consisting of the same level of power or expertise (180). We divided the nurses into focus groups consisting of experienced nurses, i.e.≥ 4 years of work experience as a nurse, and inexperienced nurses, i.e. <4 years of work experience as a nurse. The intention was to create an environment in which all the nurses felt comfortable and not reluctant to talk due to power imbalances (180).

To analyse the transcribed material from the focus groups and interviews, we used thematic analysis in a stepwise manner, as described by Braun and Clarke (155). This method is often recommended for those new to qualitative research methods because it does not require detailed theoretical knowledge, is rapidly learned and flexible, and does not require detailed procedures (155). The analysis of qualitative data can be performed in an inductive or deductive manner. In this PhD thesis, we chose to use a deductive analysis using the CFIR framework to guide the establishment of codes and themes. According to Braun and Clarke (155), a deductive approach may provide a more detailed analysis of some aspects of the data, but a possible drawback is that overall description of the data will be less rich produced. As the main purpose of the study was to explore the current practice with nutritional care and treatment at the department, and also to identify the perceived barriers to and facilitators of the use of the MyFood system, a deductive approach was considered to be most appropriate.

When conducting qualitative research, it is important to be aware of the researcher's pre-understanding; this is the knowledge, experiences and attitudes that the researcher brings with him or her to the research project (183). This pre-understanding will affect the way we collect, read and interpret our data, and may represent an advantage, but could also be a disadvantage (183, 195). The academic background of the PhD candidate of this thesis is the field of

clinical nutrition. In the planning, conduction and analysis of the transcribed material, some of the barriers associated with nutritional care and treatment were known and also that nutrition was often abandoned to the advantage of the medical treatment. These pre-understandings were handled by discussing and seeking advice from the supervisors and fellow PhD candidates.

Trustworthiness includes the terms ‘credibility’, ‘confirmability’, ‘dependability’, and ‘transferability’ (196, 197). To evaluate the trustworthiness of a qualitative research process, it is important to have information about how the analysis process was conducted and on which assumptions the analysis was based (197). Credibility is the extent to which the data can illuminate what they were supposed to, and how trustworthy the analysis and interpretation of the data are (198). Credibility is enhanced if the data are analysed by more than one researcher. In this PhD thesis, the coding of the material was discussed and revised together with an experienced co-author, hence contributing to enhanced credibility. The use of audio-taping and verbatim transcription, thereby providing written text to analyse, also added to the credibility criteria. In addition, the use of the NVivo software program to sort, organize and code the material efficiently and properly contributed to the credibility (197). Confirmability concerns the extent to which the findings are based on the data material and not the researcher’s pre-understanding, motivation or interests (196, 197). In this PhD thesis, the PhD candidate was involved in all phases of the process, including planning, development of the MyFood system, data collection and data analysis. To limit the potential bias of using just one researcher, several members of the research team were included in the qualitative research process. The use of different researchers in this process is known as researcher triangulation (196). The co-author who was most experienced with qualitative research was included in the analytical process, including the sorting of data and the development of coding categories. The remaining researchers contributed to the development of the interview guide.

Transferability is the extent to which the findings can be transferred to other settings. This is seldom the purpose of qualitative research, so this aspect involves how thoroughly the study has been described (196, 197). The qualitative study in this PhD thesis (Paper 2) was performed in two departments in one large university hospital in Norway. These results may not necessarily represent the situation in other departments or hospitals. The inclusion of several groups of health-care professionals contributed to increased transferability compared with only nurses being included.

5.1.6 The use of the CFIR

The CFIR can be used to develop the interview guide, and analyse, interpret and report results (199). In this PhD thesis, the CFIR was used to develop the interview guide for the focus groups and individual interviews and analyse the results (Paper 2). This was useful to get an overview of all potential aspects that could affect the implementation of the MyFood system in the hospital in the RCT (Paper 3). A large number of frameworks exist in the field of implementation science (134), and other frameworks were considered. The CFIR was chosen because it is widely used to identify barriers and facilitators (199).

The CFIR is broad and comprehensive, which means that it is often not possible to cover all the 39 constructs through one single study. Nor is that the intention and Damschroder *et al*. (128) claim that researchers may select the constructs that are most relevant to their study setting. The CFIR is applicable in any phase of the implementation process (128) and, in this PhD thesis, the CFIR was used before the implementation of the MyFood system in the hospital setting in the RCT (Paper 3). A systematic review of the use of CFIR argued that its use before implementation, not just during or after, is highly valuable (199). By using the CFIR before implementation, one can determine potential barriers to implementation, select implementation strategies and revise the innovation before the actual implementation process begins (199). This might, therefore, be considered an important strength of our study because we could use the results from the qualitative study (Paper 2) to plan the implementation of the MyFood system in the RCT (Paper 3).

5.1.7 The assessment of the nutritional status

As part of this PhD thesis, an objective was to investigate the effect of the MyFood system on the patients' nutritional status. However, there is currently no single 'gold standard' for the assessment of nutritional status and, therefore, a combination of several factors is usually used. As described in section 1.6.4, the nutritional assessment in this PhD thesis included the assessment of body weight, body composition, nutritional requirements and nutritional intake. In addition, the results from the PG-SGA-SF were included in the assessment.

BMI and weight change are much-used indicators of nutritional status and included in all of the most commonly used forms to screen for risk of malnutrition. The measurement of body weight is usually quick and requires only a scale. However, fluid imbalances, oedemas or

ascites in patients may influence body weight measurements (200). Increased ECW is a common feature of severe illness and systemic inflammation, and this complicates the interpretation of changes in body weight during treatment (200).

The calculation of a patient's BMI is part of the nutritional assessment. A low BMI is associated with a longer length of hospital stay, increased morbidity and mortality (32). In the MyFood RCT (Paper 3), the patient height was self-reported in most cases. As the height decreases through life, this could affect the classification of malnutrition in older patients if this decrease were not taken into account (201). In this PhD thesis, we were most interested in change during hospital stay, and therefore the use of self-reported height was not a serious limitation.

The BMI does not describe variability in body composition (i.e. muscle mass versus adipose tissue) and body composition can vary across patients with the same BMI (58). Skeletal muscle mass is increasingly emphasized as important for a range of health outcomes (58). Reduced muscle mass was also proposed as one of three phenotypical criteria for diagnosing malnutrition in the recent GLIM initiative (15).

In this PhD thesis, BIA was used to estimate the patients' body composition. BIA is a quick, portable, and non-invasive method that is associated with low costs and minimal risk (202). However, a limitation is that BIA devices rely on population-specific regression equations. The potential for use is also limited for obese patients with a BMI >34 kg/m^2 (202). The ASPEN recently published guidelines for the validity of body composition assessment in clinical populations (203). Due to various equations and regression models used by the different manufacturers of BIA devices, it is challenging to compare studies. In addition, few studies have evaluated the use of BIA for hospitalized patients and the studies carried out are small. Hence, the quality of evidence was considered to be low and the authors concluded that no recommendation could be made regarding the validity of using BIA in clinical populations (203). A Norwegian study validated the use of two different BIA devices in estimating FFM for colorectal cancer patients. DXA was used as the reference method and the authors found good agreement between BIA and DXA (204). Through the use of BIA, the patient's muscle mass can be estimated from the predictions of TBW and ECW. This means that patients who have an imbalance in the ECW/TBW ratio will often see an increase in the output of muscle mass, even though this is not the case. Fluid imbalances are, therefore, often considered contraindications for the use of BIA (205). In our study population, fluid imbalances were

highly prevalent, with only approximately 20% of the patients having a normal fluid balance during their hospital stay. As a consequence, the weight measurements and the BIA estimations were uncertain and had to be interpreted with caution.

The phase angle from the BIA measurements may be used as a more objective measure of nutritional status (206) because the phase angle is directly obtained from the measured resistance and reactance (203). The phase angle gives information about hydration status, body cell mass and cell integrity without the need to assume constant tissue hydration. A low phase angle indicates a breakdown of cell membranes, and thus a change in the performance of metabolic functions and the ability to store energy, whereas a high phase angle signals intact cell membranes and high cell mass in the body (207). Disease, inflammation and malnutrition may affect the phase angle (207) and a low phase angle is associated with an increased risk of malnutrition and increased morbidity and mortality in different diseases (208). By measuring the phase angle, malnutrition could be discovered early in the disease process (206). Cut-off values of ≤ 5 for men and ≤ 4.6 for women are suggested for use in the identification of malnutrition (208). A recent study in 80 hospitalized British patients found that the phase angle could detect malnutrition when compared with subjective global assessment (SGA) (205). The association was consistent for both normally hydrated patients and patients with fluid retention (205). The phase angle is found to be a marker for nutritional status in several studies (208-210) and several reviews have provided evidence for the potential of the phase angle in the screening, assessment and monitoring of malnutrition (206, 207, 211).

Biochemical markers were not measured in the current project, because there are no reliable biochemical indices of nutritional status (10). Concentrations of albumin and pre-albumin/transthyretin in plasma can be used to suggest the degree of catabolic activity, but their validity as measures of nutritional status is low (10).

The NRS 2002 was used to screen the patients for the risk of malnutrition in the RCT (Paper 3). This screening tool was chosen because the NRS 2002 is recommended for hospitalized patients in Norway (9) and also incorporated in the electronic patient record at the hospital where the RCT took place. We also used the PG-SGA-SF. This form may be used as a malnutrition screening tool and a diagnostic tool for malnutrition, but, in this project, we used it as part of the nutritional assessment. The NRS 2002 form is filled in by a health-care professional, whereas the PG-SGA-SF is completed by the patient. A recent Norwegian

publication by Balstad *et al*. (212) investigated how patients interpreted the PG-SGA-SF. The authors found that most of the patients managed to complete the form without problems, however, some participant- and questionnaire-related sources of misinterpretation were identified (212). In this PhD thesis (Paper 3), we experienced that completion of the PG-SGA-SF once a week was considered too often by several patients. The first part of the form includes questions about weight change over the last 6 months, 1 month and 1 week. The patients reported trouble remembering, from week to week, the previously reported weights of 6 months and 1 month ago. Balstad *et al*. (212) found that, in the second box of the PG-SGA-SF where the patients report their food intake, the word 'only' bothered the patients when reporting several types of nutrition, e.g. if they both ate normal food and consumed oral nutritional supplements (212). The same was true for the patients in the MyFood RCT, because it was quite common to consume several categories of nutrition, so the patients needed to report several options.

5.1.8 The RCT

An RCT is often named the 'gold standard' for evaluating a dietary hypothesis (115, 154, 213). The strength of an RCT is that the different variables should in principle be randomly distributed between the intervention and control groups. An RCT should ideally be conducted as a double-blind experiment (115). This means that the patient, the researcher, the one doing the statistical analysis, and the health-care professional should be unaware of which patients are assigned to each group. In the MyFood RCT, blinding of the patients was not possible due to the use of the MyFood system by the patients in the intervention group. In theory, we could have blinded the person doing the statistical analysis. However, the candidate in this PhD thesis conducted both the data collection and the analysis.

Even though RCTs are often considered the 'gold standard', they are not free of limitations. The time between the intervention and the expected change in the outcome variable is often uncertain. If an effect is not found, it will usually be difficult to know whether the reason was too short a follow-up time or that there was no effect (115). In the MyFood RCT, the included patients had different follow-up times according to their hospital length of stay. This complicates our design, because the follow-up time was not standardized. As described in Paper 3, we saw a tendency towards an increased effect of the MyFood intervention for patients with the longest length of hospital stay. This may indicate that the follow-up time for

some patients was too short, because 23% had a length of stay of ≤1 week. Possibly a larger effect on weight change would have been seen if the patients were followed up after hospital discharge, or only patients with an expected length of stay, e.g. ≥10 days, were included. However, the tendency towards improved effect among the patients with the longest length of stay may also be due to other causes, e.g. related to the severity of the disease or the treatment course they underwent.

Compliance with an intervention is in general likely to decrease during a trial of long duration (115). In the MyFood RCT, the patient compliance was high, also for the patients with a long length of hospital stay (Paper 3). Hospitalized patients may differ from the general population, in this regard. Recording of food intake may be the one thing that the patient can take control of in a setting where so much about the disease and treatment is out of the patient's power. However, we do not know whether the dietary recordings were complete, i.e. included the total consumption during the day, only that something was recorded.

A contamination effect may arise in an RCT if the intervention is thought to be beneficial and, hence, the control group could adopt the dietary behaviour of the intervention group (115). Such trends may camouflage the real effects of the treatment (115). We cannot exclude the possibility of such a contamination effect in the MyFood RCT, especially among the nurses because patients in the intervention and control groups were in the same department. The nurses received training in the use of the MyFood system and reminders to follow up the patients using the system. It is not unlikely that this also affected the nutritional care for the patients in the control group. However, based on the significant difference in the documentation of nutritional treatment in the electronic patient record between the MyFood group and the control group (Paper 3), we cannot assume that this was the case.

The RCT was conducted by researchers that had been involved in the development of the MyFood system. A meta-regression of 162 randomized trials investigating features of effective CDSS found that evaluations performed by the system developers were more likely to show effect than evaluations performed by a third party (214). This should be kept in mind when interpreting the results.

As described in section 3.2.2, an implementation plan was developed after the conduction of the qualitative study (Paper 2) and before the initiation of the RCT (Paper 3). In parallel with the effect study, a process evaluation was performed to study the implementation of the

MyFood system into the clinical hospital setting and explore the nurses' and patients' experiences and attitudes to the MyFood system. The results of this process evaluation will be analysed and presented in the future. A criticism of intervention studies has been that outcome analyses frequently are performed and reported without an assessment of the implementation of the intervention (215, 216). This is often called the 'black box approach' which assumes that the intervention has been implemented to all it was supposed to (217). This may result in a conclusion of the intervention as not being effective when it was not implemented correctly or completely; a so-called 'Type III error' (217). The use of process evaluation may prevent type III errors through monitoring and evaluation of the extent to which the intervention was implemented as intended and, hence, get into the 'black box' of the intervention (215). By analysing these results we will be able to evaluate the implementation plan for the MyFood intervention study and which implementation strategies worked and which did not. It could also provide knowledge about if, how or why the MyFood system was used as intended or not.

5.2 Ethical considerations

In the evaluation study described in Paper 1, the patients' meals were photographed to allow a comparison of the actual intake with the intake estimated in the MyFood app. Taking photographs of ill patients' meals may raise ethical dilemmas. A person who is ill and aware that their nutritional status is decreasing may feel a pressure to eat, or that they have to 'perform' in the eating situation because photos will be taken, although these photos will not be of the patients, only the trays. According to the Declaration of Helsinki, it is required that significant amounts of information are being given to the participants, who must understand the information. It is further stated that 'In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests' (218). All included patients received oral and written information, and gave informed consent. The patients were free to leave the study at any time without any particular reason, in line with the Convention on Human Rights and Biomedicine, which states 'the person concerned may freely withdraw consent at any time' and 'the interest and welfare of the human being shall prevail over the sole interest of society or science' (219).

Due to few interviewees in some of the health-care professional groups in Paper 2, the names of the departments and the hospital were not given in Papers 2 and 3, or in this PhD thesis.

This choice was made to limit the opportunity for identifying the specific interviewees. However, the hospital and department were the same in Papers 2 and 3 to make use of the results from Paper 2 in planning the RCT in Paper 3.

In the MyFood RCT (Paper 3), the intervention group received the MyFood intervention, whereas the control group did not receive any measures other than routine care. A potential ethical dilemma could have been that the control patients believed that they did not get the best follow-up, compared with the patients in the intervention group. We found that the patients in the intervention group actually received more frequent nutritional treatment and individual nutrition care plans were developed more often than in the control group.

5.3 Discussion of the results

The results from the three papers included in this PhD thesis describe the MyFood system with regard to the evaluation, the perceived barriers to and facilitators of use in clinical practice, and the effects on patients' nutritional status, nutritional care and treatment. These results are discussed in more detail below.

5.3.1 The validity of the MyFood app as a dietary recording tool

The dietary recording function in the MyFood app could estimate the consumption of energy, protein and liquids satisfactory for the majority of patients when compared with the reference method, however, some challenges were identified (Paper 1).

As described earlier, we were more interested in the accuracy of the recording function in the MyFood app on the individual level than on the group level, and more interested in the patients' actual intake on a specific day than the 'usual' intake. However, differences found at the group level could indicate challenges in the method.

At the group level, we found no difference between the MyFood app and the reference method in the median estimated total energy intake on day 1, whereas, on day 2, a lower median estimated energy intake was found in the MyFood recordings compared with the reference method. The median estimated protein intake was lower in the MyFood app on both days. Underestimation of energy and protein intake is relatively common and reported among both healthy adults (220-224) and hospitalized patients (191). This also accounts for

technology-based methods (225, 226). No significant differences between the methods were seen for the median estimated total liquid intake, except for breakfast on day 1. Beverages are often found to be the most accurately reported in validation studies (114). The reason for deviations between the methods could be either under- or overestimation by the patients with regard to the type of food item or the amount consumed. It could also be due to errors in the portion sizes or the food database.

At the group level, a significant difference between the methods was found for bread and cereals and fruit. It turned out that the portion size for sliced bread in the food database incorporated in the MyFood system was higher than the standard portion size served at the hospital. As bread-based meals constitute a significant part of breakfast, lunch and evening meals in the Norwegian diet, it was important to reveal this disparity between the MyFood app and the hospital setting. This led to a revision of the portion size of bread in the MyFood app before the RCT (Paper 3) was initiated. For fruit, the opposite was observed: during the data collection period, the portion size for cups with sliced fruit in the food database in the MyFood app was lower than the content of the fruit cups served at the hospital. This resulted in a significantly lower fruit intake being recorded in the MyFood app, compared with the estimated intake from the reference method. Due to large day-to-day variations in the amount of sliced fruit in the fruit cups, no revision in the MyFood food database was made for fruit.

At the individual level, about 70% of the patients had ≥80% agreement between the MyFood recordings and the observed intake from the reference method on both days for energy, protein and liquids. For total intake, the agreement between the methods improved from day 1 to day 2. This may indicate a learning effect, which is commonly described in the literature (114, 227, 228). The meal with the lowest agreement between the methods on the individual level was dinner. This may indicate that the selection of portion size for hot meals was more challenging than for bread-based meals, which were most commonly consumed for breakfast and lunch. We also observed that the size of a full dinner portion, as defined in the hospital's nutrition calculation system, was often larger than the portion size actually served to the patient. This often led to an overestimation of small portion sizes and underestimation of large portion sizes in our data. The tendency of overestimation of small portion sizes and underestimation of large portion sizes is often seen in validation studies (114, 229).

Omissions of food items were a challenge in our method. Butter, margarine and mayonnaise were the food items most often omitted. Condiments, e.g. margarine and dressings are,

according to Willet (114), among the food items that are most difficult to estimate. An older validation study of a dietary recording form in a similar hospital population also found that margarine was frequently omitted by the patients (191). Omission of condiments and side dishes is also often reported in validation studies of children and adolescents (230, 231). As a consequence of the results in the evaluation study (Paper 1), prompting about the use of butter and margarine was incorporated into the dietary recording function of the MyFood app before the RCT (Paper 3) was implemented.

When using dietary records, an error may be introduced by the diet record itself, because the process of writing down the foods may lead to changes in eating behaviour. This could be due to either misreporting, or under-eating, or both. Thus, the record may be accurate for the foods actually eaten, but not represent what one would normally have eaten, and hence does not represent the usual intake (156). This is found to be relevant for both paper-based and digital dietary recordings (232). However, most of such studies are performed with overweight or obese individuals. In our study population, which included severely ill adult patients with the majority at risk of malnutrition, it is probably less likely that the patients would change their dietary behaviour to indicate less food intake. It may be more likely that the opposite is true if the nurses nag the patients about eating, as found in the qualitative study (Paper 2). In addition, our primary interest was not to validate how accurately the dietary recording function in the MyFood app estimated the usual intake of the patients, but rather to validate whether it could capture the patients' actual intake during their hospital stay.

The collection of data on food intake by dietary records is associated with placing a high burden on respondents. The use of this method, therefore, requires a high level of motivation (114). Lack of motivation to record their nutritional intake may also be a barrier for patients, especially those spending a long time in hospital, and this could affect the accuracy of the recordings. However, compared with the current practice in hospitals, with dietary recording on paper-based forms, recording in an app tailored for the hospital setting may be a more appealing alternative. When exploring potential barriers to and facilitators of use of the MyFood system (Paper 2), the nurses reported that they perceived the MyFood system as being more motivational and fun to use than the current practice. Patient compliance concerning dietary recordings in the MyFood app was surprisingly high (Paper 3). When interviewing the patients as part of the process evaluation in parallel with the RCT, many said that the use of the MyFood app had increased their motivation to eat and that they had

become more aware of their own nutritional needs. An example quote illustrates this: '*It [the MyFood app] has given me a better overview. … I saw what types of food that contributed a lot and which types contributed less. That had a large impact. I understood how different types of food contributed. … In periods where I needed to increase my body weight the app was perfect for me.*'

Summarized, the dietary recording function in the MyFood app was found satisfactory for the majority of the patients in its estimation of the nutritional intake. However, a concern should be raised regarding those approximately 30% of the patients who overestimated or underestimated their nutritional intake in the MyFood app and, hence, obtained less than 80% agreement between the methods. Those patients who overestimated their intake in the MyFood app could be regarded as eating sufficiently when the opposite was true and those patients who underestimated their intake could be regarded as eating less than what was the case. This should be kept in mind and emphasized to the nurses. The revision of the portion size of sliced bread in the food database will most likely lead to increased precision in the patients' dietary recording of bread. The inclusion of prompting questions for butter and margarine and meal condiments will probably limit the omissions of these food items.

5.3.2 Facilitators of and barriers to use

We found that the health-care professionals and the hospital departments included in the present PhD thesis were ready for change concerning nutritional care and practice. Their current practice with screening for risk of malnutrition, dietary assessment and nutritional treatment deviated from national and international nutritional guidelines (Paper 2). This corresponds to results previously reported by Henriksen *et al*. (20) and Tangvik *et al*. (78) in similar Norwegian hospital populations. Halvorsen *et al.* (233) found that the nurses' main focus was on medical treatment and little on nutritional care and treatment. Our results regarding the current practice were, thus, in line with the researchers' pre-understanding and what had been shown in the literature earlier.

The perceived facilitators of using the MyFood system in clinical practice were many. The MyFood system was anticipated to be more trustworthy, accurate, motivational and fun compared with the current practice. The health-care professionals perceived the MyFood system as easy to use. High self-efficacy for use and low level of complexity were found to be facilitators for the adoption of eHealth systems among health-care professionals in a

systematic review by Li *et al.* (234). The use of MyFood was believed to lead to earlier implementation of nutritional treatment and measures (Paper 2). In the RCT we found that patients were highly compliant with the use of the MyFood app (Paper 3) and several patients said that MyFood was a useful tool during their hospital stay, which increased their motivation to eat (unpublished data). In the evaluation study, the patients reported that using the MyFood app made them more aware of their nutritional requirements (Paper 1).

Despite advance knowledge of the many perceived facilitators, we experienced that the nurses' compliance was relatively low in the RCT (Paper 3). This may be due to the barriers described below. An Australian study compared clinicians' perceptions about a decision support system for antibiotic approval with actual use (235). Those clinicians who perceived the system as being most useful were also the ones who used the system the most. However, the response rate in the study was low (235).

