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Menu Planning based on the MRC-Guidance to Increase Energy and Protein Intake in Nutritional Risk Patients by Development and Test of the Kulina-Model

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MENU PLANNING BASED ON THE MRC-GUIDANCE TO INCREASE ENERGY AND PROTEIN INTAKE IN NUTRITIONAL RISK PATIENTS BY DEVELOPMENT AND TEST OF THE KULINA- MODEL

**BY
MARIE NERUP MORTENSEN**

DISSERTATION SUBMITTED 2019



AALBORG UNIVERSITY
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CV



Marie Nerup Mortensen is a food developer from Aalborg University hospital, Denmark, who holds a master's degree in humanities and health and a bachelor's degree in nutrition and home economics.

Three years ago, Marie started the KULINARIUM-food lab as a part of her PhD. Kulinarium is a research and development unit within nutrition, food and mealtimes, anchored in the Hospital kitchen department. She previously worked as a nutrition consultant for 14 years linking kitchen and wards together at Aalborg University hospital.

Marie's job experience includes working with evidence-based practice, developing study protocols, supervision and teaching, including being a clinical supervisor for bachelor students in nutrition and health. She has extensive experience in the development and implementation of new strategies related to malnutrition and food at the hospital in cooperation with the Food and Beverage industry and the clinical staff at Aalborg University Hospital.

Her main research interest is to study and develop hospital food as an integrated part of overall treatment.

Since November 2016, Marie Nerup Mortensen has been enrolled as a PhD student at the Faculty of Medicine, Aalborg University.

ENGLISH SUMMARY

Background and Aims

Every day, hospital kitchens prepare a substantial number of meals to be served to patients to support their treatment. Despite the fact that food in rich amounts is provided for all patients, disease-related malnutrition (DRM) is a common problem that affects one-third of hospitalized patients. DRM may be related to many different aspects; however, appetizing foods, snacks or special meals tailored to patients with low appetite play a key role in patients' food intake.

The aim of this PhD-thesis was to increase energy and protein intake in patients at risk of DRM by the development and introduction of a multimodal model, "The Kulina-model", for developing and testing patient targeted hospital food, based on the MRC-guidance (Medical Research Council).

Methods

The project was performed with patients at nutritional risk (screened by NRS-2002) from the departments of Thoracic Surgery, Vascular Surgery, Abdominal Surgery and Lung Medicine at Aalborg University Hospital.

Study I: A pilot study was conducted to increase energy and protein intake (average protein to at least 20g) at breakfast in a population of surgical patients (thoracic surgery and vascular surgery) at risk of DRM. This was accomplished by development and pilot-testing of a multimodal model, "The Kulina-model". The study was conducted with a control group and an intervention group including three days of food records, combined with semi-structured interviews regarding patients' meal experiences, preferences, appetite and eating patterns, as well as food-image selection related to breakfast. The data were audio recorded, transcribed, and used as inspiration in a co-design session for the development of a new breakfast menu which was tested in the study.

Study II: The results from study I formed the basis for study II, which was conducted as a case study refining the Kulina-model in order to obtain more systematic in depth data regarding patients' eating patterns, food preferences and appetite, this time piloted in relation to in-between meals, in a population of surgical and medical patients. Semi-structured interviews with image selection were supplemented with measurement of appetite. The interviews were audio recorded, transcribed and analysed. The food-image selection results underwent descriptive and statistical analyses, and appetite was measured using a numerical rating scale. The results were used in a co-design session where high-energy and high-protein in-between meals were developed. A model of food sensory quality to promote intake in patients at

nutritional risk was incorporated in combination with a sensory test of the developed in-between meals. The case study was completed with an intervention, with the purpose to increase energy and protein intake for in-between meals in the population, by implementing targeted high-energy and high-protein in-between meals (three servings per day). The study was conducted with a control group and an intervention group including three-days of food records.

Results

Study I: Ten patients participated in the semi-structured interviews including food-image selection. The pilot study included Sixty-two patients. An overall significant difference in intake was identified between the control group (n=32) and the intervention group (n=30). The protein-fortified breakfast delivered, on average, 22% (20g) of the individual daily requirements of protein and 24% of the energy vs 14% (protein) and 18% (energy) at baseline.

Study II: Fourteen patients participated in the semi-structured interviews including appetite measurement. Over half of the patients did not have anything to eat between breakfast and lunch and in the evening. Not all patients were used to eating in-between meals at home. The food-image selection showed varying preferences, identifying the need for all tastes and consistencies in the menu, and that especially soft and fluid consistencies may be especially useful in the weakest patients, but no overall tendency was found. In general, a moderately affected appetite was identified. Based on the qualitative data, twenty-three new in-between meals were developed with an average content of 9.7 g of protein and 721 kJ/ 172 kcal per serving. During the study, 46 patients (intervention group) were served the high-energy and high-protein in-between meals, and 46 patients (control group) were served standard in-between meals. The high-energy and high-protein in-between meals significantly increased energy and protein intake for in-between meals and in daily total. The average energy intake improved from 55% to 118% of requirements, and protein intake increased from 30% to 112% for in-between meals.

Conclusions

A multimodal model, “The Kulina-model”, was developed as a method to develop meals targeted specific barriers, preferences and requirements and thus increase food intake in patients at nutritional risk. The application of this model improved energy and protein intake in patients at risk of DRM compared to the novel breakfast and in-between meals concept. Additional long-term studies are required to determine whether the model can demonstrate an increase in energy and protein intake in patients at nutritional risk on a longer term basis and in other settings.

DANSK RESUME

Hospitals køkkener tilbereder dagligt et stort antal måltider der serveres for patienter til støtte for behandling. Til trods for dette, er sygdomsrelateret underernæring (DRM) et ofte forekommende problem, der berøre en tredjedel af alle indlagte patienter. DRM kan relateres til mange forskellige aspekter, men appetitlig mad, snacks eller måltider målrettet patienter med lille appetit, spiller en vigtig rolle for patienternes indtag af mad. Formålet med denne Ph.d. afhandling var at øge energi og protein indtaget hos patienter i risiko for DRM, gennem udvikling, introduktion og testning af en multimodal model, "Kulina-modellen" til udvikling af hospitals mad målrettet patienter i ernæringsrisiko, baseret på MRC-guiden (Medical Research Council).

Metode

Projektet er gennemført på patienter i ernæringsmæssig risiko (med screening ved NRS-2002) indlagt på Thorax Kirurgisk, Karkirurgisk, Abdominal Kirurgisk og Lunge Medicinsk afdeling, på Aalborg Universitets Hospital.

Studie I: Et pilotstudie blev igangsat med henblik på at øge energi og protein indtaget (minimum 20g. i gennemsnit) til morgenmad i en population af kirurgiske patienter (Thorax Kirurgisk og Karkirurgisk) i risiko for DRM. Studiet blev gennemført med udgangspunkt i udvikling og pilot-testning af en multimodal model "Kulina modellen"

Studiet blev designet med en kontrolgruppe og en interventionsgruppe baseret på tre dages kostregistreringer kombineret med semistrukturerede interviews relateret til patienternes mad oplevelser, præferencer, appetit og spisemønstre, samt foto-selektion relateret til morgenmad. Data blev båndet og transskriberet, og brugt som inspiration i en co-design session i forbindelse med udvikling af en ny morgenmads menu, som blev testet i studiet.

Studie II: Resultaterne fra studie I dannede baggrund for studie II som er udformet som et case studie med fokus på at teste en forbedret version af Kulina-modellen, i form af en mere systematisk tilgang til patienternes spisemønstre, fødevarerpræferencer og appetit relateret til mellemmåltider i en population af kirurgiske og medicinske patienter. Det semistrukturerede interviews blev udvidet og en måling af niveau for appetit blev tilføjet. Data blev båndet, transskriberet og analyseret. Resultaterne fra foto selektionen blev behandlet ved deskriptiv statistisk, og appetit blev målt ud fra en numerisk skala. Resultaterne fra de indsamlede data blev anvendt i en co-design session hvor høj-energi og høj-protein mellemmåltider blev udviklet. En model for sensorisk mad kvalitet til at fremme ernæringsindtaget hos patienter i ernæringsmæssig risiko, blev anvendt sammen med sensoriske test af de udviklede mellemmåltider. Studiet blev afsluttet med en intervention, med det formål at øge energi og protein indtaget til mellemmåltiderne i populationen, gennem implementering af målrettede høj-energi og høj-protein mellemmåltider (3 servering

pr. dag). Studiet var designet med en kontrolgruppe og en interventionsgruppe med hver 3 dages kostregistrering.

Resultat

Studie I: 10 patienter deltog i semistrukturerede interviews inklusiv foto-selektion. I interventionsstudiet deltog 62 patienter. Signifikant forskel blev fundet mellem kontrolgruppen (n=32) og interventionsgruppen (n=30). Den protein berigede morgenmad bidrog med i gennemsnit 22% (20g) af det individuel daglig behov for protein og 24% af behovet for energi vs. 14% (protein) og 18% (energi) i den retrospektive kontrolgruppe.