Several perceived barriers for use of the MyFood system were identified. The lack of automatic communication with the electronic patient record was perceived as a major barrier. Better integration between the CDSS and the electronic patient record was also reported to be essential in a mixed-method study among Dutch general practitioners (236). The clinicians experienced that they had to do the work twice: once in the CDSS and once in the electronic record (236). Berner and Lande (101) argued that this double entry can limit the usefulness of CDSS. Patients from other cultures who did not speak Norwegian, elderly patients unfamiliar with tablet computers and technology and the use of tablet computers by patients with special infection precautions were other perceived barriers to use of the MyFood system (Paper 2). Patients who were unfamiliar with Norwegian were excluded from the RCT (Paper 3). The future development of the MyFood system should consider including English language as an option. Patients from other cultures, who would potentially eat other types of foods to what was offered at the hospital, did not represent a particular challenge in the RCT. With regard to the infection precautions, this was solved by using the same practice as used for other medical equipment at the hospital department, i.e. spraying and washing with special detergents according to the current guidelines for each specific source of infection. Time was emphasized as both a potential barrier and a facilitator. Some thought the use of MyFood would be a time-saver, whereas others were worried about the time used to follow up the system. As there was a gap between the current practice with nutritional care and the national guidelines for malnutrition in our population, the introduction of the follow-up tasks in the

MyFood system probably represented new tasks for most of the nurses. Time constraint was the factor most cited as a barrier to the adoption of CDSS, in a systematic review by Deveraj *et al*. (237). The authors discussed the time constraint corresponding to the nature of clinicians' high pressure and the fast-paced work environment (237).

5.3.3 The effects of using the MyFood system in clinical practice

In the MyFood RCT, a significantly higher proportion of men was allocated to the MyFood group than to the control group (Paper 3). Malnutrition risk has been reported for older adults to be higher in women than in men (238, 239). Our study population was relatively young, i.e. mean age of 52 years, and we do not consider it likely that this skewness in gender affected the results to a large extent.

Weight change during the hospital stay did not differ between the MyFood group and the control group. As discussed in section 5.1.7, imbalances in a patient's hydration status can affect weight measurements. Such imbalances were present in 80% of the patients in our study sample and disturbed the accuracy of the weight measurements (Paper 3). Other studies have also been unable to demonstrate significant effects of nutritional intervention on weight change during stays in hospital (68, 69, 72), even though effects on outcomes such as mortality and adverse outcomes have been found (72). A tendency to an increased effect on weight change was seen for the patients spending a longer time in the hospital. We also found a significant difference in the phase angle between the MyFood group and the control group at 4 weeks of hospital stay. These findings may indicate an improved nutritional status among the patients in the MyFood group, for patients using the system over a longer period.

At hospital discharge, a lower proportion of the patients in the MyFood group was at risk of malnutrition, defined as an NRS 2002 score ≥3, compared with the control group (Paper 3). This was due to a significant difference in the part of NRS 2002 involving the patient's nutritional status, whereas no difference between groups was present for the part including severity of the disease. We know that being identified as at risk of malnutrition is associated with adverse outcomes for the patient. Both international and national studies have found the risk of malnutrition to be associated with increased morbidity and mortality rates, and also prolonged length of stay in hospital (19, 32, 240). The results from the NRS 2002 and PG-SGA-SF forms at discharge also indicated that a higher proportion of patients covered their energy requirements in the MyFood group than in the control group. In future studies, one

should consider also collecting information about the nutritional intake for the control group to compare effects on the consumption of energy, protein and liquids.

The results in this PhD thesis indicated that the use of the MyFood system significantly improved the precision for the nurses' documentation of nutritional intake and increased the proportion of patients receiving a nutrition care plan (Paper 3). Proper documentation of nutritional status makes it more feasible to follow up the nutritional needs and give appropriate nutritional treatment and care for hospitalized patients (233). The majority of the patients in the control group had a low degree of accuracy regarding the documentation of their nutritional intake, e.g. 'ate little', 'had cornflakes for breakfast'. This corresponds to the findings by Halvorsen *et al.* (233) of inadequate and unsystematic documentation of nutritional intake compared to requirements in Norwegian hospitals and nursing homes. The authors also found that documentation of nutritional treatment or nutrition care plans was rarely performed (233). The same tendency was also demonstrated in a Belgian university hospital, where the nurses' documentation of nutrition-related data were found to be scarce when analyzing more than 500 health records retrospectively (241). Even though we found a relatively large difference between the MyFood group and the control group in the proportion of patients with documentation of nutritional treatment and a nutrition care plan in their electronic record, we do not know how the nutrition care plan was followed up in practice or how the nutritional treatment was evaluated.

We found that the patients were highly compliant with the use of the MyFood system, whereas the nurses were less compliant. This may indicate that the positive results from the RCT were partly due to patients' improved insight into their nutritional situation and possibly an increased motivation to increase their nutritional intake to reach their requirements. In the patient interviews that were conducted as part of the process evaluation conducted in parallel with the RCT, several quotes indicated this, e.g. *'... the appetite is very low, but it has become – I manage to eat more than I would have done without that app*'. In the evaluation study (Paper 1), the patients reported becoming more aware of their nutritional requirements after using the MyFood app for two days. The fact that the patients became more aware of their nutritional requirements and intake when using MyFood could also have resulted in more patient-initiated dialogue between the patient and the nurse about the patient's nutritional status. Also, this might have led to an increased demand of oral nutritional supplements or other nutritional measures from the patient so that a higher proportion of patients in the

MyFood group received nutritional treatment and a nutrition care plan compared to the control group. The future analysis of the patient interviews will provide more information about this. The involvement of the patient in the use of CDSS is shown to be more effective than only involving the health-care professional (214). Roshanov *et al*. (214) argue that this probably is due to the increased empowerment of the patients when they become actively involved in their own care.

Our results suggest that there is a large potential for better nutritional treatment and care through the use of the MyFood system in a hospital setting. Focus on strategies to improve the nurses' compliance may in the future improve the MyFood system's potential even further.

5.4 Implications for clinical practice

There is a need for a better system to integrate and follow up the guidelines for disease-related malnutrition (9, 43). However, such systems have been lacking both in Norway and internationally.

The results from this PhD thesis indicate that the MyFood system may be a valuable tool for nurses to monitor and follow up patients' nutritional care and treatment through their hospital stay. The health-care professionals' perceptions of the MyFood system as a trustworthy, precise and motivational tool to use, imply that the system may have a significant impact if we could manage to implement the system as an integral part of the hospital organization. Even though we found that the use of the MyFood system improved documentation of nutritional intake, nutritional treatment and creation of nutrition care plans, we did not observe the expected effects on weight change during hospital stay for the patients. The lower proportion of patients at risk of malnutrition at hospital discharge in the MyFood group, compared with the control group, indicates that the use of the MyFood system in hospitals may contribute to a reduction in the prevalence of disease-related malnutrition.

Despite the high proportion at risk of malnutrition in our study population and that many faced severe nutritional challenges due to the treatment they received, only 23% of the patients in the MyFood group and 16% of patients in the control group saw a dietitian during their hospital stay. An increased emphasis on the need to referring a registered dietitian in

complex nutritional situations, or if the nutritional measures and treatment do not show the expected effects, should be included in the future development of the MyFood system.

An unexpected observation in the present PhD thesis was the high involvement of the patients in the use of the MyFood app and also their interest and focus on the output for nutritional intake compared to individual requirements. The MyFood system was intended for use by nurses, however, we found that the patients were more compliant with the use of MyFood than the nurses. This could indicate that our results related to risk of malnutrition are due to the knowledge or insight about nutritional requirements and intake that the patients acquired, and to a smaller degree the follow-up from the nurses. Bjornsdottir *et al*. (83) argue that an acceptable method to monitor dietary intake for hospitalized patients at risk of malnutrition should be simple and easy for health-care professionals to use with minimal training. Based on our experience in the MyFood project, we argue that a method that involves the patients in their nutritional situation and is easy to use for both patients and health-care professionals might be even better.

The future analyses of the process evaluation conducted in parallel with the RCT will enrich our understanding of how the MyFood system can be implemented in a clinical hospital setting.

6 Conclusions

In this PhD thesis, the development, evaluation, assessment of perceived barriers and facilitators, and clinical effects of the MyFood decision support system have been presented.

- ✓ A prototype of the MyFood decision support system has been developed. The interface of MyFood consisted of an app for tablet computers and a webserver and included four functions: 1) registration of patient information; 2) dietary recording; 3) evaluation of nutritional intake compared with individual requirements; and 4) report to nurses including recommendations for tailored nutritional treatment and a nutrition care plan for the patient.

- ✓ The dietary recording function in the MyFood app was found satisfactory in its ability to estimate the intake of energy, protein and liquids for the majority of the patients when compared with a reference method. Approximately 70% of the patients had ≥80% agreement between the estimated intake in the dietary recording function in the MyFood app and the reference method. For food and beverages, the agreement between the recordings in the MyFood app and the reference method varied with food groups.

- ✓ Most of the patients found the MyFood app easy to use and navigate. They reported becoming more aware of their nutritional requirements after using MyFood for 2 days, and few patients claimed that they needed to acquire new knowledge to use MyFood.

- ✓ The current practice with nutritional care and treatment at the included hospital departments deviated from the guidelines for prevention and treatment of malnutrition. Readiness for change was identified and the nurses claimed that they should perform nutritional monitoring, treatment and care better.

- ✓ The health-care professionals perceived the MyFood system as being more trustworthy, precise, motivational and fun to use than the current practice. The use of MyFood was perceived to lead to earlier implementation of nutritional treatment and to save time.

- ✓ The perceived barriers to the use of the MyFood system in a hospital setting were lack of automatic transfer of information to the electronic patient record, patients not understanding Norwegian, patients from other cultures with different food habits, hygienic aspects related to use of tablet computers by patients with infections and concerns related to time used to follow up the system.

- ✓ In the effect study the following results were found when comparing the MyFood group with the control group:

    - o No difference between the groups in body weight change during the hospital stay.

    - o No difference between the groups in body composition change during the hospital stay.

    - o Significantly more frequent documentation in the electronic patient record of nutritional treatment and nutritional intake compared with individual requirements in the MyFood group compared with the control group.

    - o A significantly higher proportion of the patients in the MyFood group received a nutrition care plan than in the control group.

    - o A lower proportion of the patients in the MyFood group than in the control group were classified as at risk of malnutrition on hospital discharge.

    - o No difference between the groups was found for the length of hospital stay.

7 Final remarks and future perspectives

We are facing rapid technological development and the use of digital solutions in health-care will increase, aiming to make the health-care services better and more effective. The development and evaluation of the MyFood system could be a first step in the digitalization of the process of dietary recording and evaluation, monitoring and follow up the nutritional care and treatment for patients at risk of malnutrition in the hospital sector. As part of the overall project, we also wanted to study the implementation of the MyFood intervention into the clinical hospital setting. A process evaluation was conducted in parallel with the RCT to study the reach, implementation, adoption, feasibility, fidelity and maintenance using the RE-AIM framework for implementation research (242). The data collected in this process evaluation will be analyzed and presented in a scientific paper later. By analyzing these data, the implementation plan we developed based on the findings in Paper 2, can be evaluated in terms of which implementation strategies were effective and which were not. This knowledge could make us better suited to tailor the implementation of the MyFood system to a health-care setting in the future.

The results from the proof-of-concept study presented in this PhD thesis should be followed up with further development of the MyFood system and more research, as described below.

Suggestions for future development and modifications of the MyFood system:

- Increase the food composition database in the system and provide a more generic solution so that the system can be used independently of the hospital setting and for patients receiving home-based care. New tools and technologies are constantly changing. One might consider connecting the MyFood system to a food composition database that is continually updated.

- Explore the opportunities to scan barcodes, take photographs of meals or use audio recording to make the dietary recording functions easier for patients living at home.

- Include a module to screen for risk of malnutrition so that the MyFood system can be used through the entire pathway of nutritional care and treatment.

- Explore opportunities for connecting the technology of the MyFood system to the electronic patient record to automate the transfer of information.

- Increase the use of audit and feedback functionalities for the patient. A selection of easy-to-adapt recommendations for food choices and fortification to cover nutritional needs could be made available for those patients who are motivated.
- Investigate methods to increase compliance by nurses. This may include the use of reward mechanisms or gamification.
- Include an electronic solution for patient-reported outcome measures (PROMs). The PROMs will enable the patient to report on self-perceived health status and facilitate the follow-up of nutritional measures and functional status throughout the entire treatment course

Suggestions for future research:

- Study the effects of the MyFood system in the general hospital population, performing a multi centre study in several hospitals and different patient groups.
- Study the cost-effectiveness of using the MyFood system in a hospital setting.
- Study the effects of using the MyFood system for patients living at home who receive outpatient follow-up or hospital-in-the-home treatment.
- Explore the potential for use of the MyFood system for patients receiving home-based services in the communities.
- Explore the potential for use of the MyFood system for patients in nursing homes.

To summarize, the MyFood system or a similar digital solution could have huge potential for use in the health-care system. There is a need for a digital system to monitor and follow-up the nutritional care and treatment for the large group of patients who are at risk of malnutrition. However, more development and research should be performed to increase the possibilities for use of the MyFood system in different patient groups and different settings within the health-care sector. More research on the implementation process will also most probably be crucial, to understand whether MyFood or a similar system can be used as an integral part of patient health-care.

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Paper 1:

A Dietary Assessment App for Hospitalized Patients at Nutritional Risk: Development and Evaluation of the MyFood App.

1

Original Paper

A Dietary Assessment App for Hospitalized Patients at Nutritional Risk: Development and Evaluation of the MyFood App

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Abstract

Background: Disease-related malnutrition is a common challenge among hospitalized patients. There seems to be a lack of an effective system to follow-up nutritional monitoring and treatment of patients at nutritional risk after risk assessment. We identify a need for a more standardized system to prevent and treat disease-related malnutrition.

Objective: We aimed to develop a dietary assessment app for tablets for use in a hospital setting and to evaluate the app's ability to measure individual intake of energy, protein, liquid, and food and beverage items among hospitalized patients for two days. We also aimed to measure patients' experiences using the app.

Methods: We have developed the MyFood app, which consists of three modules: 1) collection of information about the patient, 2) dietary assessment function, and 3) evaluation of recorded intake compared to individual needs. We used observations from digital photography of the meals, combined with partial weighing of the meal components, as a reference method to evaluate the app's dietary assessment system for two days. Differences in the intake estimations of energy, protein, liquid, and food and beverage items between MyFood and the photograph method were analyzed on both group and individual level.

Results: Thirty-two patients hospitalized at Oslo University Hospital were included in the study. The data collection period ran from March to May 2017. About half of the patients had ≥90% agreement between MyFood and the photograph method for energy, protein, and liquid intake on both recording days. Dinner was the meal with the lowest percent agreement between methods. MyFood overestimated patients' intake of bread and cereals and underestimated fruit consumption. Agreement between methods increased from day 1 to day 2 for bread and cereals, spreads, egg, yogurt, soup, hot dishes, and desserts. Ninety percent of participants reported that MyFood was easy to use, and 97% found the app easy to navigate.

Conclusions: We developed the MyFood app as a tool to monitor dietary intake among hospitalized patients at nutritional risk. The recorded intake of energy, protein, and liquid using MyFood showed good agreement with the photograph method for the majority of participants. The app's ability to estimate intake within food groups was good, except for bread and cereals which were overestimated and fruits which were underestimated. The app was well accepted among study participants and has the potential to be a dietary assessment tool for use among patients in clinical practice.

(JMIR Mhealth Uhealth 2018;6(9):e175) doi: 10.2196/mhealth.9953

KEYWORDS

decision support system; disease-related malnutrition; eHealth; mHealth; dietary assessment; validation study

Introduction

Disease-related malnutrition is a common challenge in patients with chronic or severe diseases [1] with a prevalence of 30%-50% in hospitals [1-7]. Malnutrition has several health-related consequences for patients. It increases morbidity and mortality [1,2,8-10], length of stay [2,3,9,11,12], and readmission rates [2]. Disease-related malnutrition has significant economic consequences for the health care system [8,12-13].

According to the Norwegian "National guidelines for prevention and treatment of malnutrition" [14] and European guidelines recommended by the European Society of Clinical Nutrition and Metabolism [15], all patients should be screened for nutritional risk upon admission to hospital and weekly thereafter. Information on the patient's nutritional status and treatment should be documented in medical records and communicated to the next level of care. All patients at nutritional risk should have an individual nutrition plan including documentation of nutritional status, needs, dietary intake, and recommended actions. Hospitals, nursing homes, and home care services are responsible for integrating nutrition in the care and treatment of all patients [14].

European data from the nutritionDay survey indicates that dietary assessment is only performed for a small number of patients at nutritional risk and that documentation of food intake is rarely done [16]. Norwegian studies have reported that about half [17] or fewer than half [7] of patients identified to be at nutritional risk receive nutritional treatment. A barrier to adequate nutritional care for malnourished patients in hospitals is the absence of routines, as demonstrated in qualitative studies among nurses in Norway and Sweden [18,19]. Nurses report a lack of tools to estimate patients' needs and the content of energy and protein in hospital menus [11]. They also report insufficient knowledge and skills to identify and treat malnourished patients [18,20].

In the next decade, the need for healthcare will increase and, there will be a shortage of labor. This should be met with more effective, less people-demanding services and increased use of welfare technology [21]. There seems to be a lack of an effective system to follow up nutritional treatment in the healthcare system. We have identified a need for a more standardized system for prevention and treatment of disease-related malnutrition. To the best of our knowledge, no studies regarding development of an electronic decision support system for prevention and treatment of disease-related malnutrition among hospitalized patients at nutritional risk have been performed.

We developed an app, MyFood (MinMat), for mini tablet computers as part of a decision support system to prevent and treat disease-related malnutrition. Assessment in the app is based on self-reported dietary intake where the patient (or a nurse) records consumption of food and beverages. The memory of intake, ability to estimate portion sizes, and perceptions of socially desirable responses are well-known challenges associated with self-reported dietary intake [22]. Self-reported methods for assessment of dietary intake have been found to underestimate energy intake by approximately 20% when compared to doubly labeled water [23-25]; dietary assessment methods should always be validated because of these methodological challenges [22]. Therefore, evaluation of MyFood's ability to track the patients' dietary intake is of crucial importance.

The aim of this study was to develop a dietary assessment app for tablets for use in a hospital setting and to evaluate the app's ability to measure individual intake of energy, protein, liquid, and food and beverages for two days compared to photograph observations combined with partial weighing as the reference method. We also aimed to measure the patients' experiences using the app.

Methods

Development of the MyFood App

My Food was developed by researchers at the University of Oslo and Oslo University Hospital (OUH) and by interaction designers and developers at the University Center for Information Technology (USIT).

Nurses and patients were involved in the design process. Paper sketches of MyFood were developed and explored with three nurses and three patients at the Department of Gastrointestinal Surgery at OUH, Rikshospitalet. The feedback we received was used to modify the design and content of the app before the technical development process began. A prototype of MyFood was then developed and tested by four patients and two nurses. Their feedback was used for additional modifications of MyFood before the evaluation study was performed.

MyFood consisted of the following three modules:

Module 1: Collection of Information About the Patient

In the first module, the nurse, or other healthcare professional, recorded information about the patient. This information included: Norwegian patient registry (NPR) number, gender, date of birth, height (in centimeters), weight (in kilograms), whether the patient had a fever (and, if so, the number of degrees, and whether the patient was following a special diet or had any special preferences with regard to food or beverages.

Module 2: Dietary Assessment Function

Figure 1 shows the main menu in the dietary assessment function in MyFood.

Recording of food intake was done by first selecting the relevant meal category and then selecting the category for the food or beverage item. The food and beverage categories included pictures of the different items. Pictures could also be found using free text search. After selecting the food or beverage item consumed, the item amount was recorded. Portion size could be selected with a precision of a half unit. Figure 2 is a flowchart of dietary recording in the app. Multimedia Appendix 1 shows some selected print screens from MyFood.

Figure 1. The main menu of dietary recording in the MyFood app.

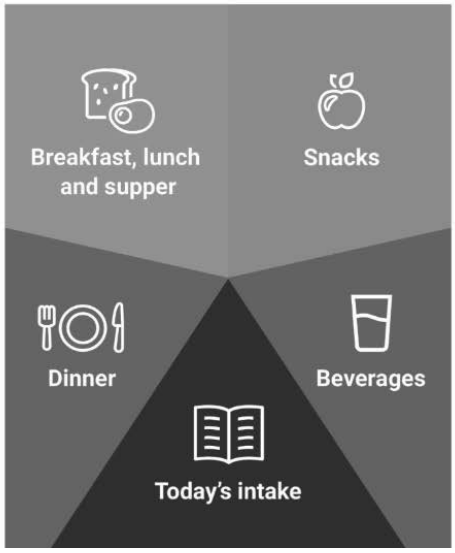
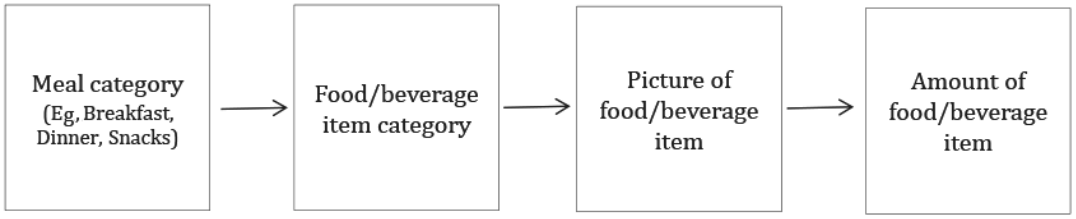


Figure 2. Flowchart on the dietary recording function in module 2.



Intake of energy, protein, and liquid was calculated based on information of the nutrient content in standard units (eg, 1 slice of bread, 1/2 glass of milk). The app included prompting questions (eg, regarding the use of spreads when recording intake of bread or regarding intake of beverages together with meals). Hot dishes were recorded by selecting an icon depicting the portion consumed (full, three quarters, half, one quarter; Figure 2). If only components of the meal were consumed (eg, 1 potato) this could be recorded by choosing the "ate only components" function shown in Figure 3. Portion sizes for beverages were recorded by selecting an icon depicting sections of a glass/cup (full, three quarters, half, one quarter) or by inputting the number of deciliters consumed.

The app included pictures of all food and beverages served at OUH, Rikshospitalet. It also included pictures of different groceries, food, and beverages that may be brought by relatives or friends from outside the hospital as well as advanced medical nutrition products. Nutritional information in the app was given for the intake of energy (kcal), protein (grams), and liquid (milliliters). Nutritional data were retrieved from an in-house data program (KBS version 7.0), based on the Norwegian food composition table [26], and from manufacturers.

Module 3: Evaluation of Recorded Intake Compared to Individual Needs

The third module automatically compared dietary intake with individual requirements for energy, protein, and liquids. This module was developed by including several algorithms in the app. The algorithms estimated the patients' daily requirements for energy, protein, and liquids and were based on recommendations from the Norwegian Directorate of Health [14,27].

Technological Features

The data flow in the app used a Web form and secure storage in "Services for sensitive data" (or TSD, Tjenester for Sensitive Data) [28] hosted by USIT (Figure 4). TSD meets the stringent requirements for the processing and storage of sensitive research data and is included in NorStore, the Norwegian national infrastructure for handling and storage of scientific data [29]. All recorded data were sent to TSD continuously during the data collection period. The recorded data were also stored locally on the iPad and visible in the app until 3 am the following day. This made it possible for the respondents to edit their recordings of dietary intake and the app was able to give the users feedback on their intake of energy, protein, and liquid during the current day. If the iPad was not able to send the data to TSD (eg, missing internet connection), the data were encrypted, temporarily queued, and resent as soon as the iPad was online again. All iPads were "clean" every morning and could possibly be given to a new patient. The data were later retrieved from TSD for data analysis in the evaluation study.

The Mobile Device Management System, AirWatch, was used to control the iPads during the data collection period. If tablets disappeared, we were able to clean the disappeared tablet remotely and make it impossible to use until reopened via AirWatch. It was possible to maintain total control of sensitive data stored on the tablets using this system.

Figure 3. Recording of hot dishes in MyFood.

Figure 4. Data flow in the MyFood app. TSD: services for sensitive data.

Evaluation of the MyFood App

Participants

The evaluation study was performed at OUH, Rikshospitalet in the Departments of Gastrointestinal Surgery and Hematology.