Studie II: 14 patienter deltog i semistrukturerede interviews inklusiv appetit måling og foto-selektion. Over halvdelen af patienterne fik ikke noget at spise mellem morgenmad, frokost og sent aften. Ikke alle var vant til at spise mellemmåltider der hjemme. Foto-selektionen viste variation i præferencer, og at der således er brug for en menu med alle smage og konsistenser, samt at der formentlig er brug for fødevarer med især blød konsistens og drikke til de svageste patienter, men ingen generelle tendenser kunne påvises. Appetit målingen viste generelt en moderat påvirket appetit. Baseret på de kvalitative data, blev der udviklet 23 nye mellemmåltider med et gennemsnitligt indhold på 9.7 g. protein og 721 kJ/ 172 kcal.pr. servering. 46 patienter (intervention) fik serveret høj-energi -protein mellemmåltider, mens 46 (kontrol) fik serveret standard mellemmåltider. Høj-energi-protein mellemmåltiderne øgede signifikant energi og protein indtaget til mellemmåltiderne og totalt over døgnet. Gennemsnitlig energi indtag blev øget fra 55% til 118% og protein indtaget steg fra 30% til 112% til mellemmåltiderne i forhold til behov.

Konklusion

En multimodal model, ”Kulina-modellen”, blev udviklet som en metode til at udvikle måltider målrettet specifikke barrierer, præferencer og behov med henblik på at øge ernæringsstruede patienters indtag af mad. Implementering af denne model forbedrede energi og protein indtaget hos patienter i risiko for DRM sammenlignet med standard koncepter for morgenmad og mellemmåltider.

Dog er der behov for flere længere varende studier, til at vurdere om modellen kan påvise øgning i energi og protein indtag hos patienter i ernæringsmæssig risiko, samt undersøge effekten af modellen i andre settings.

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This PhD is established on my belief in food as a powerful part of treatment to avoid or treat risks related to malnutrition in hospitals, as well as on a substantial interest in food, combined with the aim of improving meal experiences. This would not have succeeded without some lovely people, whom I would like to thank:

Pernille Hougaard Nørbak, Head of the Kitchen department at AAUH, for supporting my work both in this PhD and the implementation of KULINARIUM.

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ABBREVIATIONS, TABLES, FIGURES AND APPENDICES

Abbreviations

DRM: Disease-related malnutrition
ESPEN: European Society for Clinical Nutrition and Metabolism
NRS: Nutritional risk screening
BMI: Body mass index
SSS: Sensory specific satiety
MeSH: Medical subject headings
MRC: Medical Research Council

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Appendix E: Menu - Breakfast

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DEFINITION OF CENTRAL CONCEPTS

In- between meals: *Snack meals, served between the main meals*

Nutritional risk: *Prior to the diagnosis of malnutrition, the criteria for being “at nutritional risk” according to any validated nutritional risk screening tool must be fulfilled (Cederholm et al., 2017).*

Malnutrition: *A state resulting from a lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass, leading to diminished physical and mental function and impaired clinical outcome from disease (1).*

Disease-related malnutrition (DRM): *Specific type of malnutrition caused by a concomitant disease with or without inflammation (1).*

Cytokines: *Cytokines are small secreted proteins released by cells and have a specific effect on the interactions and communications between cells. There are both pro-inflammatory cytokines and anti-inflammatory cytokines (2).*

Clinical Nutrition: *Interaction between food deprivation and catabolic processes related to disease and ageing (1).*

LIST OF PUBLICATIONS

The PhD study presented in this thesis has been carried out at the Faculty of Medicine at Aalborg University and Aalborg University Hospital (AAUH). The research work was carried out at Aalborg University Hospital in collaboration with the departments of Lung Medicine, Abdominal Surgery, Vascular Surgery, Thoracic Surgery, Centre for Nutrition and Bowel Diseases and the Central Kitchen.

The PhD thesis includes the following four papers:

Paper I (Study I)

Beermann T, **Mortensen MN**, Skadhauge LB, Høgsted RH, Rasmussen HH, Holst M. **Protein and energy intake improved by breakfast intervention in hospital.** *Clinical Nutrition ESPEN*. 2016;13:e23-e27. doi:10.1016/j.clnesp.2016.02.097.

Paper II (Study II)

Mortensen M.N, Larsen A.K, Skadhauge L.B, Høgsted R.H, Kolding J, Beermann T, Rasmussen R.H, Mikkelsen B.E, Holst M. **An investigation exploring patients eating patterns, food, drinking and texture preferences, and appetite for in-between meals during hospitalization.** Submitted 01.10.2019. *Journal of foodservice business research*.

Paper III; Extended abstract (Study II)

Mortensen M.N, Larsen A.K, Skadhauge L.B, Høgsted R.H, Kolding J, Beermann T, Rasmussen R.H, Mikkelsen B.E, Holst M. **Catering for patients at nutritional risk using in-between meals – An evidence-based multidisciplinary menu planning approach.** *Captive Food Studies, AAU*, 2017. p. 221-231.

Paper IV (Study II)

Mortensen M.N, Larsen A.K, Skadhauge L.B, Høgsted R.H, Kolding J, Beermann T, Rasmussen R.H, Mikkelsen B.E, Holst M. **Protein and energy intake improved by in-between meals: A targeted intervention study in hospitalized patients.** *Nutrition ESPEN*. 2019. Doi: 10.1016/j.clnesp.2019.01.007.

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INTRODUCTION

Public institutions are responsible for many individuals' meals, as well as their health. Every day, half a million meals are prepared in public institutions in Denmark (3). In the kitchen of Aalborg University Hospital, approximately 1.650 meals are prepared, cooked and served every day throughout the hospital.

Despite the high number of prepared meals, disease-related malnutrition, DRM (*DRM -specific type of malnutrition caused by a concomitant disease*), often occurs in hospitals. Studies have shown a prevalence that ranges from 23 to 60%, with an estimated 40% of hospitalized patients at risk of DRM (4–7). At Aalborg University Hospital, a study investigated the prevalence of patients at nutritional risk by the NRS-2002 screening tool in 2009 and 2010. The results showed a prevalence of nutritional risk of 48% (2009) and 49.8% (2010)(4).

DRM in hospitalized patients may be related to many different and often several simultaneous aspects, including symptom burden of illness, as well as those related to treatment and hospitalizations. However, appetizing foods, snacks or special meals and services tailored to patients with low appetite play a key role in obtaining sufficient food intake in patients (8,9).

To date, substantial studies have been published on the effect of nutritional therapy using oral nutritional supplements (ONS) in patients at nutritional risk (10–12). However, ONS do not seem to have solved the entire challenge, which calls for other nutritious food and beverage solutions that are rich in protein and energy and targeted individual needs.

Limited attention has been drawn to energy- and protein-dense food or food preferences in hospitalized patients. Only a few studies have been published in relation to hospital food and malnutrition. One example is Nottingham University hospital in the UK, where a study compared food intake from a standard hospital menu with an energy-dense menu. The results showed that the fortified menu provided 14% more energy than the normal menu. In addition, nutrition intake increased by 25% with the fortified menu. However, the mean protein intake remained below the recommended level (13). Another study carried out at Herlev Hospital in Denmark investigated whether a novel food service concept with protein supplementation would increase protein and energy intake in hospitalized patients at nutritional risk. The results showed a significantly positive impact on overall protein intake, weight-adjustment and energy intake (14).

Two systematic reviews have been conducted to investigate the effects of dietary enrichment with conventional foods in older adults. The results from the two reviews included nine (15) and seven (16) studies, with an overall positive conclusion

regarding improved energy and protein intake; however, there was a remark on the lack of sufficient quality to provide reliable evidence.

The lack of substantial studies indicate that more research is needed to ensure a better place for food to be included in nutritional treatment of hospitalized patients.

Thus, the focus of this PhD project is the systematic development of hospital food that targets patients at risk of DRM, with the purpose of increasing protein and energy intake. This is accomplished by developing and designing of a multimodal model, The Kulina-model, for targeted hospital menu planning. The design of the model is based on the MRC-guidance (Medical Research Council - a guidance on developing and evaluating complex interventions) (17) in order to handle the complex field of DRM and food development in hospital, using both quantitative and qualitative methods to generate varied data related to patient's individual nutritional needs, preferences and eating challenges.

The project was developed and carried out in two strategically chosen servings, breakfast and in-between meals. The choices of servings/meals were selected based on the following:

Breakfast: Hospital food for patients at risk of DRM in Denmark is recommended to include three main meals and two to three in-between meals (3). The overall focus of the kitchen at Aalborg University Hospital is to ensure the right level of energy and protein in combination with a good sensory food quality. Patients admitted to the hospital often have difficulties in eating “normal size” main meals, and the protein intake is often too low according to calculated needs (14,18–22). Studies indicate that the protein synthesis would benefit from having the total protein intake distributed among three main meals (morning, lunch and dinner) with quantities of 30 g of protein per meal (23), instead of only having a very high intake at lunchtime and dinner (24). Breakfast therefore holds substantial promise in providing patients with more protein; moreover, according to our knowledge, breakfast as a source to improving protein intake, has not been systematically investigated to date.