Inclusion criteria were:

- ≥18 years of age
- ≥2 days of expected stay

Exclusion criteria were:

- Pregnancy
- Special infection precautions
- Psychiatric patients
- Critically ill patients
- Patients not able to read the Norwegian language

Even though MyFood is designed to be used by patients at nutritional risk, this was not an inclusion criterion as we wanted to include patients eating various amounts of food to evaluate the app. Based on a power of 0.8, a significance level of P=.05 and a calculated standardized difference of 1.0, 32 patients were included in the evaluation study.

Ethics

The study was performed in accordance with the Helsinki declaration and was acknowledged by the Norwegian Regional ethical committee (2016/1464), the Data protection officer at OUH, and the Chief Information Security Officer at the University of Oslo. Informed written consent was collected from all participating patients.

Performance

Information about the study, including the nurses' responsibilities in the data collection period, was sent to all nurses via e-mail. In the Department of Hematology, a ten-minute presentation by the project workers was held for the nurses during the morning meetings of the first two days of the data collection period. The responsible nurse in each department identified patients who met all of the inclusion criteria and none of the exclusion criteria.

The patients were registered in the app by a nurse or by one of the project workers before breakfast. Information including the

NPR number, height, weight, presence of fever, special diet, or special preferences was registered in the app before patient use.

Written instructions on how to record dietary intake in MyFood were given to the patients and the nurses. Once included in the study, patients answered a form with information about education, living conditions, and level of experience with apps and tablets or smartphones.

Included patients were given a tablet (iPad mini 32GB) and were asked to use MyFood for two days to record their intake of food and beverages for the breakfast, lunch, and dinner meals. If patients were not able to or did not want to record information themselves, a nurse performed the dietary recording for them. The patients were instructed to record dietary intake as soon as possible after the meals in order to get as precise recordings as possible. They were also informed both verbally and in writing to record the intake for the breakfast, lunch, and dinner meals only, not snacks or beverages consumed between the respective meals. If patients did not find exactly what they had consumed in the app, they were instructed to record something similar.

After two days of using MyFood, participants were asked to answer a form regarding assumptions about comprehension, content, and perceived value and usability of the app.

Reference Method

We used observations from digital photography of the meals combined with partial weighing of meal components as the reference method to evaluate the dietary assessment function in MyFood. The reference method is further described as the photograph method. A digital system camera (Sony A500/16-50mm PZ objective) was mounted to a removable trolley (85 cm * 50 cm) on an adjustable and pivotable tripod. The camera lens was approximately 0.6 m above the trolley. A researcher photographed the trays with the patients' meal before and after consumption. The trays were marked with the study participant number. The numbered trays were placed on a marked area on the trolley and a 30-cm ruler was placed on the tray as a reference size. The photographs were taken at an angle of 45° to the trays so that in-depth images could be taken for more convenient meal content estimation. In addition to the observations from photographs, partial weighing of meal components was performed by the researchers. Plates, glasses, cups, and food items in separate packaging were weighed on an electronic scale before and after the meal. In cases where determining the type of food or beverage from the photographs were challenging (eg, whole fat or skimmed milk, sugar-sweetened or light soft drinks, butter or margarine), the patients were asked about what specific type of foods or beverages they included in the meal.

Training of Project Workers

Two project workers underwent practice in photographing and estimating portion sizes before the data collection, to secure a standardized method and higher level of agreement. Thirteen meals (both bread-based meals and hot dishes) were prepared by a third person. The meals were prepared to illustrate the portion size before consumption and after consumption, by removing all or parts of the food. The meals were photographed before and after some or all the food were removed from the tray. Glasses, plates, cups, and food items in separate packaging were weighed. Both project workers observed the photographs and calculated the weights to estimate the consumption of food and beverages. The interobserver reliability (IOR) between the two project workers was calculated to be 0.92 for energy content. The project workers' estimations of energy content matched with the known energy content by 0.94. This was considered satisfactory, based on criteria in other studies [30].

Data Handling and Statistical Analyses

The food and beverage intake observed from the photographs and estimated from partly weighing in the evaluation study were compared with the intake recorded in MyFood. Observed and weighed intake was estimated separately by the two project workers, before recording the data in an in-house diet calculation system (KBS version 7.0). The project workers estimations were compared with the requirement of an IOR above 0.85 for energy, protein, and liquids in each meal. If IOR was <0.85 the calculations were repeated and recompared. In cases with obvious typing mistakes, this was corrected by the respective project worker. If the project workers had estimated different amounts, the pictures were re-evaluated, and the project workers agreed on where to adjust the estimated amounts (in grams). After corrections, the total IOR was 0.97 for energy, 0.98 for protein, and 0.98 for liquid. A final data file with estimated consumption based on the photograph method was created by averaging the estimations of the two project workers.

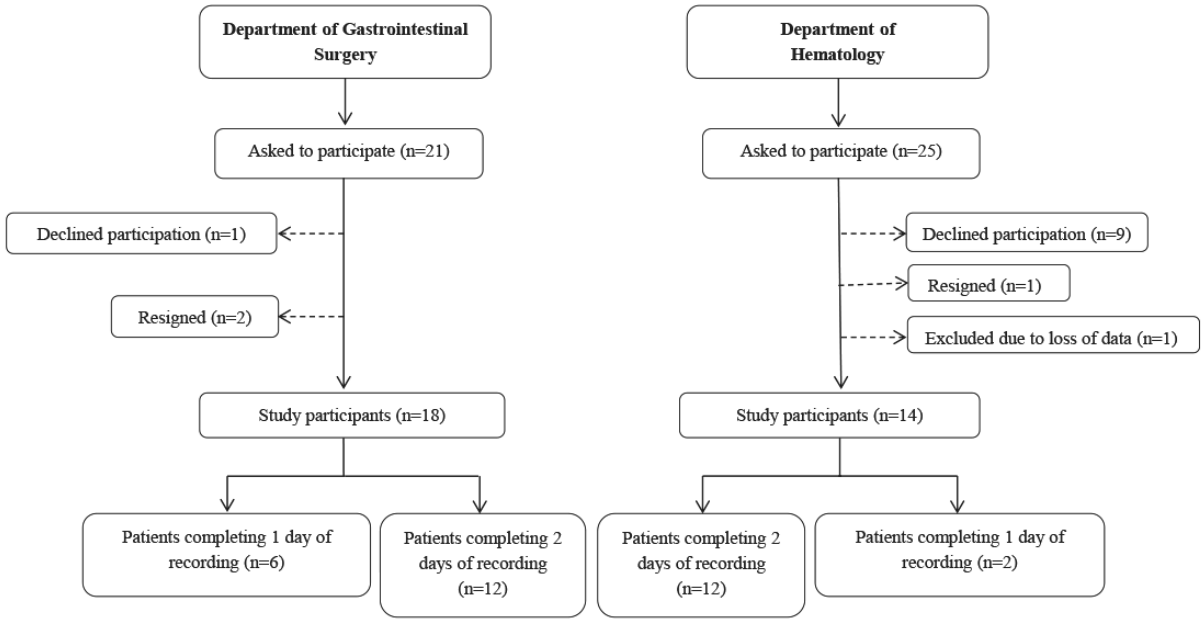
Statistical analyses were performed using the statistical software package IBM SPSS Statistics 24. All tests were two-sided with a 5% level of significance. The data were analyzed on both group and individual level. Differences in the intake estimations of energy, protein, liquid, and food groups, between MyFood and the photograph method, were analyzed with Wilcoxon Signed Ranks Test due to nonnormally distributed variables. Multiple scatter plots of consumption of energy, protein, liquid, and selected food groups were used to illustrate the difference between the estimated intake in MyFood and from the photograph method for each individual subject. The differences between the methods were assessed in total and divided into the breakfast, lunch, and dinner meals for recording days 1 and 2 separately. To calculate omitted food items, one omission was counted as an item observed from photographs in a meal but not recorded in MyFood.

Results

Participants

The study sample consisted of 32 patients at OUH, Rikshospitalet; 18 from the Department of Gastrointestinal Surgery and 14 from the Department of Hematology. The data collection period ran from March to May 2017, and the participants were recruited continuously during the period. A flowchart describing the recruitment process is illustrated in Figure 5.

Figure 5. Flowchart of the recruitment process of study participants.



Characteristics of the study participants are illustrated in Table 1. More than two-thirds were men and the age distribution was from 17 to 77 years. About 40 percent of the participants were characterized as normal weight, according to body mass index (BMI) and more than half as overweight or obese. The majority of the participants had some or a lot of experience with apps and smartphones or tablets.

Estimations of Energy, Protein, and Liquid Consumption in MyFood Compared to the Photograph Method on Group Level

Table 2 shows the intake of energy, protein, and liquids estimated in MyFood and the photograph method. The results are presented for the total of breakfast, lunch, and dinner, and separately for each meal.

The median intake of energy was not significantly different between the methods the first day, except for lunch where median recorded intake in MyFood was significantly higher compared to the photograph method. The second day a significantly lower median total energy intake was found in MyFood compared to the photograph method. The opposite was observed for the lunch and dinner meal.

The recorded median protein intake in MyFood was significantly lower for total intake, breakfast, and lunch, compared to the photograph method on day 1. The second day the median intake of protein for breakfast was significantly lower in MyFood, compared to the photograph method. No other statistically significant differences were found for median protein intake on day 2.

The median liquid intake showed relatively good agreement between the methods on the group level. Only for breakfast the first day the median recorded intake was significantly lower in MyFood compared to the photograph method.

Estimations of Energy, Protein, and Liquid Consumption in MyFood Compared to the Photograph Method on Individual Level

Table 3 shows the percentage of the patients who had 90 and 80 percent agreement between their recordings in MyFood compared to the photograph method, in total and separately for the breakfast, lunch, and dinner meal.

About half of the patients had ≥90% agreement in total for energy, protein, and liquid intake, somewhat lower for protein and higher for liquids both recording days. The breakfast meal had the highest proportion of participants with ≥80% agreement between the methods for all nutrient components both days, except for protein intake the first recording day. The agreement between the methods was lowest for the dinner meal.

Energy intake

Recorded individual energy intake in MyFood and intake estimated from the photograph method are illustrated in Figure 6, which shows individual drop-plots from the first and second recording days.

MyFood estimated the energy consumption relatively accurate for the majority of the patients. On average for the two days, approximately 70% of the participants had less than 20% disagreement between the two methods, and approximately 50% had less than 10% disagreement (Table 3). For some participants, the intake was overestimated in MyFood compared to photograph observations (Figure 6). This overestimation was more pronounced on day 1 than day 2. The largest discrepancies with regard to energy consumption at the individual level were found for the dinner meal the first day (Table 3).

Table 1. Characteristics of participants (n=32) in the evaluation study of MyFood.

Characteristic	n (%)
Hospital department	
Gastrointestinal surgery	18 (56)
Hematology	14 (44)
Gender	
Men	22 (69)
Women	10 (31)
Age (years)[a]	
<30	3 (10)
30-39	3 (10)
40-49	7 (23)
50-59	8 (26)
60-69	8 (26)
70-80	2 (7)
Body mass index (kg/m^2)	
<18.5	1 (3)
18.5-24.9	13 (41)
25-29.9	14 (44)
>30	4 (13)
Education	
Primary and secondary schools	4 (13)
Comprehensive school/high school	16 (50)
College/university ≤4 years	6 (19)
College/university >4 years	6 (19)
Earlier experiences with apps and smartphones/tablets	
None/little	3 (9)
Some (use sometimes)	9 (28)
A lot (use often/daily)	20 (63)

[a]Missing n=1.

Protein Intake

The individual protein consumption recorded in MyFood, compared to the photograph method showed relatively coinciding agreement. The agreement was most coinciding on day 2 (Multimedia Appendix 2). On average for the two days, about 70% of the participants had less than 20% disagreement between the two methods, and just below half of the participants had less than 10% disagreement (Table 3). The discrepancy between the methods was largest for the dinner meal (Table 3).

Liquid Intake

The agreement between the methods for low and medium liquid intake was good, with a tendency to increased deviations for higher intakes. This was seen on both recording days (Multimedia Appendix 3). On average for the two days, about 60%-70% of the participants had less than 20% disagreement in liquid intake between the two methods, and about 50% had less than 10% disagreement (Table 3).

Estimations of Food Intake in MyFood Compared to the Photograph Method on Group Level

The consumption (grams) within food groups are shown in Table 4. No statistically significant differences were seen between the methods, except for bread and cereals, and fruits. The median recorded intake of bread and cereals was significantly higher in MyFood compared to the photograph method, both recording days. Median fruit intake was significantly lower in MyFood the first recording day.

Table 2. Energy, protein, and liquid consumption recorded in MyFood compared to the photograph method. The data are presented as a total of the breakfast, lunch, and dinner meals, and separately for each meal.

Energy, protein and liquid	Mean	Median (25-75 percentile)	*P* value
Energy			
Day 1			
Breakfast (n=28)			.73[a]
MyFood	471	398 (244-616)	
Photograph method	458	373 (222-373)	
Lunch (n=27)			.04[a]
MyFood	408	389 (262-494)	
Photograph method	382	308 (201-308)	
Dinner (n=27)			.58[a]
MyFood	476	468 (210-711)	
Photograph method	461	477 (226-575)	
Total (n=32)			.11[a]
MyFood	1157	1039 (556-1541)	
Photograph method	1102	951 (446-1495)	
Day 2			
Breakfast (n=29)			.74[a]
MyFood	400	374 (223-527)	
Photograph method	407	367 (175-630)	
Lunch (n=20)			.02[a]
MyFood	454	501 (258-608)	
Photograph method	394	418 (245-514)	
Dinner (n=20)			.01[a]
MyFood	489	413 (134-820)	
Photograph method	425	368 (105-696)	
Total (n=29)			.009[a]
MyFood	1050	928 (380-1876)	
Photograph method	972	957 (308-1720)	
Protein (g)			
Day 1			
Breakfast (n=28)			.02
MyFood	16.2	13.5 (6.4-23.5)	
Photograph method	18.2	14.3 (6.9-27.7)	
Lunch (n=27)			.001
MyFood	13.0	10.0 (8.0-18.0)	
Photograph method	14.6	13.1 (7.8-20.2)	
Dinner (n=27)			.22
MyFood	15.2	14.5 (3.0-20.5)	
Photograph method	16.8	14.3 (6.1-22.8)	
Total (n=32)			.046
MyFood	38.0	35.0 (17.4-45.6)	

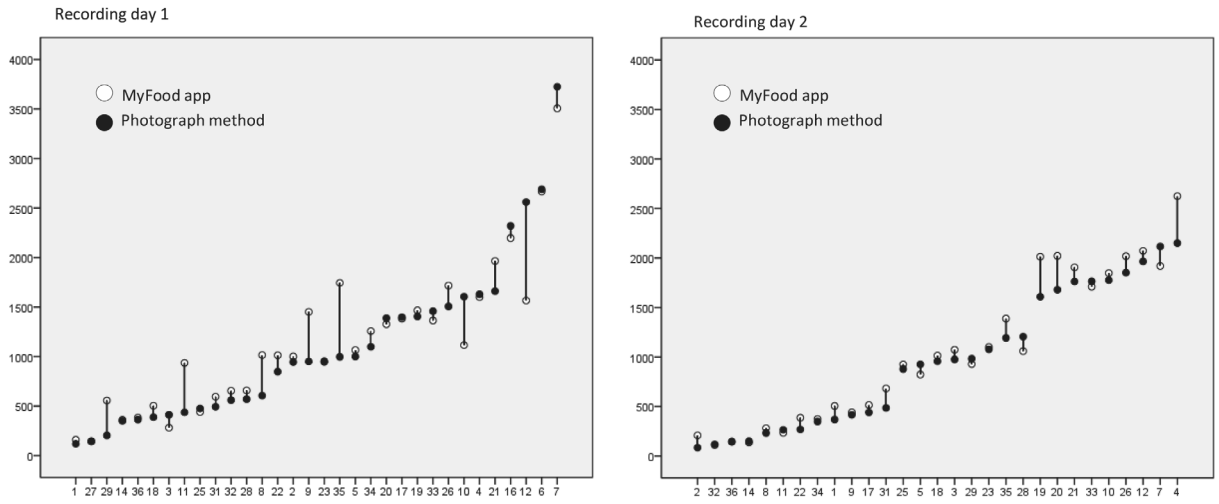
Energy, protein and liquid	Mean	Median (25-75 percentile)	*P* value
Photograph method	42.2	38.4 (14.0-62.1)	
Day 2			
Breakfast (n=29)			<.001
MyFood	14.1	11.0 (5.0-19.8)	
Photograph method	16.1	15.8 (5.7-22.0)	
Lunch (n=20)			.31
MyFood	14.2	13.3 (5.9-20.3)	
Photograph method	12.9	11.5 (7.8-16.7)	
Dinner (n=20)			.97
MyFood	17.6	15.3 (5.3-30.4)	
Photograph method	17.6	16.5 (3.9-28.7)	
Total (n=29)			.15
MyFood	36.1	28.0 (8.5-61.5)	
Photograph method	37.1	34.6 (9.1-61.4)	
Liquid (ml)			
Day 1			
Breakfast (n=28)			.02
MyFood	292	272 (158-412)	
Photograph method	339	320 (202-466)	
Lunch (n=27)			.72
MyFood	287	256 (194-409)	
Photograph method	285	257 (159-374)	
Dinner (n=27)			.33
MyFood	336	304 (189-304)	
Photograph method	332	326 (222-445)	
Total (n=32)			.71
MyFood	781	696 (479-1047)	
Photograph method	808	643 (461-1227)	
Day 2			
Breakfast (n=29)			.97
MyFood	301	287 (169-429)	
Photograph method	303	312 (162-435)	
Lunch (n=20)			.87
MyFood	275	251 (142-405)	
Photograph method	260	256 (154-345)	
Dinner (n=20)			.06
MyFood	311	269 (84-540)	
Photograph method	273	245 (58-487)	
Total (n=29)			.11
MyFood	706	587 (313-1077)	
Photograph method	670	559 (318-1029)	

[a]Differences between MyFood and the photograph method for the breakfast, lunch and dinner meal. The totals of these meals are tested with Wilcoxon Signed Rank test separately for each recording day.

Table 3. Proportions with 90% and 80% agreement between MyFood and the photograph method in estimated intake of energy, protein, and liquids.

Energy, protein and liquid	Percent agreement	
	90%	80%
Day 1		
Energy		
Total (n=32)	47	69
Breakfast (n=28)	46	79
Lunch (n=27)	48	59
Dinner (n=27)	30	52
Protein		
Total (n=32)	44	66
Breakfast (n=28)	32	64
Lunch (n=27)	44	74
Dinner (n=27)	19	41
Liquids		
Total (n=32)	53	63
Breakfast (n=28)	39	68
Lunch (n=27)	48	63
Dinner (n=27)	26	44
Day 2		
Energy		
Total (n=29)	55	76
Breakfast (n=29)	45	66
Lunch (n=20)	40	55
Dinner (n=20)	25	50
Protein		
Total (n=29)	48	83
Breakfast (n=29)	52	69
Lunch (n=20)	35	55
Dinner (n=20)	40	50
Liquids		
Total (n=29)	59	72
Breakfast (n=29)	52	69
Lunch (n=20)	45	65
Dinner (n=20)	45	55

Figure 6. Drop plots illustrating individual intake of energy recording day 1 (n=32) and recording day 2 (n=29). Y-axis represents energy intake (kcal). X-axis represents participant number ranged with increasing energy intake according to the photograph method. Equal energy intake from app and photograph observations is presented with only black dots.



Estimations of Food Intake in MyFood Compared to the Photograph Method on Individual Level

Table 5 shows the percentage of the participants who had 90 and 80 percent agreement between their recordings in MyFood compared to the photograph method within food groups. Egg was the food group with the best agreement between MyFood and the photograph method with the majority of the estimations ≥90% agreement. The food groups with the lowest agreement were fruit and vegetables. The agreement between the methods increased from day 1 to day 2 for bread and cereals, spreads, egg, yogurt, soup, hot dishes, and desserts.

Estimated bread and cereal consumption was, in most cases, higher in MyFood compared to estimations from the photograph method (Multimedia Appendix 4). On average for the two days, about 60% of the participants had less than 20% disagreement in estimated bread and cereal intake between the two methods, and about 25% had less than 10% disagreement (Table 5).

Recordings of spreads tended to be lower in MyFood compared to the photograph method when the intake increased (Multimedia Appendix 4). About 70% of the participants had less than 20% disagreement between MyFood and the photograph method in estimated intake of spreads on day 2, compared to 50% on day 1 (Table 5).

The food group with the largest deviations between the methods was hot dishes. The discrepancies were highest the first day (Multimedia Appendix 5). About 30%-40% of the participants had ≥80% agreement between the methods (Table 5).

On average for the two days, about 70% of the participants had less than 20% disagreement in estimated intake of cold beverages between the two methods, and about 50% had less than 10% disagreement (Table 5). No particular pattern in discrepancies of cold beverages between the methods was seen (Multimedia Appendix 5).

Omitted Food Items in MyFood Recordings Compared to the Photograph Method

The number of food and beverage items recorded in MyFood and observed from photographs was calculated (Multimedia Appendices 6 and 7). The first day the number of medical nutrition drinks, cheese, fish-based spreads, and meat-based spreads recorded had 100% matches between the methods (Multimedia Appendix 6). The second day 100% matches were found for the recordings of hot dishes, medical nutrition drinks, vegetables, and meat-based spreads (Multimedia Appendix 7). Butter, margarine, and mayonnaise (27% omissions both days), fruit (27% omissions on day 1), vegetables (28% omissions on day 1), yogurt (27% omissions on day 2) and meal condiments (29% omissions on day 1, 33% omissions on day 2) were the food groups most often omitted among participants (Multimedia Appendices 6 and 7). Five participants had duplicate recordings of some meal components the first day and one participant the second day.

Patients' Experiences Using the MyFood App

Ninety percent of the participants reported that MyFood was easy to use. All but one (97%) of the participating patients found the app easy to navigate in. Most of the patients (87%) experienced to record correct amount of foods and beverages. Thirteen percent had to acquire new knowledge to use the app. Seventy-one percent reported to be become more aware of the amount of foods and beverages needed, after using MyFood.

Table 4. Food and beverage intake (grams) recorded in MyFood and estimated in the photograph method. Significant *P* values (<.05) are in italics.

Food and beverages	MyFood (grams)		Photograph methods (grams)		*P* value[a]
	Median (25-75 percentile)	Mean (SD)	Median (25-75 percentile)	Mean (SD)	
Day 1					
Bread and cereals (n=23)	110 (50-180)	134 (106)	93 (44-150)	110 (80)	*<.001*
Spreads[b] (n=22)	72 (22-120)	77 (59)	89 (20-135)	90 (74)	.17
Egg (n=11)	56 (56-72)	61 (34)	56 (56-96)	68 (29)	.18
Yogurt (n=9)	150 (100-223)	154 (81)	190 (101-292)	186 (94)	.09
Cold beverages (n=30)	350 (200-463)	360 (216)	400 (203-534)	383 (185)	.35
Hot beverages (n=9)	200 (149-350)	244 (147)	200 (145-394)	261 (175)	.24
Oral nutritional supplements (n=3)	200 (0-400)	200 (200)	200 (150-400)	250 (132)	.32
Soup (n=9)	225 (225-270)	235 (114)	202 (147-307)	219 (119)	.37
Hot dishes (n=20)	217 (0-419)	222 (212)	238 (80-344)	245 (165)	.58
Desserts (n=12)	58 (10-80)	49 (32)	57 (27-78)	63 (50)	.86
Fruit (n=10)	30 (0-94)	44 (49)	91 (57-148)	101 (47)	*.04*
Vegetables[c] (n=10)	35 (5-60)	51 (64)	60 (38-103)	76 (50)	.18
Day 2					
Bread and cereals (n=24)	83 (40-159)	100 (67)	72 (30-137)	86 (62)	*<.001*
Spreads[b] (n=17)	44 (23-60)	56 (47)	54 (24-81)	64 (50)	.13
Egg (n=8)	56 (50-56)	67 (60)	56 (50-56)	68 (59)	.32
Yogurt (n=8)	150 (75-150)	118 (63)	145 (90-170)	131 (50)	.78
Cold beverages (n=25)	300 (200-600)	362 (247)	335 (183-559)	358 (239)	.88
Hot beverages (n=9)	200 (170-300)	221 (133)	182 (112-282)	192 (124)	.16
Oral nutritional supplements (n=3)	125 (50-225)	135 (96)	200 (220-225)	210 (22)	.11
Soup (n=5)	135 (0-225)	117 (113)	111 (79-226)	144 (80)	.35
Hot dishes (n=14)	390 (74-425)	296 (221)	329 (150-384)	296 (142)	.62
Desserts (n=11)	80 (55-80)	75 (42)	55 (45-126)	80 (54)	.77
Fruit (n=6)	13 (0-98)	43 (61)	63 (55-104)	80 (46)	.09
Vegetables[c] (n=10)	13 (0-71)	36 (47)	13 (0-71)	36 (18)	.88

[a]Differences between the methods are tested with Wilcoxon Signed Rank test.