In-between meals: Based on the high prevalence of patients at risk of DRM and the fact that many patients suffer from early satiety and struggle to eat even small amounts of food at a time (25,26), there is a need to focus on every meal served for patients. According to the national Danish guidelines for hospital food (3), patients at risk of DRM are recommended to be served in-between meals equivalent to 30-50% of the total daily nutritional needs. Studies that targeted in-between meals have been conducted (21,79); however, many of these studies are based on oral nutritional supplements (27,28). Thus, there is a lack of knowledge regarding common food and meals served for in between meals.

Aims of the thesis

The overall *aim* of this thesis is to increase energy and protein intake in patients at risk of disease related malnutrition by the development and pilot testing of a multimodal model based on the MRC-guidance, and in this thesis referred to as the Kulina-model, including patient's eating patterns, food preferences and appetite for development of targeted hospital food. The development of The Kulina-model will be proceed through study I, and refined and tested in study II based on a multidisciplinary approach.

This thesis consist of two studies presented in four papers (I-IV) with the following aims

1. To develop a new concept for a protein and energy rich breakfast based on patients preferences. Further, specifically to increase protein intake at breakfast to at least 20g/day (I).
2. To improve protein and energy intake at breakfast in patients at nutritional risk during hospitalization in a surgical department, by investigation of patients preferences (I).
3. To gain insight into patient's eating patterns, food and drinking preferences, and appetite for in-between meals during hospitalization at a medical and a surgical department (II)
4. To develop high protein and energy rich in-between meals and menus targeted preferences of patients at nutritional risk based on a multidisciplinary menu planning approach (III).
5. To examine if total protein- and energy intake in medical and surgical patients at nutritional risk, may be improved by protein fortified and energy rich in-between meals, tailored to the preferences of patients at nutritional risk by use of the Kulina-model (IV).

BACKGROUND

Hospitalized patients are highly exposed of not sufficiently reaching nutritional needs because of physiological and psychological changes that appear in relation to being ill. This chapter will look into some of the predominant changes that may affect nutritional intake and how a targeted food intervention may likely lead to an increased intake of energy and protein.

At risk for disease-related malnutrition

Disease-related malnutrition (DRM) in hospitalized patients is not a newly developed problem, as it has been reported since the 1970s (29,30). However, the problem remains unsolved. DRM affects approximately one-third of hospitalized patients and is associated with a wide range of adverse effects, which lead to serious consequences for the patients and the health care system. A European study conducted in 2008 showed that patients at nutritional risk had significantly higher complication rates, increased mortality and a longer hospitalization than patients not at risk (5). This tendency has been identified in several other studies performed in subsequent years (31–36).

Malnutrition is particularly prevalent in the elderly population aged >65, where the prevalence may be as high as up to 60% (9). In 2015, older adults occupied approximately 35% of the hospital beds in Denmark (37). The prevalence of older adults worldwide is estimated to triple by 2050, thus affecting the frequency of malnutrition in hospitals (38). These changes in the population might lead to an increased prevalence of nutritional risk in patients and provide a rationale for a more proactive treatment of malnutrition.

To understand the nutritional changes that occur in hospitalized patients and the pivotal role of nutrition, it is essential to include the evidence-based terminology and classifications that are widely accepted regarding nutritional challenges during disease. The European Society for Clinical Nutrition and Metabolism (ESPEN) has developed the *ESPEN guidelines on definition and terminology of clinical nutrition* (1), which aim to unify the understanding of terminologies and classifications towards a more consistent development of critical nutrition practice and research. In the guidelines, clinical nutrition is defined as an interaction between food deprivation and catabolic processes related to disease and ageing. The guidelines define five types of nutrition disorders and nutrition related conditions, including malnutrition, sarcopenia and frailty, obesity, micronutrient abnormalities and re-feeding syndrome (Figure 1). Obesity and micronutrient abnormalities will not be explained further in this thesis.

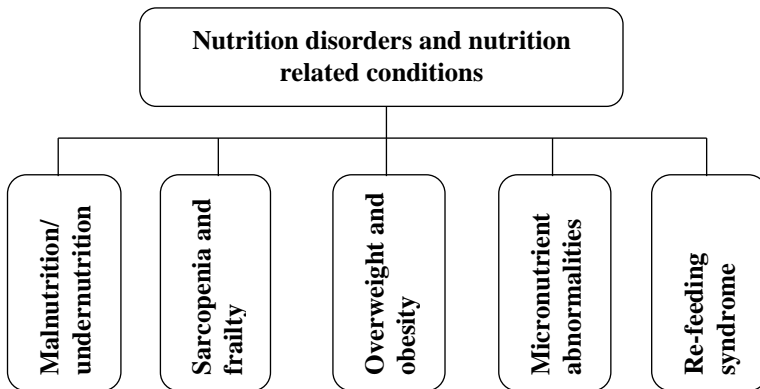


Figure 1. Overview of nutrition disorders and nutrition-related conditions (1)

Looking into the consensus on the terminology related to malnutrition, malnutrition may be defined as “*a state resulting from a lack of uptake or intake of nutrition leading to altered body composition and body cell mass, again leading to diminished physical and mental function and impaired clinical outcome from disease*” (39). This definition has also been accepted by ESPEN to diagnose malnutrition and subordinate aetiology-based types of malnutrition. Sub-classifications of malnutrition are categorized in two types, disease-related malnutrition with or without inflammation and malnutrition/ undernutrition without disease as illustrated in Figure 2.

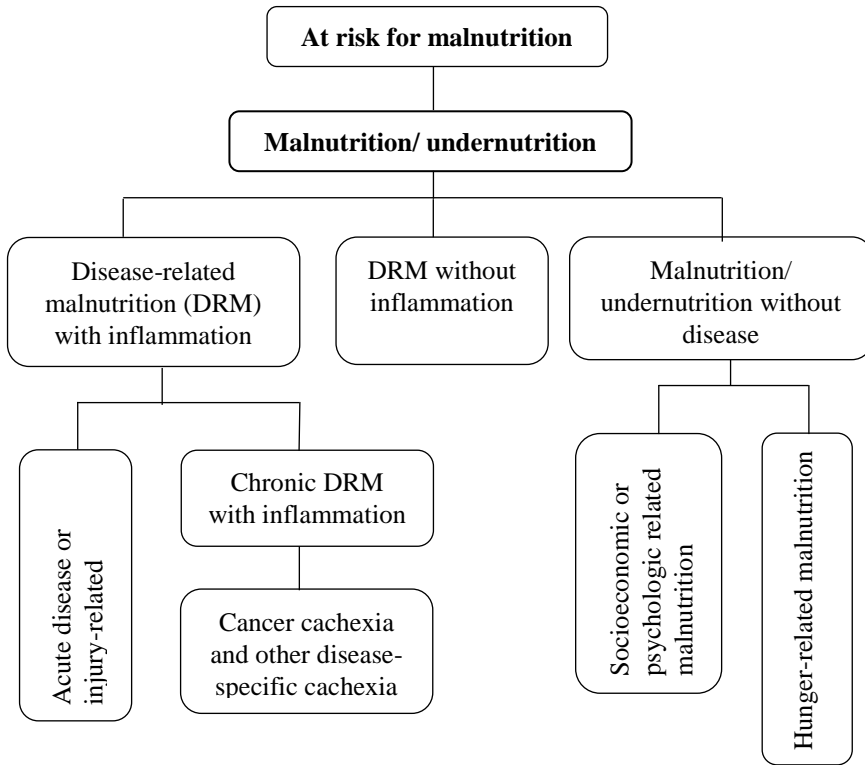


Figure 2. Diagnosis tree of malnutrition (1)

To understand the differences in the classification, a short description is provided in the subsequent section.

Disease-related malnutrition with inflammation is elicited by an underlying disease that leads to anorexia and tissue breakdown, characterized as a catabolic condition from the inflammatory response. Advanced ageing seems to play a role in contributing to the state of inflammation (1).

Chronic disease-related malnutrition with inflammation is synonym with cachexia. Cachexia is a complex metabolic syndrome associated with an underlying illness and is characterized by the loss of muscle mass with or without the loss of fat mass. Cachexia is often characterized by weight loss in adults (40).

Acute disease- or injury-related malnutrition is associated with a high stress metabolism, such as increased cytokine activity and hormonal action; moreover, reduced muscle loading and no- or reduced food intake are involved (41).

Disease-related malnutrition without inflammation is related to certain diseases, such as dysphagia, neurological disorders, age related anorexia and dementia (1,42).

Malnutrition/ undernutrition without disease is related to hunger and starvation and is often identified in poor developed countries or in connection with natural disasters (1).

Sarcopenia is the loss of skeletal muscle mass, strength and function. Sarcopenia is divided into primary sarcopenia, which is related to ageing and prior to frailty, and secondary sarcopenia, which is related to pathogenic mechanisms that are disease and activity-dependent (43).

Frailty is mainly related to advanced age; however, it is also modifiable by lifestyle. It is a state with a limited capacity in major organ system that leads to reduced resistances to stress, such as trauma and disease. The condition involves nutrition-related components that lead to weight loss, sarcopenia and weakness (44).

As described in the previous section, malnutrition may be caused by various factors related to illness and age, with substantial consequences for the individuals who suffer from it. This knowledge must be taken into consideration when planning targeted nutritional treatment to secure nutritional needs to prevent or treat malnutrition.

When focusing on treating DRM with nutritional therapy, it is also essential to examine how appetite develops and changes in relation to illness.