[b]Includes butter/margarine/mayonnaise, sugary-based spreads, meat-based spreads, mayonnaise-based spreads, fish-based spreads, and cheese.

[c]Does not include vegetables as part of hot dishes.

Table 5. Proportions with 90% and 80% agreement between MyFood and the photograph method in estimated intake within food groups.

Food and beverage items	Percent agreement	
	90%	80%
Day 1		
Bread and cereals (n=23)	22	57
Spreads[a] (n=22)	23	50
Egg (n=11)	82	82
Yogurt (n=9)	33	67
Cold beverages (n=30)	57	77
Hot beverages (n=9)	44	67
Oral nutritional supplements (n=3)	67	67
Soup (n=9)	22	56
Hot dishes (n=20)	15	30
Desserts (n=12)	8	42
Fruit (n=10)	10	20
Vegetables[b] (n=10)	20	40
Day 2		
Bread and cereals (n=24)	29	63
Spreads[a] (n=17)	53	71
Egg (n=8)	88	88
Yogurt (n=8)	50	75
Cold beverages (n=25)	44	68
Hot beverages (n=9)	44	67
Oral nutritional supplements (n=3)	67	67
Soup (n=5)	40	60
Hot dishes (n=14)	14	36
Desserts (n=11)	27	55
Fruit (n=6)	0	17
Vegetables[b] (n=10)	10	20

[a]Includes butter/margarine/mayonnaise, sugary-based spreads, meat-based spreads, mayonnaise-based spreads, fish-based spreads, and cheese

[b]Does not include vegetables as part of hot dishes.

Discussion

Principal Findings

The MyFood app is developed for use among hospitalized patients at nutritional risk. According to the Norwegian Safety Program: "In Safe Hands" [31] all patients at nutritional risk should have a nutritional assessment, including dietary recording to compare intake against individual needs of energy, protein, and liquids. Further, nutrition-related measures should be performed and an individual nutrition plan created, before performing a reassessment after 3 days [31]. We found that 60%-80% of the participants had less than 20% disagreement between estimated intake of energy, protein, and liquids in MyFood and the photograph method. The agreement between the methods was higher the second recording day, compared to the first, and for the breakfast and lunch meal compared to the dinner. Recorded consumption of bread and cereals was higher in MyFood compared to the photograph method both days. Spreads; particularly butter, margarine, and mayonnaise, fruit, vegetables, and meal condiments were the food groups most often omitted by the patients. The majority of the patients rated MyFood as easy to use.

To our knowledge, no similar study has been conducted in patients to allow direct comparison of results.

The Accuracy of MyFood's Estimations of Energy, Protein, and Liquid on Group Level

Even though the main objective of the study was to evaluate recorded intake in MyFood on the individual level, estimated intake on the group level was analyzed to investigate if overall

disagreement was present. The median total energy intake was not different between the methods the first recording day, however, a lower median intake in MyFood compared to the photograph method was found the second day. Underestimation of energy intake is often seen in validation studies of self-reporting dietary assessment tools among healthy adults [32] and among hospitalized patients [33]. This is also found for technology-based records [34,35]. MyFood's target population is patients at nutritional risk who often have reduced food intake compared to needs [16]. Intentional underreporting of food intake may not be as relevant for our target population compared to healthy populations.

Median recorded protein intake was lower in MyFood compared to estimations from the photograph method in total, for breakfast, and for lunch recording day 1, and for breakfast recording day 2. This deviates from results in other validation studies on electronic dietary assessment tools. Raatz and coworkers [36] and Fukuo and colleagues [37] did not find a different recording of protein intake among healthy subjects in a personal digital assistant and a Web app, compared to 24-hour dietary recall and paper-based food records, respectively. Sliced bread with different types of spreads typically constitutes Norwegian breakfast and lunch meals, also in hospitals. Half of the participants had up to 20% disagreement in consumption of spreads between MyFood and the photograph method, and the individual drop-plots demonstrated that MyFood estimated lower intake of spreads compared to the photograph method for several participants on day 1. Spreads are often a protein source in bread-based meals. The agreement between the methods in intake of spreads was better the second day.

Recorded liquid intake in MyFood showed generally good agreement with the photograph method. However, recorded intake to the breakfast meal the first day was significantly lower compared to the photograph method. Several of the participants consumed both cold and hot beverages for the breakfast meal. This may have increased the chance of not remember to record all types of beverages consumed.

The Accuracy of MyFood's Estimations of Energy, Protein, and Liquid on Individual Level

The main aim of the present study was to evaluate MyFood's ability to estimate the patients' dietary intake on an individual level. This contrasts most other validation studies which focus on mean intake on group level and cross-classification, but not on absolute intakes. We evaluated MyFood compared to the photograph method for two separate days. A comparison of one-day and three-day calorie counts to estimate dietary intake by Breslow and Sorkin [38] suggested that 1-day calorie counts may be a valid alternative to the more labor-intensive 3-day count commonly performed in hospitalized patients. Førli and coworkers argue, however, that one day may be too short to estimate dietary intake among hospitalized patients [33]. The MyFood app is intended for use over several days, to follow-up dietary intake. This is in line with the common recommendation at Oslo University Hospital of using paper-based dietary assessment forms on a daily basis for patients at nutritional risk. The dietary recording in MyFood is more detailed than the paper-based forms used today by including a higher differentiation between type of meals and meal items. MyFood also includes more alternatives for portion sizes and provides the possibility to only record components of composite dishes. By these means there are reasons to assume that MyFood will provide a higher accuracy of the patient's diet than the paper-based forms, if used correctly.

The individual drop-plots presented in the present study showed an overestimation of energy intake in MyFood, compared to the photograph method for some participants and underestimation for others. An explanation may be that both duplicate recordings and omissions of food items were observed. Five participants had duplicate recordings of some meal components the first day and one participant the second day. The largest discrepancies in energy intake between the methods on the individual level were found for the dinner meal the first day. This may be explained by inaccurate estimation of portion sizes for hot dishes. We found that several participants selected a full portion, even though not consuming a whole plate. The discrepancies in individual energy intake between the methods were wider the first recording day, and more coinciding the second day. We also observed fewer duplicate recordings in the app the second, compared to the first recording day. This may be due to a learning effect where the patients became more familiar with the app after one day of recording. A tendency to such a learning effect was observed in general in the evaluation study. A potential learning effect with the repeated use of a computerized dietary assessment tool was also found in a validation study among 41 adults with type 2 diabetes mellitus. The authors argued that the patients became more familiar with the website with repeated use [39].

We found a tendency to lower recorded protein intake in MyFood compared to the photograph method for participants with higher protein intake. This may be explained by the omission of typical protein-rich spreads with higher intakes due to recall bias. Cheese was omitted by three participants, ham by two participants, and egg by one participant. The second recording day the recorded protein intake in MyFood was more coinciding with the estimated protein intake in the photograph method.

Liquid consumption on individual level showed a tendency to increased deviations between MyFood and the photograph method among participants with a higher liquid intake. The first day the patient with the largest deviation had omitted both coffee and milk from the app recordings. The second day the intake recorded in MyFood was higher compared to the photograph method for some of the participants due to the recording of a full glass in the app, even though only consuming half or three-quarters of a full glass size.

The proportion of participants having less than 20% disagreement in MyFood and the photograph method was 69% for energy intake, 66% for protein intake, and 63% for liquid intake the first day, whereas the corresponding proportions were 76% for energy, 83% for protein and 72% for liquid intake the second day. This may be due to a learning effect as discussed above.

The Accuracy of MyFood's Estimation Within Food Groups

The majority of the food groups showed good agreement between MyFood and the photograph method on the group level. Good agreement in recording of food groups is consistent with findings from a validation study on a dietary assessment app for smartphones compared to repeated 24 h recall interviews [40] and Foodbook24; a Web-based dietary assessment tool [41]. The median intake of bread and cereals was higher in MyFood compared to the photograph method both recording days. Based on photograph observations and partial weighing this was found to be due to too large portion sizes of sliced bread and bread rolls in the app compared to the actual sizes served at the hospital. Recorded fruit intake was significantly lower in MyFood than consumption observed from photographs the first recording day. A possible explanation is that fruit intake was omitted by 27% of the participants on day 1. Medin and coworkers also found a high omission rate of fruits in a validation study among school children [30]. About 80% of the participants had more than 20% disagreement between estimated fruit consumption in MyFood and the photograph method both recording days. The majority of the participants' fruit consumption was preprepared fruit boxes with sliced fruits. Based on the photograph method including observations and partial weighing we found the fruit boxes in the app to be disproportionately lower than the size most often observed and weighed. Revision of portion sizes for bread and cereals, and fruit cups, will probably lead to more accurate recordings of these food groups in the MyFood app.

In the present study, some of the standard portion sizes of hot dishes included in MyFood seemed to be too large compared to actual size served to the patients. A full portion size in MyFood was based on information from the hospital kitchen at OUH, Rikshospitalet on how standard portion sizes should be constituted when served. The visibility and description of what constitutes a full portion size in MyFood (Figure 2) may not have been clear enough for the patient. Several patients may have assumed eating a whole standard portion if the plates seemed full. In addition, studies have shown that small portion sizes tend to be overestimated and large portion sizes to be underestimated [42,43], and the former may have occurred in our study.

Twelve percent of foods and beverages were omitted in MyFood the first day, and 11% the second day. The food group most often omitted both recording days was butter, margarine, and mayonnaise. When recording several types of spreads, butter and margarine are typically easy to forget. Spreads were found to be among the food items most often omitted in a validation study of a Web-based dietary assessment tool among 117 school children [30]. The omission of food items in meals consisting of several secondary ingredients, like sandwiches, has been argued to be more common than in less composite meals [44]. Frequent omission of margarine was also found by Førli and colleagues [33] in a validation study of a self-administered dietary assessment form among 45 patients at OUH, Rikshospitalet. Prompting of questions related to the use of butter/margarine will be included in the further development of MyFood.

Acceptance of Use by the Patients

The majority of the patients found MyFood easy to use and more than 70% became more aware of own nutritional needs. Electronic dietary assessment tools are generally well accepted and preferred over conventional methods among healthy subjects [46]. Our study population included patients ranging from 17 to 77 years with a mean age of 51 years. It is possible that use of an app for tablets is a larger barrier among older patients. However, qualitative studies among older persons have demonstrated that elderly persons often are positive to using tablets and eager to learn, even though cognitive deficits increase by age and low self-efficacy may limit the potential for use [47,48].

Strengths and Limitations

The development process of the MyFood app involved nurses and patients, which is considered an important strength. The evaluation of recorded dietary intake in MyFood was compared to observations from meal photographs. The photograph method is a validated tool for assessment of dietary intake, compared to weighed records [45,49]. In addition, we combined the photograph observations with partial weighing of meal components which probably strengthened the method. Our photograph method is associated with different measurement errors than the dietary assessment functionality in MyFood, which is also considered an important strength. In addition to validate the MyFood app with regard to the accuracy of dietary recording we also investigated the users' experiences with the tool. A recent scoping review on the use of technology in identifying hospital malnutrition highlighted the importance of establishing usability rating to determine the app's actual usefulness in practical settings [50].

A limitation of the study is that only dietary intake to breakfast, lunch, and dinner was evaluated. Energy consumption for the breakfast, lunch, and dinner meals together have been reported to account for 85% of patients' total intake [33]. By not including the total intake we do not know how accurate the dietary assessment function in MyFood estimate intake to snack meals, evening meals, and beverage intake in-between meals. Another potential limitation is that the patients knew that the researchers were taking photographs of their meals before and after consumption. This may have influenced their recording in the app by acting as a reminder. The evaluation study was performed among patients at a hematology and a gastrointestinal surgery department. We do not know whether our findings are representative for other groups of patients. The included patients were all sick, some quite severe. The presence of disease and fatigue may have influenced the precision of the recordings. MyFood is intended for use among patients at nutritional risk. Nutritional risk was, however, not an inclusion criterion in the present study, as we wanted to evaluate the app for patients with both small and larger food intake. Only patients with a certain food intake orally were included and we, therefore, do not know how the dietary assessment function in MyFood measures the intake for patients with tube feeding or parenteral nutrition.

MyFood's Potential for Use as a Dietary Assessment Tool Among Hospitalized Patients at Nutritional Risk

Based on the results in the present evaluation study, we consider MyFood as having good potential for use as a dietary assessment tool among hospitalized patients at nutritional risk. MyFood may provide support to health care workers in their tasks related to the nutritional treatment of patients at nutritional risk. This support may contribute to prevent development of disease-related malnutrition among at-risk patients. Corrections of some of the portion sizes in the app and prompting related to use of butter/margarine and portion size of dinner may increase the accuracy of the app further. An evaluation study among other patient groups may be valuable to amplify the potential for use of MyFood in the hospital setting.

Conclusion

We have developed an app for tablets for use among hospitalized patients at nutritional risk. The app includes dietary assessment functionality for evaluation of patients' dietary intake compared to individual needs of energy, protein, and liquids. The recorded intake of energy, protein, and liquids in MyFood showed good agreement with the photograph method for the majority of the participants. The app's ability to estimate intake within food groups was good, except for bread and cereals which were overestimated, and fruit which was underestimated. MyFood was well accepted among the study participant and has the potential to be a dietary assessment tool for use among patients in clinical practice.

Acknowledgments

The development of the MyFood app was performed on the TSD facilities, owned by the University of Oslo, operated and developed by the TSD service group at the University of Oslo, IT-Department.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Selected screenshots from the MyFood app.

[MP4 File (MP4 Video), 4MB-Multimedia Appendix 1]

Multimedia Appendix 2

Drop plots illustrating individual intake of protein recording day 1 (n=32) and recording day 2 (n=29). Y-axis represents protein intake (grams). X-axis represents participant number ranged with increasing protein intake according to the photograph method. Equal protein intake from app and photograph observations is presented with only black dots.

[PNG File, 177KB-Multimedia Appendix 2]

Multimedia Appendix 3

Drop plots illustrating individual intake of liquid recording day 1 (n=32) and recording day 2 (n=29). Y-axis represents liquid intake (grams). X-axis represents participant number ranged with increasing liquid intake according to the photograph method. Equal liquid intake from app and photograph observations is presented with only black dots.

[PNG File, 190KB-Multimedia Appendix 3]

Multimedia Appendix 4

Drop plots illustrating individual intake of bread and cereals, and spreads recording day 1 and recording day 2. The Y-axis represents grams of food item. X-axis represents participant number ranged with increasing intake according to the photograph method. Equal food intake from app and photograph observations is presented with only white dots.

[PNG File, 316KB-Multimedia Appendix 4]

Multimedia Appendix 5

Drop plots illustrating individual intake of hot dishes and cold beverages recording day 1 and recording day 2. The Y-axis represents grams of food or beverage item. X-axis represents participant number ranged with increasing intake according to photograph observations. Equal food intake from app and photograph observations is presented with only white dots.

[PNG File, 308KB-Multimedia Appendix 5]

Multimedia Appendix 6

Number of food and beverage items observed from photographs and recorded in MyFood the first recording day. One item means one type of food or beverage in each meal.

[PNG File, 63KB-Multimedia Appendix 6]

Multimedia Appendix 7

Number of food and beverage items observed from photographs and recorded in MyFood the second recording day. One item means one type of food or beverage in each meal.

[PNG File, 69KB-Multimedia Appendix 7]

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Abbreviations

BMI: body mass index
IOR: interobserver reliability
NPR: Norwegian patient registry
OUH: Oslo University Hospital
TSD: services for sensitive data
USIT: University Center for Information Technology

Edited by G Eysenbach; submitted 27.01.18; peer-reviewed by A Rangan, N Unciano, M Boaz; comments to author 31.03.18; revised version received 03.05.18; accepted 08.05.18; published 07.09.18

Please cite as:
Paulsen MM, Hagen MLL, Frøyen MH, Foss-Pedersen RJ, Bergsager D, Tangvik RJ, Andersen LF
A Dietary Assessment App for Hospitalized Patients at Nutritional Risk: Development and Evaluation of the MyFood App
JMIR Mhealth Uhealth 2018;6(9):e175
URL: http://mhealth.jmir.org/2018/9/e175/
doi: 10.2196/mhealth.9953
PMID: 30194059

Paper 2:

Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study.

2

Original Paper

Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study

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Abstract

Background: Disease-related malnutrition is a challenge among hospitalized patients. Despite guidelines and recommendations for prevention and treatment, the condition continues to be prevalent. The MyFood system is a recently developed decision support system to prevent and treat disease-related malnutrition.

Objective: To investigate the possible implementation of the MyFood system in clinical practice, the aims of the study were (1) to identify current practice, routines, barriers, and facilitators of nutritional care; (2) to identify potential barriers and facilitators for the use of MyFood; and (3) to identify the key aspects of an implementation plan.

Methods: A qualitative study was performed among nurses, physicians, registered dietitians, and middle managers in 2 departments in a university hospital in Norway. Focus group discussions and semistructured interviews were used to collect data. The Consolidated Framework for Implementation Research (CFIR) was used to create the interview guide and analyze the results. The transcripts were analyzed using a thematic analysis.

Results: A total of 27 health care professionals participated in the interviews and focus groups, including nurses (n=20), physicians (n=2), registered dietitians (n=2), and middle managers (n=3). The data were analyzed within 22 of the 39 CFIR constructs. Using the 5 CFIR domains as themes, we obtained the following results: (1) Intervention characteristics: MyFood was perceived to have a relative advantage of being more trustworthy, systematic, and motivational and providing increased awareness of nutritional treatment compared with the current practice. Its lack of communication with the existing digital systems was perceived as a potential barrier; (2) Outer settings: patients from different cultural backgrounds with language barriers and of older age were potential barriers for the use of the MyFood system; (3) Inner settings: no culture for specific routines or systems related to nutritional care existed in the departments. However, tension for change regarding screening for malnutrition risk, monitoring and nutritional treatment was highlighted in all categories of interviewees; (4) Characteristics of the individuals: positive attitudes toward MyFood were present among the majority of the interviewees, and they expressed self-efficacy toward the perceived use of MyFood; (5) Process: providing sufficient information to everyone in the department was highlighted as key to the success of the implementation. The involvement of opinion leaders, implementation leaders, and champions was also suggested for the implementation plan.

Conclusions: This study identified several challenges in the nutritional care of hospitalized patients at risk of malnutrition and deviations from recommendations and guidelines. The MyFood system was perceived as being more precise, trustworthy, and

motivational than the current practice. However, several potential barriers were identified. The assessment of the current situation and the identification of perceived barriers and facilitators will be used in planning an implementation and effect study, including the creation of an implementation plan.

(JMIR Form Res 2019;3(2):e11890) doi: 10.2196/11890

KEYWORDS

malnutrition; implementation science; eHealth; qualitative research; decision support systems, clinical

Introduction

Disease-related malnutrition is a challenge in hospitals, with 30% to 50% of patients being malnourished or at risk for malnutrition [1-5]. The condition leads to higher morbidity and mortality rates among patients [5-8] and longer length of stay [6,9,10]. This generates increased economic costs for the health care sector [7,10,11]. According to Norwegian [12] and European [13] guidelines, all patients at malnutrition risk should have an individualized nutrition care plan, including documentation of nutritional status, needs, dietary intake, and recommended treatment. The reported barriers to adequate nutritional care for hospitalized malnourished patients include the absence of routines [14,15], lack of knowledge, assignment of responsibility [16], and lack of skills and tools to estimate individual dietary needs and the energy and protein content in hospital food [14,17].

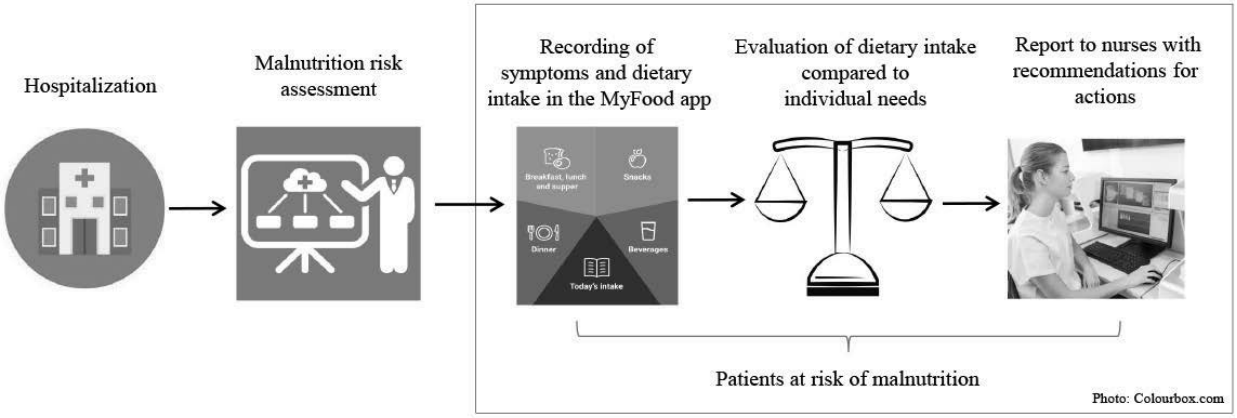
Studies have shown that hospitals can benefit from implementing technology to identify, handle, and follow up with patients at risk of malnutrition. Digital tools and apps may reduce the workload of health care professionals and the time spent for nutritional assessment [18].

We developed the *MyFood* tool, a decision support system for use among hospitalized patients at risk of malnutrition. The MyFood system includes an app for tablets and a website. Figure 1 shows the intended use of the MyFood system.

A consistent finding in clinical and health services research is the failure to translate evidence into practice [19]. The implementation of electronic health (eHealth) interventions is often challenging, with many failing to demonstrate predicted benefits [20]. For implementation to succeed, it is recommended that the readiness for implementation be assessed and the barriers and facilitators be identified in advance [21]. Theoretical frameworks may guide this assessment. The Consolidated Framework for Implementation Research (CFIR) [22] is widely used to identify barriers and facilitators [23-26].

To obtain a better understanding of how to implement the MyFood system in clinical hospital practice and to be able to create an implementation plan, we performed a qualitative study among health care professionals. The specific aims were (1) to identify current practice, routines, barriers, and facilitators for nutritional care; (2) to identify potential barriers and facilitators for the use of a decision support system (MyFood); and (3) to identify the key factors for an implementation plan.

Figure 1. Patient flow from hospitalization, identification of malnutrition risk, and use of the MyFood system.



Methods

This study is part of a research project involving the development and evaluation of a decision support system to prevent and treat disease-related malnutrition as a proof of concept. The MyFood intervention will be implemented in the hospital departments in a randomized controlled trial after this study is completed.