Appetite and illness

Appetite is essential for the urge to eat, and the loss of appetite has a high impact on food intake. However, how does appetite work, and can illness affect appetite?

To be able to understand the function of appetite, it is essential to define the mechanism of appetite and how it works. According to Mattes et al. (45), appetite is the desire to fulfil a bodily need and may be divided into three components: Hunger, satiation and satiety. Hunger is the sensation that promotes food consumption, satiation is the sensation of fullness during eating that leads to meal termination and satiety is the fullness that exists between eating occasions.

To understand appetite in relation to satiety and satiation, Blundell et al. refers to a relation between satiation and satiety, which is illustrated in the satiety cascade (Figure 3). The cascade illustrates factors that affect the process between satiation, the process that leads to the termination of eating, and satiety, the process that leads to the inhibition of further eating, a decline in hunger and an increase in fullness after a meal has (46).

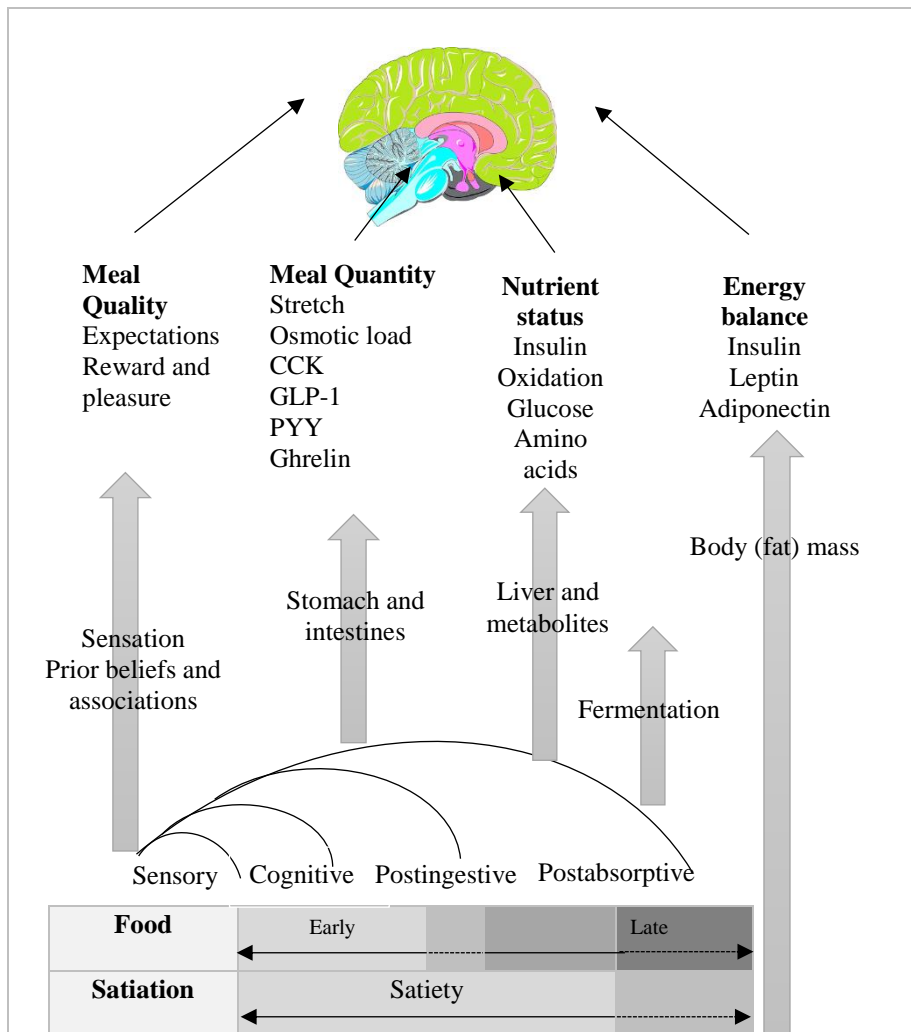


Figure 3. Satiety cascade (46)

The satiety cascade includes the sensory, cognitive, post-injective and post-absorptive mechanisms, as well as other factors related to the meal and energy balance. In the sensory phase, stimuli from the five senses, including sight, hearing, smell, taste and touch, are activated followed by the cognitive phase, which involves earlier food experiences and expectations. The post-ingestive phase involves signals from the gastrointestinal tract that lead to the activation of satiety signals, and the post-absorptive phase includes the absorption of nutrients and signals from metabolism (47).

However, not only physical factors are involved. Cognitive factors do also have a central role in meal termination and are related to experiences from previous food intake, social norms and a learned ability to estimate the satiating effects of many foods. These learning mechanisms define expectations and affect the amount of food consumption. Psychological factors, such as emotion and loss of control, can suppress physiological signals (47,48).