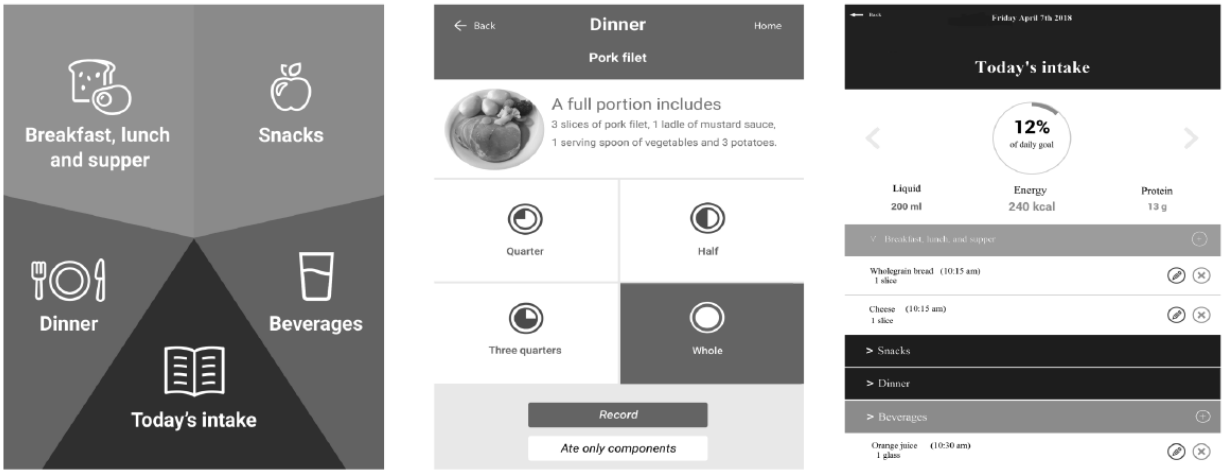
The MyFood System

The MyFood system is developed in response to an identified need for better tools to follow up with patients who suffer from disease-related malnutrition. The functions and content of the tool are based on the Norwegian guidelines for prevention and treatment of disease-related malnutrition [12], the Norwegian Directorate of Health recommendations on nutrition in health and care services [27], and the recommended tasks included in the focus area of disease-related malnutrition in the Norwegian Patient Safety Program [28]. According to the patient safety program, 4 tasks are necessary to prevent and treat disease-related malnutrition in hospitals: (1) screening for risk of malnutrition; (2) dietary assessment; (3) nutritional treatment; and (4) documentation [28]. Hence, MyFood does not provide new tasks for health care professionals but intends to provide a system to perform and follow the guidelines and recommendations available.

The MyFood system consists of 4 modules: module 1, collection of information about the patient (body weight, height, nutrition-related symptoms, nutritional situation, and allergies); module 2, dietary assessment function; module 3, evaluation of recorded dietary intake compared with individual needs for energy, protein, and liquids; and module 4, report function, including recommendations for nutrition-related actions tailored to the individual patient and a template for a nutrition care plan. Figure 2 illustrates the dietary assessment and evaluation functions (modules 2 and 3) of the app. The patients record their daily dietary intake in the app. If the patient is unable to record, the nurses perform the recording on behalf of the patient. Both patients and health care professionals may keep track of the evaluation in module 3. The development of the MyFood app (modules 1 to 3) and evaluation of the dietary assessment function are described in a previous study [29]. The report function (module 4) is intended for use by nurses or other health care professionals to monitor and follow up on a patient's nutritional status and treatment. Module 4 is a website where the nurses gain access and retrieve information about patients by logging into the system.

The MyFood system was externally developed in cooperation with selected hospital departments. The managers of the hospital departments were involved in the structural issues and facilitated the research project. Nurses, registered dietitians, and patients participated in the development of the design, content, usability, and functionality [29].

Figure 2. Dietary assessment in the MyFood app and evaluation of dietary intake compared with individual needs.



Study Design and Participants

We conducted a qualitative study among health care professionals from 2 departments at a university hospital in Norway. The data collection period was January to February 2018. The study was based on 4 focus group discussions and 7 individual interviews. The health care professionals were purposively selected for the focus group discussions and interviews.

The study was performed in accordance with the Helsinki declaration and was acknowledged by the Norwegian Regional Ethical Committee (2016/1464). Written informed consent was obtained from all participants.

The Consolidated Framework for Implementation Research Framework as a Basis for the Interview Guide

The CFIR is a compilation of 39 constructs related to implementation and divided into 5 domains: characteristics of the intervention, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. These constructs can be considered when identifying local barriers to implementation [22]. According to Damschroder et al [22], researchers may select the constructs from the CFIR that are most relevant for their study setting. In this study, the 39 constructs of the CFIR [22] were explored and used to develop a semistructured interview guide. A total of 13

constructs were considered relevant for the context, and open-ended questions based on these were included. The interview guide was adapted for different groups of health care professionals to adjust for relevant differences in roles or tasks. For example, the construct regarding structural characteristics in the outer setting domain was only addressed to middle managers. Not all the CFIR constructs were considered relevant. For example, several of the constructs related to the process and the outer setting domains were not included. This study was a preimplementation study, and at this stage, we were most interested in the local factors in the 2 hospital departments to be able to set the performance goals of an implementation and effect study and to develop an implementation plan. The interview guide included questions about the organization and the routines related to the food and nutritional care of the patients, including responsibility, management commitment, and challenges. Perceived barriers and facilitators for the use of the MyFood tool and for performing an intervention study in the departments were also included in the guide. During the focus group discussions and interviews, the MyFood app was demonstrated for the health care professionals.

Focus Group and Interview Procedure

The focus group discussions and individual interviews were conducted by the first author in a meeting room in the hospital department or at the interviewee's office. A secretary assisted the first author during the focus groups. The focus group discussions were 45 to 55 min long, and the individual interviews were 30 to 50 min long. Focus groups facilitate communication between participants [30] and were chosen as the method for nurses because they are engaged in the daily care of patients. Each focus group included 4 to 7 nurses. The first focus group discussion served as a pilot to test the interview guide. After the focus group discussion, the interviewees were asked for feedback on the structure and phrasing of questions as well as the focus group situation. The pilot focus group did not result in any fundamental changes to the interview guide and was therefore included in the main analysis. Individual interviews were performed among the middle managers, physicians, and registered dietitians for feasibility reasons.

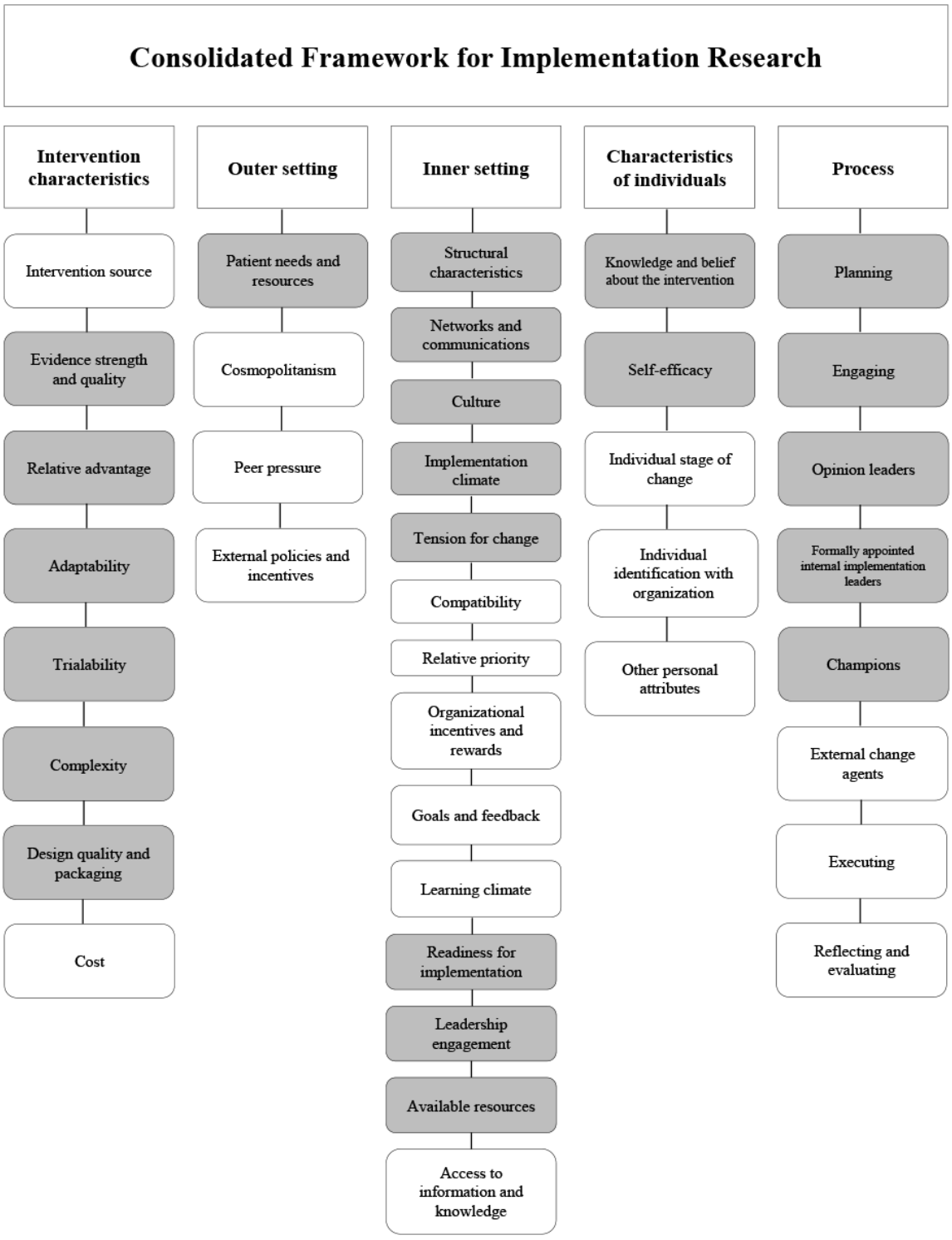
The focus group discussions and the individual interviews were recorded with a digital voice recorder (Olympus WS-853). A dictaphone app developed by the University Center for Information Technology at the University of Oslo (UiO) [31] was used as a backup. In addition, notes were taken immediately after each focus group and interview. The audio recordings were transcribed verbatim using the software f4transkript (Marburg).

Analysis

The transcripts and notes were analyzed using a thematic analysis in a stepwise manner as described by Braun and Clarke [32], using a deductive approach. The transcripts were analyzed using NVivo version 11 (QSR International). The first step in the analysis was to read through all the transcripts and take notes to obtain an overall understanding of the material. Second, initial codes were created as nodes based on the 5 domains in the CFIR framework and subnodes for the 39 CFIR constructs [22]. Some parts of the transcripts did not directly fit into any of the CFIR constructs, and in these cases, new codes were created. Phase 3 involved searching for themes. As we followed a deductive approach, based on the domains and constructs in the CFIR framework, the primary task here involved resorting and reevaluating the codes. The final step was the review process. The codes that did not fit into the CFIR framework were particularly evaluated and reconsidered. If they were found relevant, they were included in the current constructs. A total of 22 CFIR constructs were included in the analysis (Figure 3). The results described for the 22 CFIR constructs were reviewed and have been elaborated with regard to the specific study aims in the Discussion section.

To enhance trustworthiness [33], including credibility, confirmability, dependability, and transferability [34], the results were analyzed systematically in a stepwise manner. This included the following: involving all authors in the development of the interview guide and involving the first (MMP) and second (CV) authors in the development of the coding categories and the interpretation of the results; including different health care professionals in the interviews; and audio taping and transcribing the material verbatim.

Figure 3. Overview of the Consolidated Framework for Implementation Research. The analyzed data were sorted into 22 constructs (red boxes) for the assessment of current practices and the identification of barriers and facilitators. Data for the remaining constructs (white boxes) could not be obtained.



Results

Demographics

The focus group discussions included 20 nurses, with a mean age of 30 years and a range of 24 to 39 years. Table 1 shows the characteristics of the nurses in the 4 focus group discussions. The individual interviews included 2 physicians, 2 registered dietitians, and 3 middle managers. They were all female with a mean age of 39 years, ranging from 27 to 45 years.

Table 1. Characteristics of the nurses in the 4 focus group discussions.

Characteristic	FGD[a] 1 (n=4)	FGD 2 (n=4)	FGD 3 (n=7)	FGD 4 (n=5)
Gender (n)				
Male	1	1	0	0
Female	3	3	7	5
Age (years)				
Mean	32	27	29	31
Range	26-39	26-30	25-38	25-36
Experience (n)				
<4 years	0	3	2	1
≥4 years	4	1	5	4

[a]FGD: focus group discussion.

Table 2. Potential barriers and facilitators for use of the MyFood system, identified in stakeholder focus group discussions and semistructured interviews.

CFIR[a] domain	Barriers	Facilitators
Intervention characteristics	Lack of automatic transfer to the electronic patient record; Hygienic aspects of using tablet computers among the patients; Potentially demotivational for patients who strive to meet their dietary needs	More trustworthy, systematic, fun, and easy to use than the current practice; May increase awareness on nutritional care and treatment; Positive attitudes among health care providers to test the MyFood tool in an intervention study; Intuitive, neat, and user-friendly design
Outer setting	Lack of current routines for screening for malnutrition risk; Nurses' perceptions of nagging patients regarding food intake; Different cultural backgrounds among patients; Language barriers among non-native patients; Patients fasting before surgery or medical examinations; Elderly patients not familiar with tablet computers	Potentially earlier implementation of nutritional treatment among the patients; Empowerment of patients in the recording of dietary intake
Inner setting	Ambiguity among health care providers who have the primary responsibility for nutritional care and treatment; Prejudices among some physicians regarding the role of nutrition in the treatment process; Diverging focus between different health care providers, which may confuse the patients; Lack of culture and specific routines for nutritional care; Weak foundation on nutritional care among management; Limited availability of computers to use the MyFood report function; Limited available time	High stability in the departments' staff of health care professionals; Good cooperation between health care professionals; Assumptions among nurses regarding the importance of nutrition; Desire among nurses for better tools for dietary assessment and follow-up; Potentially time saving if nurses do not have to do manual calculations of dietary intake themselves
Individual characteristics	—[b]	Perceived self-efficacy among nurses in the ability to use the MyFood tool.

[a]CFIR: Consolidated Framework for Implementation Research.

[b]Not applicable.

Identification of Barriers and Facilitators Using the Consolidated Framework for Implementation Research

The current practice with nutritional care, perceived barriers and facilitators for the use of the MyFood system, and the identified key aspects to include in an implementation plan are presented according to the 5 domains of the CFIR framework and subdivided into the relevant constructs (Figure 3).

The perceived barriers and facilitators for use of the MyFood system are summarized in Table 2.

Intervention Characteristics

Evidence strength and quality relates to stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes [22]. The interviewees acknowledged that the evidence-based recommendations forming the basis of the MyFood system were known and accepted. They claimed that several of the functions in the MyFood tool were already performed at the hospital departments, although in a more unstructured manner:

> *I think this is kind of the same, but gathered more in one place. And this [MyFood] provides a better overview.* [Registered dietitian]

Relative advantage is the stakeholders' perceptions of the advantage of implementing the intervention versus an alternative solution [22]. Most of the interviewees perceived the dietary assessment function in MyFood as easier, more trustworthy, systematic, and precise compared with the paper-based dietary

assessment forms currently in use. They also reported that MyFood could increase awareness of nutritional deficiencies and lead to the implementation of nutritional treatment at an earlier stage:

> *I think it's easier when you can trust it. [...] Then the physician will trust it more I think, that this is actually correct recorded, this is exactly what was eaten [...] Compared to using a form that you don't know is complete. Then it's easier to take action if you trust the recording. I think.* [Nurse]

The health care professionals' perceptions of the dietary recording in the app were that it would be more fun and motivational than traditional paper recordings and that the tool was better suited for the future:

> *You know, we are not spoiled with new, fun technical solutions in the healthcare system. So most of us think it's fun when something new arrives. Because it's fun to have a gadget, you know. I think people would suddenly regard it as fun to record food, compared to that form [the paper-based dietary recording form] for which you need to scratch your head to guess the calorie intake.* [Nurse]

Adaptability relates to the degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs [22]. The respondents gave feedback on how they perceived MyFood could fit into their existing work practice. A potential barrier was that MyFood does not communicate with the electronic patient record (EPR), which means that the health care professionals need to copy the information from the MyFood website and paste it into the EPR. However, suggestions for how to overcome this issue were proposed:

> *It's quite okay because we try to become paperless. And if we can just copy from that [MyFood] to the electronic journal. The dietary paper forms [paper-based dietary assessment forms used today] easily gets lost. This is like... It seems more secure.* [Nurse]

The hygienic aspects of using tablet computers among the patients were discussed, including patients with special considerations regarding infections. Several solutions for getting around this issue were suggested, for example, using a cover or plastic bag around the tablet computer.

Trialability is defined as the ability to test the intervention on a small scale in the organization and to be able to reverse course if warranted [22]. Attitudes to being part of an intervention study to test the MyFood system were positive. All groups of respondents reported being used to participate in clinical trials owing to having an ongoing study in the department at almost any time.

The complexity construct describes the perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, intricacy, and the number of steps required for implementation [22]. MyFood was perceived as easy to use and navigate. None of the interviewees reported that the tool seemed complex:

> *I'm technically retarded and even I think this seems okay.* [Nurse]

Design quality and packaging are defined as the perceived excellence in how the intervention is bundled, presented, and assembled [22]. The layout of the MyFood system was described by health care professionals as having a user-friendly, intuitive, and neat design. The possibility to record only the components of a dish, in addition to the proportion of portion size (Figure 2), was highlighted as an advantage. However, a few nurses mentioned that the illustration of the percent of achievement of energy, protein, and liquid intake compared with individual needs (Figure 2) could potentially be demotivational for some patients:

> *When you have only eaten 10% of your need, and feel that you have eaten a lot and that you'll never be able to achieve your goal.* [Nurse]

Outer Setting

The patient needs and resources construct concerns the extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization [22]. The health care professionals elaborated on current practices and whether screening for malnutrition risk was performed. Some routines with screening existed in one of the departments. In the other department, there were preconceptions that few of the patients eat and, therefore, they did not conduct routine malnutrition risk screening:

> *We haven't done that [screening for malnutrition] until now. We really expect that no one eats. We expect that they either become nauseous or the food tastes strange, after quite a short time. And we expect that everyone at some time point will start with TPN [total parenteral nutrition]. So I think we aren't good enough to..., you know, we know that we'll get there [TPN] in 4 days anyway, so there's no point to keep it going with ordinary food.* [Nurse]

The experience of nagging patients about food intake was highlighted by several nurses, middle managers, and registered dietitians:

> *[...] They [the patients] think we are whining too much about the food because they don't regard it as very important. You know, sick, reduced appetite, and all that...* [Nurse]

However, some patients were described as being very motivated and perceived the achievement of eating enough and being independent of total parenteral nutrition (TPN) or tube feeding as their ticket home from the hospital. Those patients were often classified as being the most resourceful and understanding of the importance of nutrition for their overall health status.

Barriers to good nutritional care include fasting before surgery and being transferred to other hospitals with loss of the opportunity to follow-up. Different cultural backgrounds or language barriers of patients were mentioned as other potential barriers. Older patients were identified as a group that could potentially have some challenges with dietary recording in the app, especially the elderly who are not used to smartphones or

tablets. However, most of the interviewees thought the elderly would be able to use the app after a short introduction:

> *I even think that elderly persons who are not so fond of technical gadgets would have understood this, you know.* [Nurse]

Inner Setting

The social architecture, age, maturity, and size of an organization constitute the structural characteristics construct [22]. Stability in the staff was described as being high. The 2 departments included in the study were organized differently. One was subdivided into groups, where each nurse belonged to one group taking care of patients in that specific group, whereas the physicians were rotating between the groups. This department also had group leaders organizing each of the groups, which was highlighted as being successful for the organization. The other department did not have any subdivision, and all nurses were potentially involved with all patients. The registered dietitians served the whole hospital, except for the children's department.

The networks and communication construct involves the nature and quality of social networks and the formal and informal communication within an organization [22]. The middle managers of the department that was subdivided into groups reported that the communication and social networks were stronger within specific groups; however, they all recognized each other as colleagues.

There was uncertainty among the interviewees about the primary responsibility for nutritional care of patients. The majority described nurses as having the primary responsibility:

> *It's mostly something the nurses try to talk about and assess. Ehm... but personally, I usually ask how things are going related to nutrition, and the nurses notify us how they [the patients] are doing with regard to food intake and digestion in general. [...] And we may contact the dietitian if we really need help, you know.* [Physician]

However, some respondents claimed that the physicians had formal responsibility for nutritional treatment, whereas the nurses took care of the day-to-day follow-up. Several nurses reported that they had to repeatedly remind the physicians about the prospect of tube feeding if the patient had no intake or very low intake.

The cooperation among nurses, physicians, and registered dietitians on the nutritional care of patients was, however, described as good in most cases. A diverging focus among the different groups of health care professionals was described among some of the nurses. This difference could potentially be confusing for patients:

> *It's like, the physiotherapists are concerned about one thing [eg, do not drink juice because of coughing and possibility to get it in the lungs], and the dietitians are concerned about another thing [eg, eating enough protein]. We [the nurses] try to keep the threads together, and then the others are never satisfied.* [Nurse]

Culture includes norms, values, and basic assumptions of a given organization [22]. The majority of the health care professionals expressed that nutrition has an important role in the overall course of the disease for the patient, but the middle managers reported that they had no culture for specific routines related to screening for malnutrition or nutritional care:

> *Maybe it's kind of based on what you feel, I don't think it's like it's done the same way for all... [...] I guess we aren't good enough to add something extra to the food or think about whole fat milk instead of fat-reduced milk, butter instead of... I guess it's like... there's no system I think. We could get very much better.* [Middle manager]

However, a positive shift with increased focus on nutrition had occurred recently. This included increased monitoring of food intake among malnourished or at-risk patients, use of medical nutrition drinks, and availability of food service hosts in the department's buffet kitchen. Whereas an increased focus on the importance of nutrition was mentioned by several respondents, others reported on the challenges still present, especially among the physicians:

> *The physicians, the surgeons, are often pretty far away from recognizing nutrition as part of the whole. So I guess that's a group who are a little more narrow-minded than the other physicians. But, it's understandable. When you are so highly specialized you focus on your thing.* [Registered dietitian]

Tension for change is the degree to which stakeholders perceive the current situation as intolerable or needing change [22]. A general tension for change with regard to screening for malnutrition risk, monitoring, and treatment was highlighted by all groups of health care professionals. A perception among nurses was that they should probably have taken action with regard to nutrition earlier:

> *I wonder how many times I have heard like "oh, but I have several kilos to take away, so it's no problem, it doesn't matter if I don't eat." Because they are used to the disease passing away after a week when they are sick, and then there is no big deal because I eat when I get better. So I think we... Maybe you let it go too far before we start pushing that food, you know.* [Nurse]

The respondents were positive about the MyFood intervention because they wanted better tools for dietary assessment and follow-up. The nurses find the paper-based dietary recording forms used today to be time-consuming and unprecise. Uncertainty regarding the purpose of using the dietary recording forms existed. For some patients, dietary recording forms were used to identify the amount the patients could eat by themselves to supplement the remaining nutritional requirement through TPN or tube feeding. In some cases, the registered dietitians used the form to create a nutrition care plan. Several respondents described that the number of calories calculated from the forms was noted in the patient's EPR, whereas others reported that this was only done in rare cases. They reported that the nurses working night shifts were supposed to perform the calorie calculations of the forms, but the compliance varied:

> *[...] I experience many patients having a dietary recording form lying on their nightstand that no one really... that has been lying there for several days, you know. And when the night shift replaces the form it's like "Oh, this is from last week."* [Nurse]

The readiness for implementation construct describes tangible and immediate indicators of organizational commitment to its decision to implement an intervention, including leadership engagement and available resources [22]. Leadership engagement is the commitment, involvement, and accountability of leaders and managers regarding the implementation [22]. Nutrition was described as having low priority in hospital management. None of the nurses or physicians was told by the management that nutrition should be prioritized:

> *Ehm... very seldom [signals from the management of nutrition focus]. This [nutrition] is seldom an issue from the management; at least as I have noticed.* [Physician]

A similar opinion was expressed by the middle managers. Nutrition was not a particular focus of the departments. The middle managers did not experience challenges regarding nutrition in their position between the nurses and top management:

> *No, I really think it works fine. Nutrition has so far been kind of a thing like anything else. It's something we're aware of, but maybe not enough. It constitutes a small part of all the challenges our patients have. But now that more focus has been set on nutrition, I feel that it's established in all parts. That the nurses are positive about it and also those above me.* [Middle manager]

Available resources are the level of resources dedicated for implementation and ongoing operations, including finance, training, education, physical space, and time [22]. A concern regarding the availability of computers to check the reports in the MyFood system and read through recommended measures was raised. Some nurses mentioned a lack of time as a potential barrier:

> *The only thing I can think of is of course time, you know. Because that's often a challenge in everything we do and all focus areas we're supposed to have.* [Nurse]

Others expressed that the MyFood system would be a time saver:

> *This would have saved us a lot of time–not having to do that calculation [manual calculation of nutritional content] yourself.* [Nurse]

Characteristics of Individuals

Knowledge and beliefs about the intervention involve individuals' attitudes and the value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention [22]. The health care professionals expressed, in general, a positive attitude toward the MyFood intervention and saw several potential advantages related to the system compared with the current practice. Self-efficacy is the individuals' belief in their own capabilities to execute courses of action to achieve implementation goals. The health care professionals expressed that they believed they would be able to use and follow up with MyFood.

Process

Planning is defined as the degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, with the consideration of the quality of those schemes or methods [22]. The interviewees were asked to elaborate on their thoughts on how to perform an intervention study in the departments, including how to engage the nurses to follow up on the intervention within their busy schedules. The importance of providing everyone with information and assigning responsibility was highlighted among the nurses. The lack of information and assignment of responsibility will potentially decrease motivation. As the nurses are shift workers, it might be challenging to reach all nurses:

> *I think it's important to inform absolutely everyone. Because we work in triple turrets many don't get information, especially those working night shifts, and then they don't see the importance of it maybe, because they haven't received the information we have gotten now. And that has a lot to do with motivation, because if you haven't received information and don't know why we are doing it, then no one cares. So I think it's very important to inform absolutely everyone who is going to take part, you know.* [Nurse]

Concrete examples of suggestions received were communicating information during morning meetings, increasing the night shift by an extra 30 min at the end of the shift, or requiring the nurses to arrive half an hour before the shift to reach all nurses working on all 3 shifts. Email communication was not recommended, as many nurses do not read their emails daily. Availability and daily visits to the department, including assistance and follow-up, were suggested. The possibility for nurses to call if they have questions was also recommended.

Engaging involves attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities [22]. Opinion leaders are individuals in an organization who have a formal or informal influence on the attitudes and beliefs of their colleagues with regard to implementing the intervention [22]. The physicians were described by some of the nurses as filling such an opinion leader role. However, not all nurses had this impression. Some claimed that some authorities among the nurses were more important as opinion leaders than the physicians. Group leaders and nurses with developmental responsibility were suggested as important to fill the position of implementation leaders. Nurses on the night shift were also suggested as key personnel, as they have the task of summarizing daily nutritional intake. Others expressed that a criterion for success was to assign the same responsibility to all nurses in the department. Group leaders and nurses with developmental responsibility were seen as potential champions to support and drive the implementation. Creating superusers

with more experience who may inspire and help other nurses was also suggested.

Discussion

Principal Findings

This study used the CFIR framework [22] to identify current practices related to nutritional care in 2 departments in a university hospital in Norway. Perceived barriers and facilitators for the use of the MyFood system were assessed, and key aspects for an implementation plan were discussed. Screening for malnutrition risk was not prevalent or established as a routine in these departments. Dietary assessment and monitoring varied, as the nurses considered current procedures as being time- and resource-demanding. The use of the MyFood system was perceived as easier, more trustworthy, precise, fun, timesaving, and potentially facilitating increased awareness and implementation of nutritional treatment compared with the current practice. Cultural and language barriers, age of the patient, hygiene, availability of computers, time, and lack of interaction with EPRs were identified as potential barriers for use.

Current Nutritional Care Practices

To explore how the MyFood system may be utilized in a hospital setting, it was important to obtain information on the current practices related to nutritional care. Despite national and European guidelines for screening for malnutrition risk [12,13], this was not routinely performed in the 2 departments (CFIR: Culture). This corresponds with results from Eide et al [14]. A recent scoping review on the use of technology to identify hospital malnutrition revealed malnutrition in the acute hospital setting to largely be an unrecognized problem, owing to insufficient monitoring, identification, and assessment of malnourished patients [18]. We emphasized a general tension for changing nutritional care practice among all the health care professional groups investigated. For the purpose of planning the upcoming implementation and effect study in the MyFood project, it is important to be aware that screening for malnutrition risk is not routinely performed. In this study, some of the interviewees mentioned that a screening procedure was now being implemented as part of the Norwegian Patient Safety Program [28].

Dietary recording among patients at risk of malnutrition was performed to some extent, and all interviewees seemed to be aware of this practice. However, dietary recordings were seldom followed up and the forms were frequently forgotten on the patient's nightstand. A recent study at Oslo University Hospital based on the nutritionDay survey identified that only 41% of patients at malnutrition risk received nutritional treatment [1]. Several challenges with the current practice of using paper-based forms were described. The nurses in this study found it difficult to calculate the patients' intake of energy, and they described the hospital food lists as containing too few details. This is in line with previous findings in which Eide et al [14] identified nurses to be uncertain about how to evaluate nutritional status, estimate nutritional needs, and measure energy and nutrient intake among hospitalized patients. An Australian study showed that poor knowledge of the nutrition care processes among nondietetic staff was a barrier to nutritional care of elderly hospitalized patients [17]. A lack of knowledge on nutritional treatment and follow-up has been reported as an important barrier to nutritional care among physicians and nurses in Scandinavian hospitals [16,35].

We did not reveal significant differences in the responses between the different groups of health care professionals. As described in the results for the networks and communication construct, the physicians stated that the nutritional care of patients was the nurses' responsibility, whereas several nurses described the physicians as having the primary, formal responsibility. Eide et al [14] found that nurses were frustrated about the physicians' low involvement and engagement in nutritional care of the patients. They also identified that the support from physicians in nutritional care made it easier to prioritize nutrition. This corresponds to our finding of the physicians' important role in implementing new tools. Some nurses described communication between disciplines as challenging when different types of health care professionals have conflicting views. A literature review on communication between physicians and nurses revealed that communication tends to be unclear and unprecise, delaying patient care and increasing medical errors [36].

Facilitators for the Use of the MyFood System

The health care professionals were generally positive about the MyFood system and acknowledged that the evidence-based recommendations forming the basis of the tool [12,28] were acceptable, as described for the CFIR construct of evidence strength and quality. They perceived the tool as easy to use (CFIR: Complexity), having a user-friendly and intuitive design (CFIR: Design, quality, and packaging), and believed they would be able to use the tool (CFIR: Self-efficacy). They saw the tool as potentially time saving, more precise, and trustworthy compared with current practices, as it related to the CFIR constructs of relative advantage and knowledge and beliefs about the intervention. The perceptions of the preciseness and trustworthiness of the dietary recording function in the MyFood system seemed to be based on assumptions that everything recorded in the app would be correct. Self-reported dietary assessment methods are, however, often associated with errors. The memory of intake, lack of motivation to record over several days, ability to estimate portion sizes, and perceptions of socially desirable responses are well-known challenges in self-reported intake [37]. An evaluation of the dietary recording function in the MyFood app found that MyFood was relatively accurate in estimating the patients' intake of energy, protein, liquids, food, and beverages [29].

The MyFood system was perceived as potentially more fun and motivational to use compared with the current practice. Studies among adolescents have shown that dietary assessment using technology is preferred over paper-based food recording because electronic methods are perceived as more fun and motivational [38,39]. A systematic review of electronic methods to record food intake described that seeing progress toward fulfilment of goals can be highly motivational [40].

Barriers for the Use of the MyFood System

Although the health care professionals were positive about MyFood, several potential barriers were identified. MyFood was recognized as potentially time saving, but some also described time used to follow up as a barrier for use. A lack of automatic transfer to the EPR was described as another potential barrier, related to the adaptability construct. Lack of time and integration with the EPR were also found to be barriers in the implementation of the eHealth intervention *Choice* for symptom reporting into clinical practice in a Norwegian university hospital [41]. Another potential barrier linked to adaptability was hygiene aspects related to the use of tablet computers among patients.

Perceived barriers associated with the CFIR construct patient needs and resources concerned different languages and cultural backgrounds among the patients. The MyFood tool includes both icons and pictures that may overcome some language challenges. If the use of the MyFood system turns out to be effective, the inclusion of several languages may be considered in the future. With regard to cultural barriers and patients eating foods not included in the hospital's assortment, the MyFood app includes the possibility to record intake manually using a description of food or beverages consumed. In the long run, a wider range of food items may be included in the system. Challenges related to hygiene aspects may be solved by using plastic covers around the tablets. Older age was reported as a potential barrier to the use of MyFood owing to an increased risk of cognitive deficits or low self-efficacy among the elderly. However, qualitative studies among older persons have demonstrated that elderly people are often positive about using tablets and eager to learn [42,43]. A recent study describing an app to inspire home-dwelling elderly at nutritional risk to eat healthy foods showed that the elderly found the app easy to use [44].

Key Aspects for an Implementation Plan

The health care professionals were positive about performing an intervention study to test the MyFood system in their department (CFIR: Trialability). The results related to the CFIR construct planning, where the interviewees elaborated on their thoughts on how to perform the intervention study, follow up, and engage the nurses, will be particularly relevant for the creation of an implementation plan. Of interest for the implementation plan are also results from the CFIR constructs: structural characteristics, networks and communication, and available resources. Important elements may include ongoing training, local technical assistance, clinical supervision, educational materials, support, availability, establishing an implementation team, and organizing clinician implementation meetings. To engage potential users of MyFood and identify opinion leaders, the involvement of potential champions and early adopters may also be of importance. These findings are previously described as relevant implementation strategies in the Expert Recommendations for Implementing Change project [21,45]. An important finding in this study is that nutritional care has low priority in management (CFIR: Leadership engagement). Leadership support and engagement are crucial [46] for successful implementation [47] and strategies toward the leaders should be included in the implementation plan.

Strengths and Limitations

The strengths of the study are the inclusion of different health care professions and middle managers to reveal several views. The majority of the respondents were nurses, as they were considered to be the most important group with regard to the day-to-day nutritional care of the patients. Saturation is often described as the basis for sample size in qualitative studies [48]. However, this might not be the most appropriate [49]. Malterud et al [50] describe information power as related to the specificity of experiences, knowledge, or properties among the participants included in the sample. In this study, the health care professionals were holding characteristics specific to the study aim, in light of their professions. The aims of this study were relatively narrow and precise. Information power indicates that the more information the sample holds, relevant to the actual study, the lower the number of participants needed [50]. On the basis of these criteria, we considered our sample size to be sufficient.

The focus groups were originally composed of nurses with the same level of work experience to ensure that everyone's voice was heard and to enable the more inexperienced nurses to talk freely in a separate group that was not dominated by more experienced nurses. Owing to illness among some nurses on the days of the interviews, some adjustments had to be made to be able to perform the focus group discussion with a sufficient number of nurses. Interviewing patients may have strengthened this study. Therefore, the patients will be included in the planned study of the implementation and effect of using the MyFood system.

Using an existing framework within the field of implementation science is considered an important strength to better understand, describe, and identify factors that predict the likelihood of implementation success. The CFIR framework identified the importance of knowledge for designing an implementation plan [51].

This study was performed in the same departments where the planned implementation and effect study will take place, thereby providing a local identification of potential barriers and facilitators that may be crucial. However, conducting the study at only 2 departments in 1 hospital may imply that our results are not necessarily representative of other departments or hospitals. A limitation is that this study was performed before the implementation of the MyFood system. The impression of MyFood was therefore based on a demonstration and perceived barriers and facilitators for use. This perception does not necessarily correspond to the real barriers and facilitators experienced in practice.

Whether or not the MyFood or a similar system, at some point in time, will be included and implemented in the Norwegian health care system is yet to be determined. There is a shift in the health care system toward increased use of digital systems. A need for the development of information and communication technology tools to screen, assess needs, monitor food intake, create a nutrition care plan, and follow up on disease-related

malnutrition is described in a report from the Norwegian National Council for Nutrition [52].

Conclusions

This study identified several challenges in the nutritional care of hospitalized patients at malnutrition risk in 2 departments in a university hospital in Norway. The use of the decision support system MyFood was anticipated to have several advantages compared with the current practice with nutritional follow-up. The MyFood system was perceived as more precise, trustworthy, fun, and motivational than the current practice. However, cultural, language, age, and hygiene aspects were perceived as potential barriers. The identification of perceived barriers and facilitators will be used in the creation of a plan to implement the MyFood system in clinical practice in an implementation and effect study.

Acknowledgments

The development of the *MyFood* app was performed on the *services for sensitive data* (tjenester for sensitive data [TSD]) facilities, owned by the UiO, operated and developed by the TSD service group at the UiO IT Department.

Conflicts of Interest

None declared.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
eHealth: electronic health
EPR: electronic patient record
TPN: total parenteral nutrition
TSD: tjenester for sensitive data (services for sensitive data)
UiO: University of Oslo

Edited by G Eysenbach; submitted 09.08.18; peer-reviewed by J Constantin, AK Lindroos, M Mileski, G Fico; comments to author 07.01.19; revised version received 18.02.19; accepted 29.03.19; published 09.05.19

Please cite as:
Paulsen MM, Varsi C, Paur I, Tangvik RJ, Andersen LF
Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study
JMIR Form Res 2019;3(2):e11890
URL: http://formative.jmir.org/2019/2/e11890/
doi: 10.2196/11890
PMID: 31094333

Paper 3:

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

3

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

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Abstract

Background & aims: Compliance to guidelines for disease-related malnutrition is often low because of existing barriers. Due to the apparent need for better tools to improve nutritional care and treatment we developed the digital decision support system MyFood. The aim of this study was to investigate the effects of using the MyFood decision support system during hospital stay on adult patients' nutritional status, care and treatment, and hospital length of stay. The main outcome measure was weight development.

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 ± 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 development. Malnutrition risk at discharge was present in 77% of the patients in the intervention group and 94% of the patients in the control group (p=0.019). Nutritional treatment was documented for 81% 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 development during hospital stay. The absence of malnutrition risk at discharge, and the documentation of nutritional treatment and care were higher for patients using the MyFood system compared to routine care. This trial was registered at clinicaltrials.gov (NCT03412695).

Key words: Disease-related malnutrition; Decision support system; Nutritional assessment; eHealth; Nutritional status; Nutritional intervention; Nutritional treatment

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 (3-6), and nutritional status often deteriorates during hospital stay (7, 8). Poor nutritional status increases morbidity and mortality rates (9, 10), leads to a longer length of stay (11) and increases hospital costs (12, 13). A recent Swiss multicenter study showed that individualized nutrition support increased the intake of energy and protein and reduced serious complications and mortality during 30 days (14).

According to the guidelines (1, 2), all patients should be screened for malnutrition risk at hospitalization. For patients who are identified to be 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 uptake, weight, body mass index, muscle mass and disease burden/inflammation (15). Furthermore, 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 patient's medical record and passed on to the next care level (16).

However, compliance with these guidelines is challenged due to poor routines (17), lack of assignment of responsibility, and limited skills and knowledge on nutritional treatment and follow-up among health care professionals (18). The methods to record and assess 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 are suffering 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 assessment 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).

In the present randomized controlled trial, we aimed to study the effects of the MyFood system on hospitalized patients' nutritional status, care and treatment. The primary outcome was weight development during the hospital stay. Secondary outcomes were body composition, malnutrition risk score, the implementation of nutritional treatment, the creation of nutritional care plans, and hospital length of stay.

Material and methods

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. Hospitalized patients ≥18 years with an expected length of stay of ≥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.

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 bedposts with different nurses and some differences in diagnoses. The patients were stratified according to bedpost (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, nontransparent 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 ≤2 days after hospital admission.

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, diarrhea, etc.), nutritional situation (normal oral intake, tube feeding, parenteral nutrition), and 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 was compared to individual requirements for energy, protein, and liquids.
4. Report to health care professionals included an overview of the patients' nutritional intake compared to individual needs, guideline-based individualized recommendations for nutritional treatment, and a draft for a nutritional care plan tailored to the individual patient. The nutritional care plan can be copied and pasted by the nurse into the patients' electronic records.

The MyFood decision support system consisted of an app including functions 1-3 and a web site included function 4. MyFood was used both by the patient (the app) and the health care professional (the app and the web site). 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.

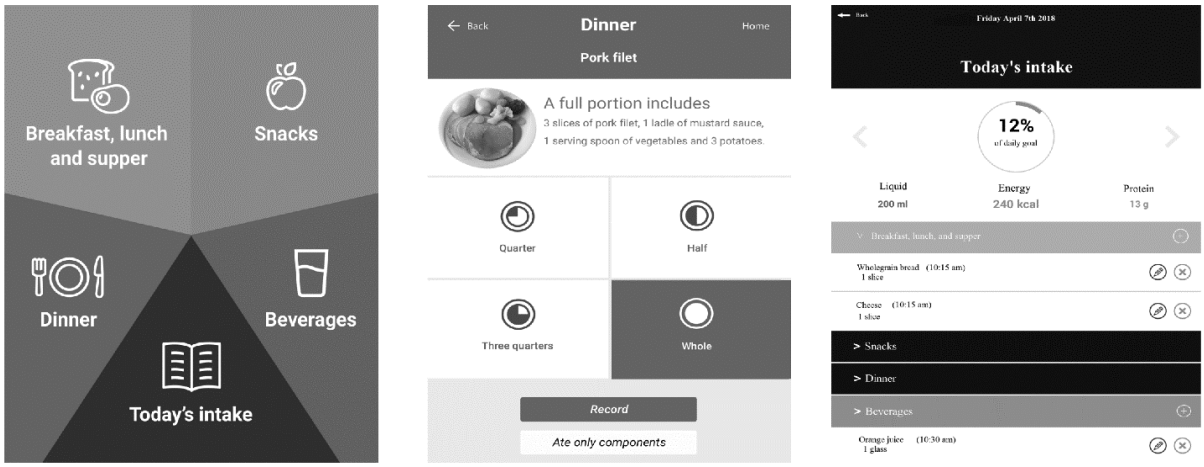

Figure 1: Dietary recording and evaluation in the MyFood app.

Encrypted data from the MyFood app were sent to "Services for sensitive data" (TSD) (**Figure 2**) as described earlier (22).

Figure 2: Data flow in the MyFood decision support system.
[1]TSD: Services for sensitive data

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 (24), and authentication was sent to the TSD server (25) to verify access to the website. Patient reports on the website were retrieved using the patient's Norwegian Patient Register (NPR) number.

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 liquids. 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.

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 web site 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.

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.

Outcomes and characteristics

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.

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.

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 (26). 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) = body weight (kg)/height^2 (m^2).

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, 27) translated to Norwegian. An NRS 2002 score ≥3 points indicates the risk of malnutrition. Both nutritional status and the degree of the disease are scored from 0-3 points related to severity and patients ≥70 years get an extra point related to age.

The Patient-Generated Subjective Global Assessment Short Form (PG-SGA SF) (28) 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 development, 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) (29) at baseline and thereafter weekly, and finally, at discharge.

Nutritional treatment, nutritional care plans, and documentation

Data on the documentation of dietary intake and nutritional treatment 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 were coded in 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 enrichment, use of oral nutritional supplements, interventions related to meal frequency, tube feeding, or parenteral nutrition.

Length of stay

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

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 records sign-up for access and log-in to the MyFood website.

Sample size

The sample size estimation was performed using weight development during the hospital stay as the primary outcome. A clinically relevant difference was defined as a 1 kg difference in weight development 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.

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; Identifier: NCT03412695).

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%.

Results

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 harms or unintended effects were reported in the trial.

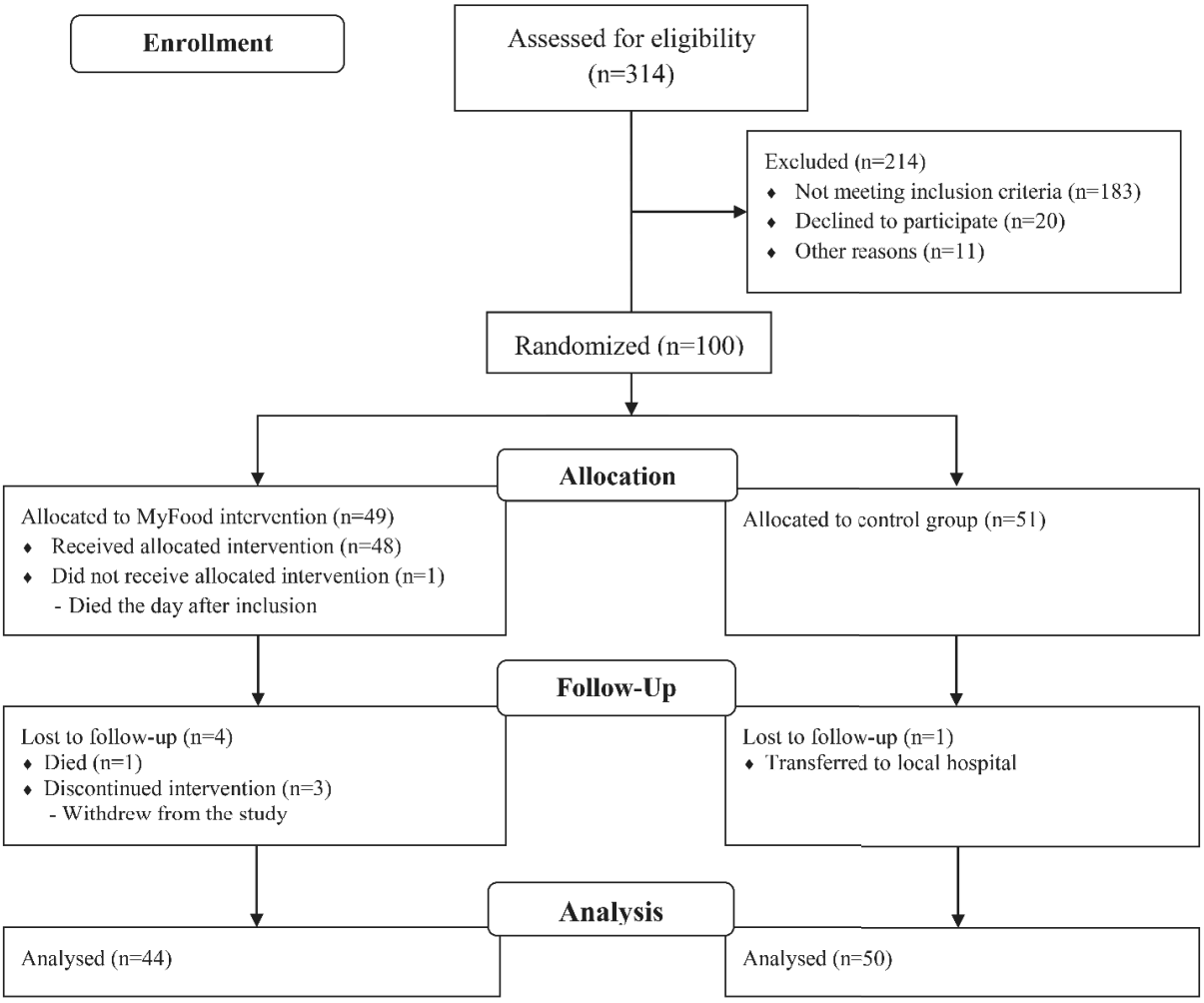

Figure 3: Consolidated Standards of Reporting Trials (CONSORT) flow diagram for patients' allocation into the intervention and control groups.

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**).

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

Variables	MyFood (n=49)	Control (n=51)
Sex, male *	35 (71%)	25 (49%)
Age (years)	50 (15)	53 (14)
Mean body mass index (kg/m^2)	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%)
Education		
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%)
Earlier experiences with apps and smartphones/tablets		
None/little	5 (10%)	2 (4%)
Some (use sometimes)	14 (29%)	13 (26%)
A lot (use often/daily)	30 (61%)	36 (71%)
Diagnosis		
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%)
Cause of admission		
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%)
Comorbidity		
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%)
NRS[1] 2002 score ≥3	22 (45%)	24 (47%)

Data are presented as the number of participants (%) or the mean (SD).
*$p<0.05$
[1]NRS: Nutritional Risk Score

279 The mean age among participants was 51.9 years, and the mean BMI was 25.5 kg/m^2. The most
280 common diagnosis among the participants was leukemia. Approximately half of the patients were
281 hospitalized to undergo bone marrow transplantation, whereas 20% were hospitalized with newly
282 discovered cancer. Just below half of the patients included in the study were malnourished or at
283 risk of malnutrition on admission, defined as NRS 2002 score ≥3.

284 ***Development in patients' body weight during the hospital stay***

285 No significant differences in body weight development from hospitalization to discharge were
286 found between the intervention and control groups. The mean weight loss was 2.4 kg in the
287 intervention group and 2.7 kg in the control group (**Table 2**).

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

	MyFood				Control				
	n	Baseline	Discharge	Change	n	Baseline	Discharge	Change	p[1]
All patients									
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
Normally hydrated patients									
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

290
291 [1]Independent samples t-test
292

293 Only 10 patients in each group were normally hydrated, defined as ECW/TBW within the normal
294 reference area (30). Approximately half of the patients had a shift in hydration status from
295 baseline to discharge; defined as either moving from normal to overhydrated or dehydrated or the
296 opposite. The large shifts in hydration status may have affected the weight analyses, and thus the
297 analyses were also performed for the subgroup of patients with normal hydration status (Table 2).

The development in mean body weight in the intervention group and the control group during the hospital stay is illustrated in **figure 4**.

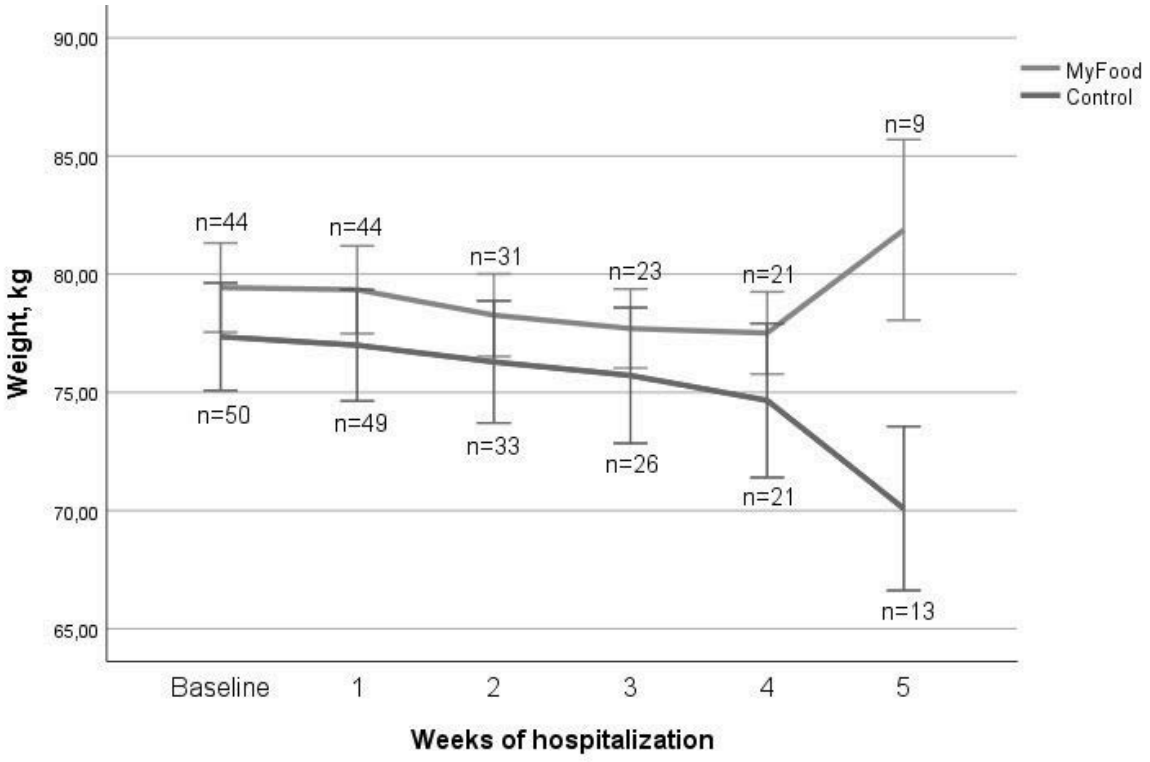

Figure 4. Unadjusted mean values for body weight development for patients in the intervention group and the control group. Data for ≥6 weeks are not shown due to few participants. Error bars: +/- 1 SE.

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**).

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

	n	MyFood	n	Control	Mean difference[1]	p
Weight						
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

[1]Mean difference (95% CI) analyzed using linear mixed models for repeated measurements adjusted for baseline differences and missing data.

Development in patients' body composition during the hospital stay

No significant differences in body composition development from hospitalization 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 (**Figure 5**).

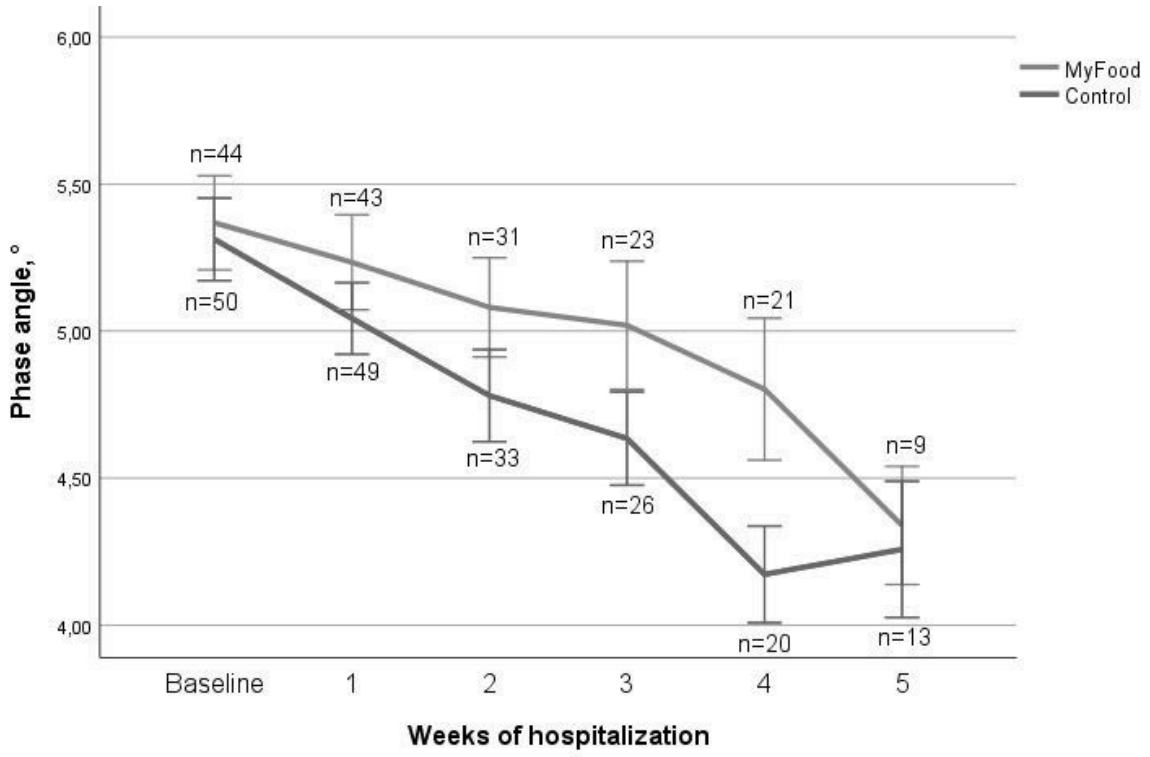

Figure 5. Unadjusted mean values for the development in phase angle during the hospital stay for patients in the intervention group and the control group. Data for ≥6 weeks are not shown due to few participants. Error bars: +/- 1 SE.

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 four weeks of hospitalization (**Table 4**). Borderline significantly higher phase angles were found in the intervention group at the second and third weeks of hospitalization compared to the control group.

Table 4. Adjusted mean phase angle (°) at each week of hospital stay.

	n	MyFood	n	Control	Mean difference[1]	p
Phase angle						
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)	**0.013**
5 weeks	9	4.8	13	4.5	0.2 (-0.2, 0.7)	0.286

[1]Mean difference (95% CI) analyzed using linear mixed models for repeated measurements adjusted for baseline differences and missing data. Bold numbers indicate significant values.

Malnutrition risk

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**).

Table 5. Malnutrition risk scores and assessment.

	MyFood (n=43)[1]	**Control** (n=49)[2]	p[3]
NRS-2002 score ≥3, n (%)	33 (77%)	46 (94%)	**0.019**
PG-SGA SF discharge, mean (SD)	10 (6)	12 (6)	0.302
PG-SGA SF food intake discharge, n (%)			0.071
Normal or higher[4]	14 (32%)	8 (16%)	
Less than normal[4]	30 (68%)	42 (84%)	

[1]Missing screening forms at discharge for 1 patient.
[2]Missing screening forms at discharge for 1 patient.
[3]Categorical data are tested with the chi-square test. Continual data are tested with independent samples t-test.
[4]Food intake indicated by the patient in the PG-SGA SF form.
Bold numbers indicates statistically significant values.

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).

Nutritional treatment and care

The documentation of nutritional treatment and care was significantly higher for the patients in the intervention group than in the patients in the control group (**Figure 6**).

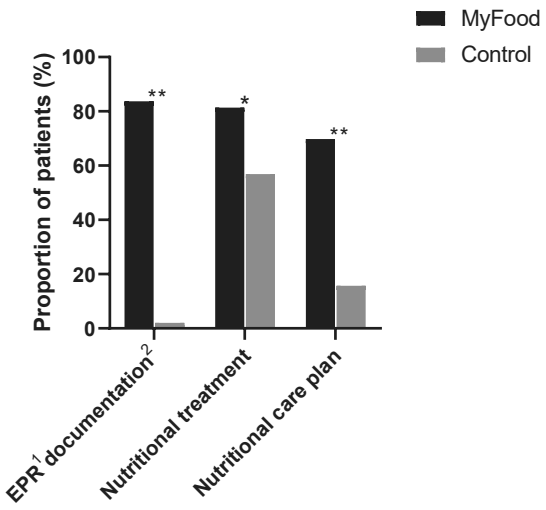

Figure 6. Comparison of documentation of the nutritional intake, nutritional treatment, and nutritional care plans between the intervention and control groups.

*p<0.05. **p<0.001, tested with chi-square test. [1]Electronic patient record. [2]Documentation in electronic patient records of intake compared to requirements.

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 electronic record (p<0.001). Nutritional treatment was documented for 81% in the intervention group and 57% in the control group (p=0.011). 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).

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.

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 their 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. A few patients needed help from the nurses with the recordings.

Eighty-six 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 for login was 3 days (min 1 day, max 18 days).

Discussion

In the present study, we found no significant differences in weight development 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. A significantly higher proportion in the intervention group had an NRS 2002 score <3 at discharge, indicating that a higher proportion of the patients in the control group were 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.

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 did not find any differences in weight development between

399 the intervention group, which received individualized nutritional support, and the control group
400 (14). Two systematic reviews identified a small effect of nutritional support on weight
401 development among hospitalized patients (31, 32). A Danish app for decision support among
402 cancer patients living at home found that patients using the app maintained weight, but the study
403 had no control group (33).

404 Fluid imbalances, edemas, or ascites in patients often influence bodyweight measurements (34).
405 Increased extracellular water is a common feature of severe illness and systemic inflammation
406 and this complicates the interpretation of changes in body weight during treatment (34) and are
407 often considered contraindications for the use of BIA (35). Fluid imbalances were highly
408 prevalent in our study population with only approximately 20% of the patients having a normal
409 fluid balance at both hospital admission and discharge. Thus, the results related to body weight
410 development and body composition should be interpreted with caution, and other measures of
411 nutritional status may be more relevant.

412 There is no “gold standard” recommended for the identification of malnutrition (35), indicating
413 that several parameters should be considered. Phase angle may be used as a more objective
414 measure of nutritional status (36). The phase angle provides information about hydration status,
415 body cell mass, and cell integrity without requiring the assumption of constant tissue hydration
416 and may be used as a prognostic parameter in various diseases (37). The phase angle is not reliant
417 on any of the predictive equations otherwise applied by BIA to determine other measures of body
418 composition that depend on assumptions of normal fluid distribution (35). A recent study found
419 comparable values in patients with or without fluid retention when studying the correlation
420 between phase angle and subjective global assessment (SGA) (35). Although no significant
421 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 hospitalization. The phase angle is a useful, independent indicator to assess the risk of malnutrition among hospitalized patients (38, 39).

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. Other studies have shown that the documentation of nutritional care in hospital practice is often unsatisfactory and limited (40, 41). Some causes for this lack of documentation have been described as barriers related to a short hospital stay, resource demands, and discrepancies in nutritional knowledge and skills among health care professionals (17, 40). 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 (42). 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 (43).

The MyFood intervention also had a significant effect on the proportion of patients with documented nutritional treatment in the electronic patient record. 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 (44). Studies performed in Norwegian hospitals have shown that a low proportion of patients at risk of malnutrition receive nutritional treatment (3, 19, 45). A clear demand and a high potential for quality improvement in nutritional care for hospitalized patients have been reported (45). Based on the results in the current study

445 the MyFood decision support system may be a driver to improve the implementation of the
446 guidelines on malnutrition.

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

458 **Strengths and weaknesses**

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

463 The same nurses could potentially be involved in the care of both patients in the intervention and
464 control groups. This may have led to a contamination effect in which components of the MyFood
465 intervention were transferred to patients in the control group. The presence of researchers at the
466 department and training nurses in the MyFood system may have increased the focus on

nutritional care and treatment during the study period, thus leading to improved nutritional care 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 may possibly interfere with the intervention. Ideally, we should have had information about the food intake of both groups to be able to study the potential effects of the MyFood intervention on the intake of energy, proteins, and liquids among 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 for reliable measurements of phase angle in a study with hospitalized patients in the United Kingdom (35).

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 NRS 2002 score ≥ 3. We might have seen other results if only patients with an NRS score ≥ 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. Thus, the group of patients in this study were at particularly high risk of malnutrition compared to the general hospital population.

This study was performed at a single department at one university hospital. The results may therefore not necessarily be generalizable to other patient groups and hospitals. The majority of

489 the patients in the present study received chemotherapy which is associated with weight loss (46),
490 and the results may have been different in other types of hospital departments. The effects of the
491 MyFood decision support system should be studied in other patient groups and hospitals in
492 follow-up studies.

493 In conclusion, this randomized controlled trial found no effect of the MyFood intervention on
494 weight development, body composition, or length of the hospital stay. However, the proportion of
495 patients with an NRS-2002 score <3 at discharge was significantly higher in the intervention
496 group than the control group, indicating less degree of malnutrition risk in the patients following
497 the MyFood intervention. Also, the use of MyFood significantly increased the proportion of
498 patients receiving nutritional treatment and an individualized nutrition care plan, compared to the
499 control group.

500

Acknowledgements

The development of the MyFood decision support system was performed on the TSD facilities, owned by the University of Oslo, operated and developed by the TSD service group at the University of Oslo, IT-Department.

We thank the patients participating in the study, the nurses and the management staff at the hospital. Thanks to Karoline Randsborg, Mona Grue, and Kaja H. Berg for contribution with the data collection.

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.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Funding sources

This study was funded by the South-Eastern Norway Regional Health Authority and the Throne Holst Foundation at the University of Oslo.

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Figure and table legends

Figure 1: Dietary recording and evaluation in the MyFood app.

Figure 2: Data flow in the MyFood decision support system.

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

Figure 4. Unadjusted mean values for weight development for patients in the intervention group and the control group. Data for ≥ 6 weeks are not shown due to few participants. Error bars: +/- 1 SE.

Figure 5. Unadjusted mean values for the development in phase angle during the hospital stay for patients in the intervention group and the control group. Data for ≥ 6 weeks are not shown due to few participants. Error bars: +/- 1 SE.

Figure 6. Comparison of documentation of the nutritional intake, nutritional treatment, and nutritional care plans between the intervention and control groups.

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

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

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

Table 4. Adjusted mean phase angle (°) at each week of hospital stay.

Table 5. Malnutrition risk scores and assessment.

Supplementary table 1. Unadjusted values for change in body composition through hospital stay for patients in the intervention group and the control group.

	MyFood				Control				
	n[1]	Baseline	Discharge	Change	n[1]	Baseline	Discharge	Change	p[2]
All patients									
FFM[3], kg (SD)	41	58.6 (12.0)	57.1 (11.4)	-1.5 (5.9)	49	55.1 (12.3)	55.5 (13.2)	0.4 (6.2)	0.156
FFMI[4], kg/m^2 (SD)	41	18.7 (2.8)	18.3 (2.5)	-0.4 (1.8)	49	18.1 (2.8)	18.2 (3.0)	-0.1 (2.0)	0.233
Body fat, kg (SD)	41	21.1 (10.5)	19.8 (11.0)	-1.3 (3.9)	49	22.3 (10.4)	19.6 (9.7)	-2.6 (5.3)	0.163
Body fat, % (SD)	41	26.3 (11.6)	25.5 (12.5)	-0.8 (5.4)	49	28.2 (10.5)	25.7 (10.7)	-2.5 (7.3)	0.214
FMI[5], kg/m2 (SD)	41	7.0 (3.8)	6.6 (4.0)	-0.5 (1.4)	49	7.5 (3.6)	6.6 (3.4)	-0.9 (1.7)	0.223
SMM[6], kg (SD)	41	26.7 (6.3)	25.6 (6.2)	-1.1 (3.3)	49	25.1 (7.4)	24.6 (7.5)	-0.5 (4.3)	0.463
PhA[7], ° (SD)	41	5.3 (1.1)	5.1 (0.9)	-0.3 (0.8)	49	5.4 (1.0)	4.8 (1.0)	-0.5 (0.8)	0.273
Normally hydrated patients									
FFM[3], kg (SD)	10	58.8 (12.4)	56.9 (13.1)	-1.9 (4.0)	9	48.6 (9.2)	48.5 (8.0)	-0.1 (7.4)	0.527
FFMI[4], kg/m^2 (SD)	10	18.6 (3.1)	18.0 (3.3)	-0.6 (1.3)	9	17.2 (3.0)	17.0 (2.0)	-0.1 (2.5)	0.613
Body fat, kg (SD)	10	16.8 (9.2)	16.1 (9.5)	-0.7 (2.9)	9	19.2 (8.9)	16.5 (7.0)	-2.7 (7.2)	0.439
Body fat, % (SD)	10	22.4 (11.8)	22.3 (12.9)	-0.1 (4.0)	9	27.5 (10.5)	24.9 (7.9)	-2.6 (11.3)	0,519
FMI[5], kg/m2 (SD)	10	5.5 (3.4)	5.3 (3.5)	-0.2 (0.9)	9	6.7 (2.9)	5.8 (2.5)	-0.8 (2.3)	0.459
SMM[6], kg (SD)	10	27.5 (7.4)	26.0 (7.3)	-1.5 (2.4)	9	20.8 (7.8)	21.1 (4.3)	0.2 (7.7)	0.504
PhA[7], ° (SD)	10	6.0 (1.2)	5.7 (1.1)	-0.3 (0.7)	9	5.8 (1.0)	5.4 (0.8)	-0.4 (0.8)	0.364

[1]Patients with 0 body fat % are excluded from analysis (n=3). [2]Independent samples t-test. [3]FFM: Fat free mass. [4]FFMI: Fat free mass index. [5]FMI: Fat mass index. [6]SMM: Skeletal muscle mass. [7]PhA: Phase angle.

Appendix 1

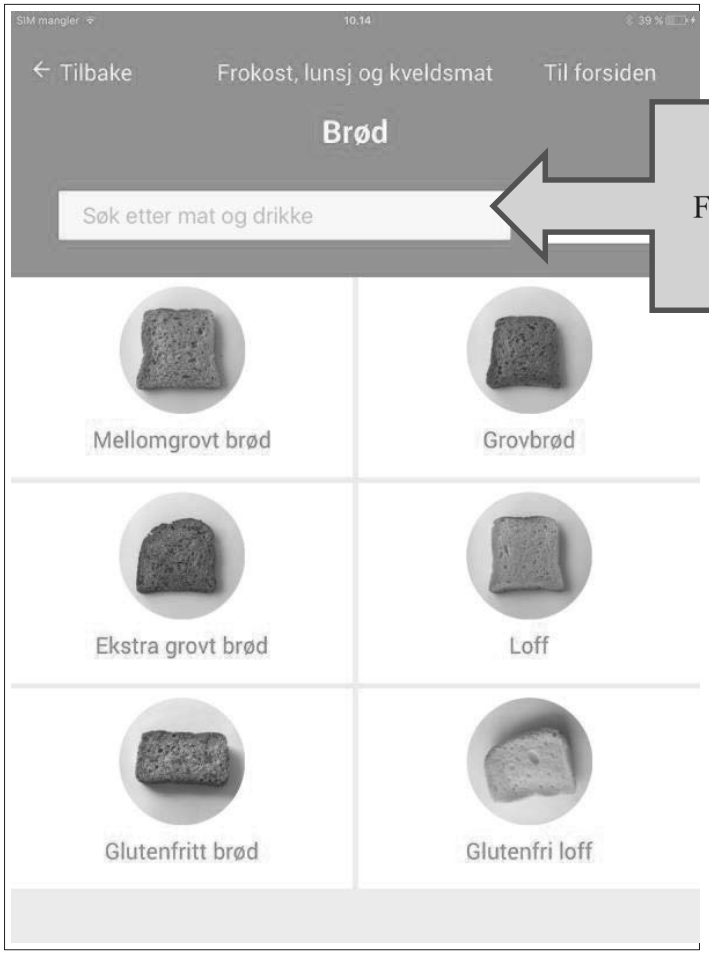
Selected screenshots from the MyFood decision support system

Main menu in the dietary recording function (app)

Select type of meal to record or get an overview of today's intake

Dietary recording (app): Select food category and food item

Select category within meal type



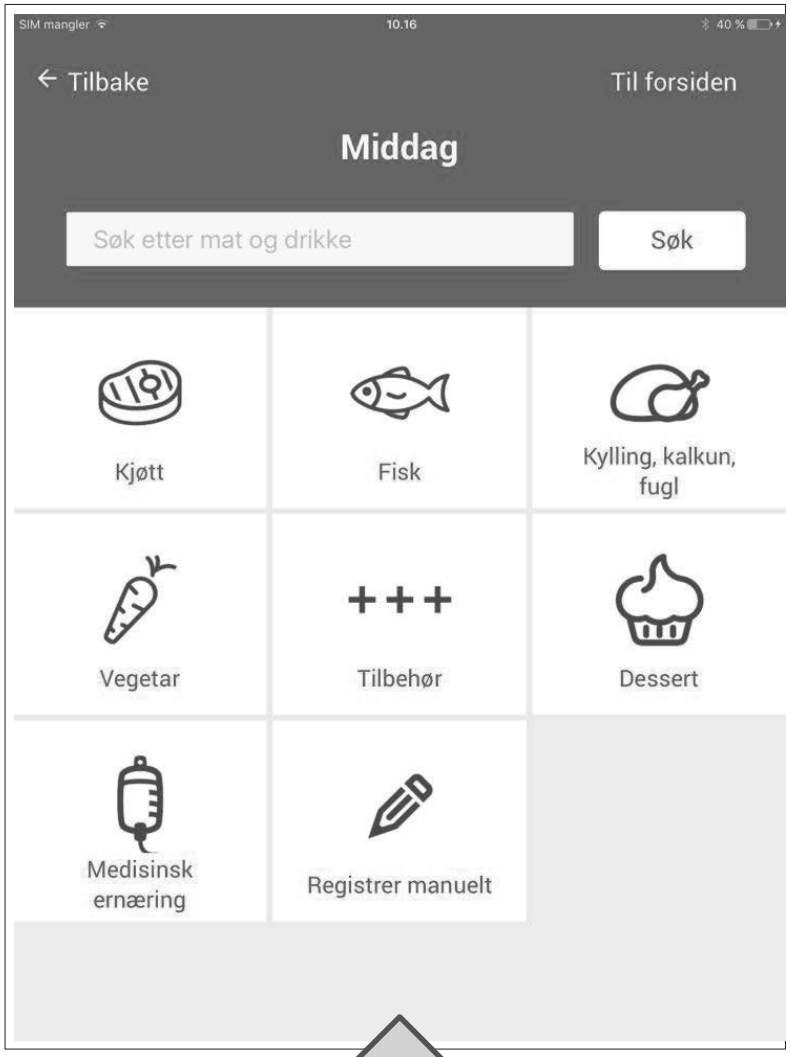
Select food item consumed

Dietary recording (app): Select amount of food

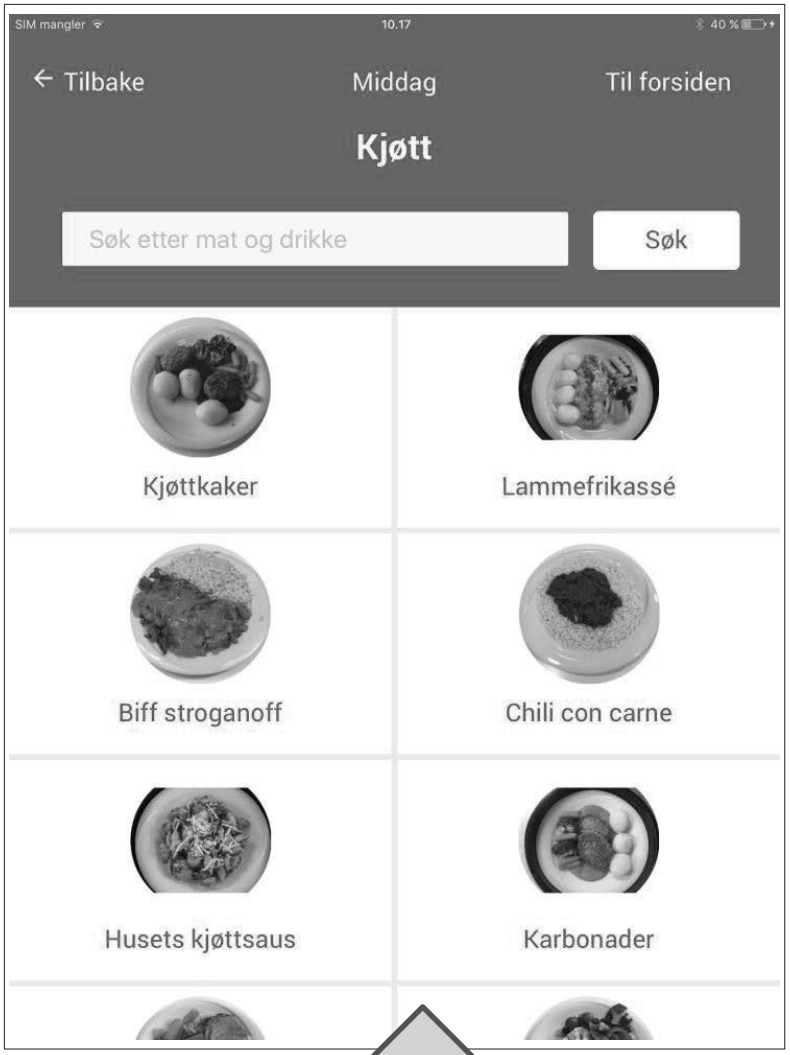
Select number of food items consumed

Prompting e.g. regarding use of spread on bread

Dietary recording (app): Select food category and food item



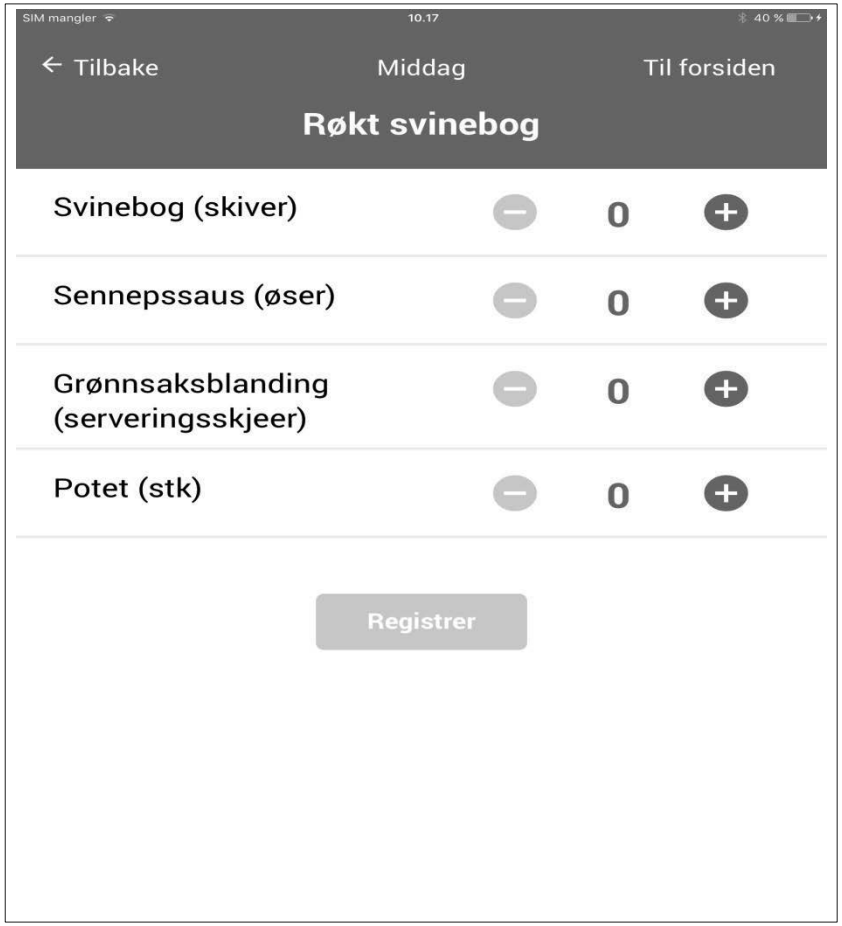
Select category within meal type (dinner)



Select food item consumed (type of dish)

Dietary recording (app): Select amount of food

Select part of the portion consumed

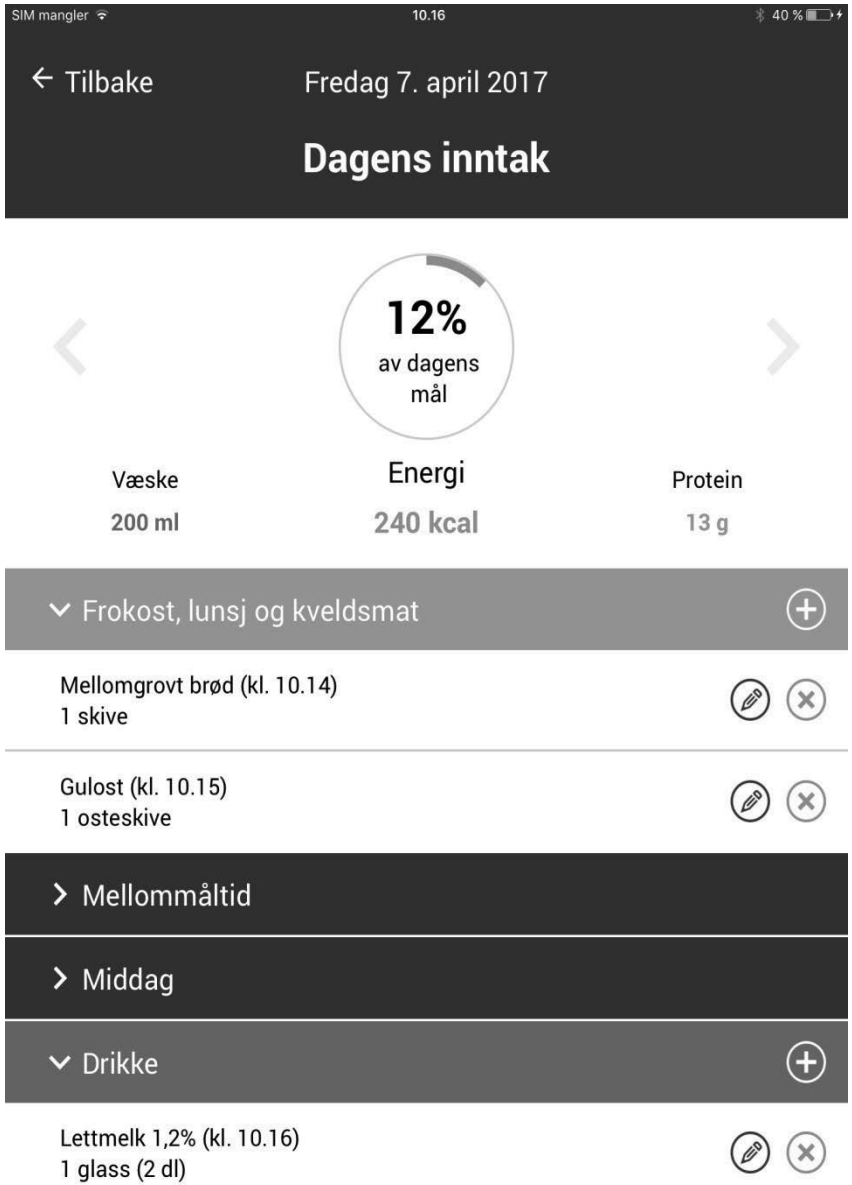


Record only components of the dish consumed (e.g. 1 potato and 1 ladle of sauce)

Evaluation of recorded intake compared to individual requirements in the MyFood app

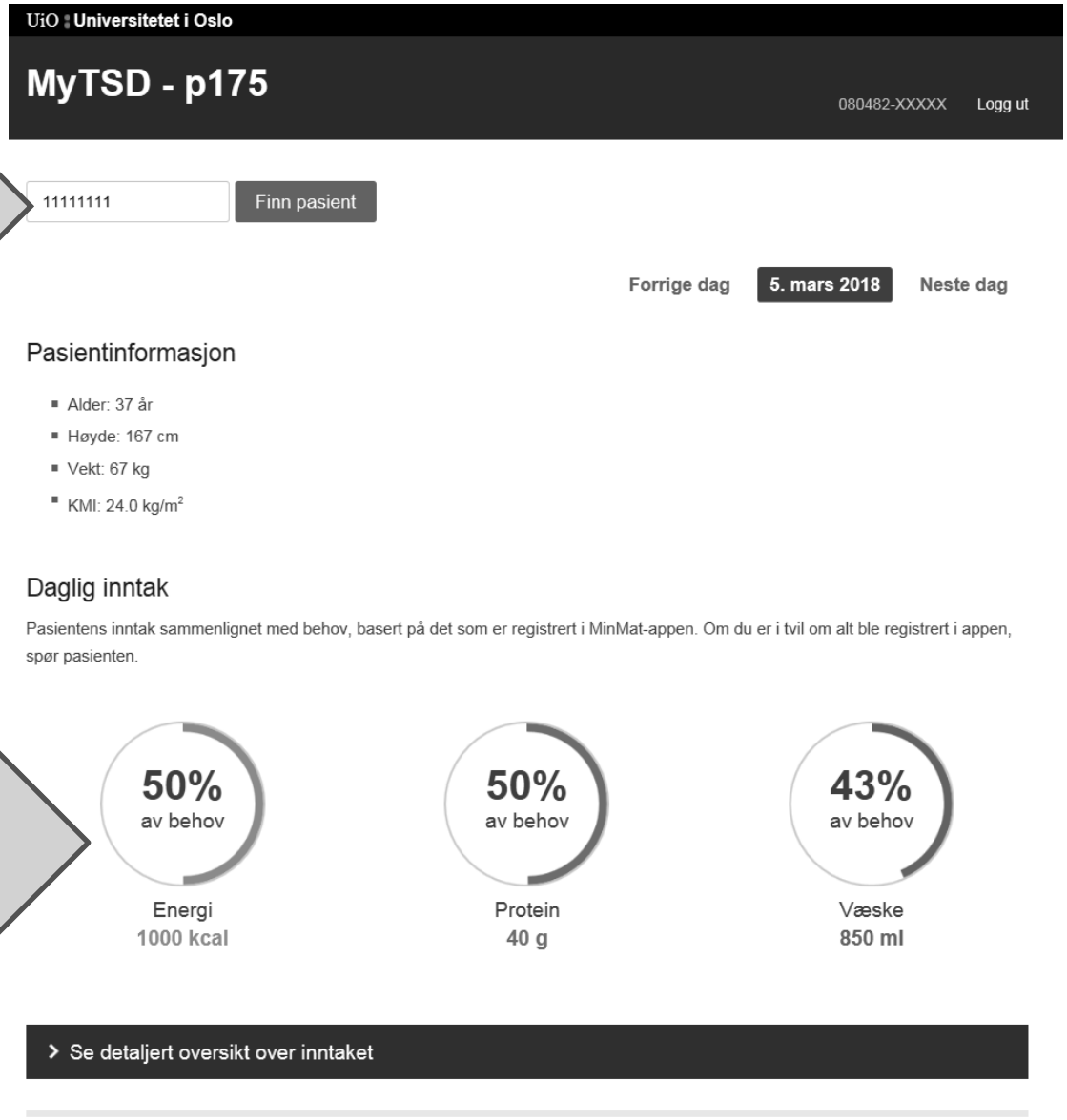
Evaluation of recorded intake of energy, protein and liquids compared to individual needs

Summary of recorded food and beverage items with the possibility to revise, delete or add food/beverage items



Report to nurses in the MyFood webserver

Patient search



Evaluation of recorded intake of energy, protein and liquids compared to individual requirements

Tailored recommendations for nutritional treatment and care in MyFood webserver

Press to see template for nutrition care plan

Recommendations for nutritional treatment and measures. Press to see the recommendations at each «level» of the nutritional stairs

Ernæringsplan

Det bør utarbeides en ernæringsplan for pasienten.

› Se utkast til ernæringsplan

Ernæringstiltak

Pasienten fikk i seg mindre enn 75 % av sitt behov for energi. Klikk på aktuelt trinn, og få anbefalinger om ernæringstiltak på ulike nivå. For denne pasienten er det trolig mest aktuelt å starte med tiltak på nivå 4 (Beriking og mellommåltider) og nivå 5 (Næringsdrikker). Generelt anbefales det at tiltak på lavest mulig nivå forsøkes før tiltak på høyre nivå. En kombinasjon av tiltak på flere trinn kan være aktuelt.

Kilde: Helsedirektoratet

› Underliggende faktorer

› Måltidsmiljø

› tilbud

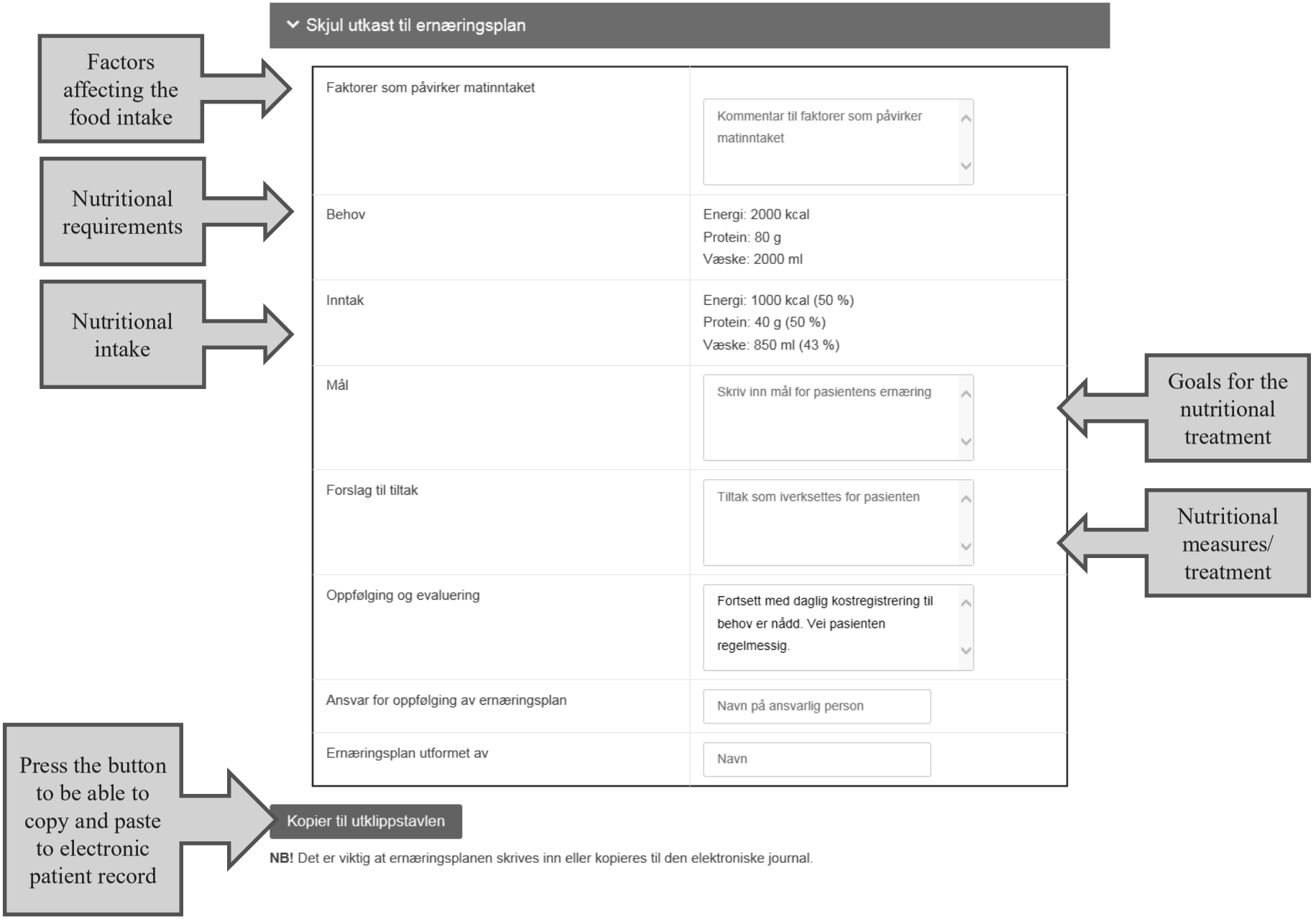
› Berikning og mellommåltider

› Næringsdrikker

› Sondeernæring

› Intravenøs ernæring

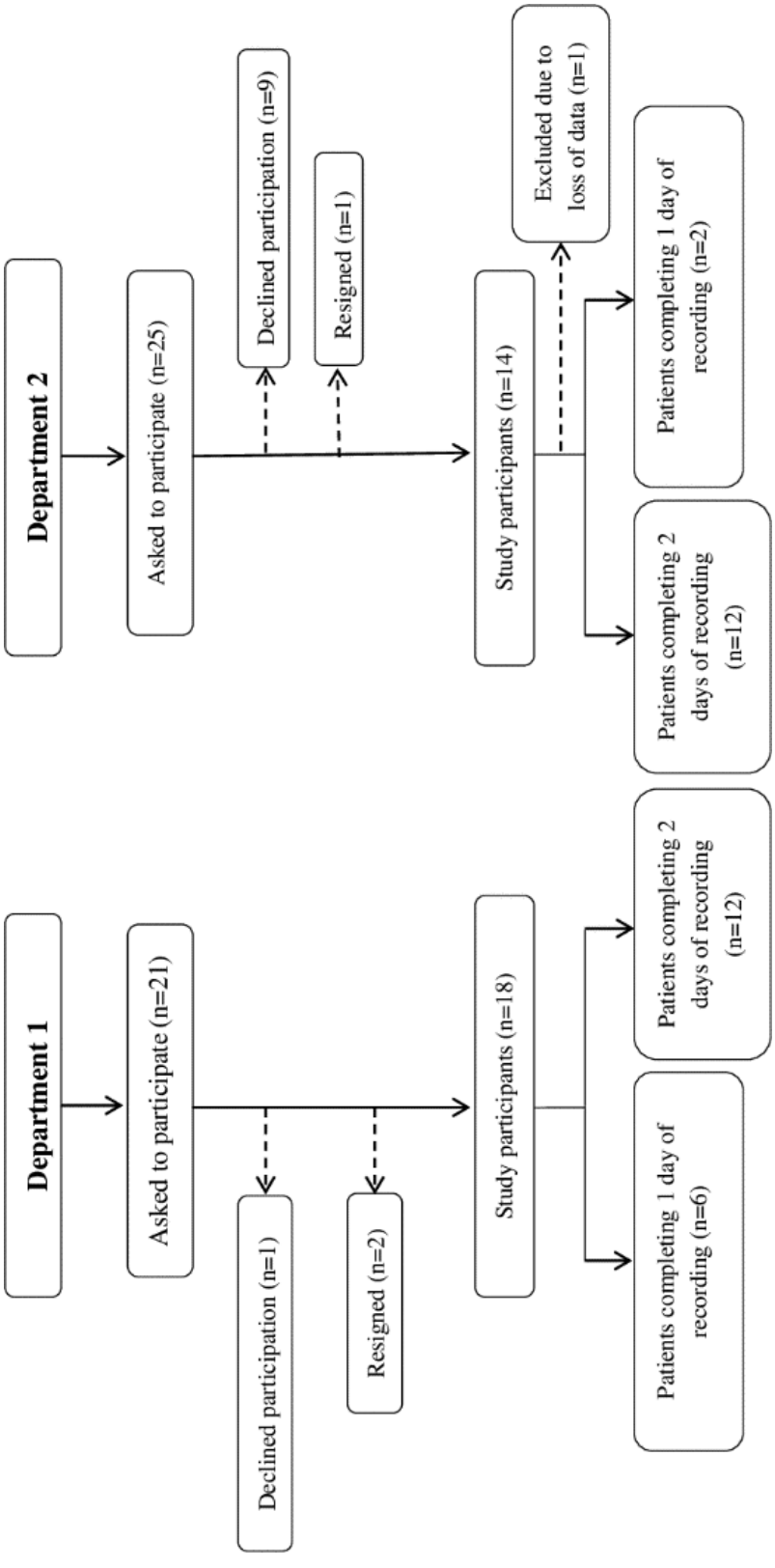
Template for a nutrition care plan in the MyFood webserver



Appendix 2

Flow chart for the recruitment of participants to the evaluation study (Paper 1)

Appendix 2 Flow chart for the recruitment of patients to the MyFood evaluation study (Paper 1)



Appendix 3

CONSORT flow diagram for the MyFood randomized controlled trial (Paper 3)

Appendix 3 CONSORT flow diagram for the MyFood randomized controlled trial (Paper 3)