Appetite regulation is complex and may be briefly described as a control system that links the brain, digestive system, endocrine system and sensory nerves together to regulate the amount of food intake (49).

However, what happens with the appetite regulation and satiety in relation to illness? It is well known that an alteration related to appetite may lead to a deterioration in nutrition status in hospitalized patients and is closely linked to decreased appetite. An acute illness and chronic disease may affect the appetite and lead to a decreased intake of food. This is mainly caused by pro-inflammatory cytokines that lead to neural activity changes in the brain areas that control food intake, independent of other acute responses, such as fever and metabolic changes (50). Sensory changes, nausea and medication side effects may also be related to a negative impact on appetite (51). In particular, elderly people are at risk of appetite loss because of the impaired dexterity and pain that affects the eating process in a negative way (52). Elderly people are furthermore exposed because of the impairments of the senses that occur with ageing. Reduced abilities in order to smell and taste affect the appetite and the inclination for food (53).

In addition to the physiological changes that appear in relation to illness, psychological changes are often identified in hospitalized patients. In particular, critical ill patients suffer from psychological consequences, such as anxiety, depression and posttraumatic stress, which may affect recovery and reduce the quality of life (54). As depression is known to negatively impair appetite, it may have serious consequences for patients (55). This is often identified in older adults because of a high prevalence for developing depression (56).

As previously described, illness affects the human body, disturbs the biological regulations, changes the metabolism and increases the need for energy and protein, in

addition to a decreasing appetite. Psychological and mental changes are also risk factors that interfere with the satiety and appetite regulation, and together with physiological changes, a disturbance in the flow of the satiety cascade will appear, followed by a negative appetite regulation, which leads to poor food intake.

Good nutritional practice - GNP

To handle DRM in hospitalized patients, *nutritional screening* may be used to predict the probability of a better or worse outcome due to nutritional depletion and whether nutritional therapy is likely to improve outcome. Thus, a routine for identification by purposeful nutritional screening is indicated. A validated screening tool that targets the population and setting is given priority, as the various screening tools weigh included parameters differently. The Nutritional Risk Screening (NRS-2002) method was developed and recommended by The European Society for Clinical Nutrition and metabolism, “ESPEN” (57), to identify the presence and risk of developing undernutrition in patients in the hospital setting. It combines the body mass index (BMI) and weight loss within the past 3 months as a score for nutritional status, as well as an estimation of nutrition intake within the past week, with a validated grading of the severity of disease. Each category is graded as mild, moderate and severe, with 0–3 points. These points are summed, providing a total of 0–6 points. For patients over 70 years of age, one risk point is added to the score. When the sum is three points or more, the patient is considered to be at nutritional risk. In Denmark, nutritional screening by the NRS-2002 is recommended as good clinical practice by the Danish National Board of Health (58).

In the GNP process, nutritional screening is followed by *nutritional assessment*, including an assessment of the Nutrition Impact Symptoms (NIS), providing the professional the ability to determine whether there are treatable symptoms that must be taken care of or treated for the patient to enhance an improved ability to eat. These symptoms may include nausea, dysphagia, or pain. Furthermore, a *nutrition plan* including a calculation of the patient’s requirements for energy and protein is created, and decision is made regarding which diet and eventually nutritional therapy will be provided for the patient. For patients at nutritional risk, an energy- and protein dense diet is provided. Serving the right portions and *monitoring* food intake represent the next step, which leads to the patient eating sufficiently or for a new assessment and plan to be created. Finally, this is followed by a plan for communication.

The Hospital diet

To treat a patient at nutritional risk and before the nutritional plan may be put into action, substantial consideration must be done to develop targeted food items and concepts to prevent or treat undernutrition. The main kitchen at Aalborg University Hospital is responsible for the development and production of the hospital food. Food developers and food scientists work together with a team of dietitians, nurses and physicians from the Center for Nutrition and Bowel disease (CET) to develop targeted hospital food. According to Danish national guidelines (3), the food served at a hospital must be compounded to cover individual needs for energy and protein in combination with a high culinary quality. The energy and protein density must be higher than that in recommendations for healthy individuals with a recommended protein level of 18E%, fat 40E% and carbohydrate 42E% and a daily meal distribution of three main meals and three snack meals. A vitamin supplement is recommended to ensure sufficient intake. The current recommendation for patients struggling to eat and with low appetite indicates that servings of small frequent portions that are easy to eat with a high nutritional density must be offered.

To comply with the recommendations, the energy and protein density must be increased in the hospital food. When adding more energy and protein into a meal, the longer term satiety might be affected, which implies a risk that patients might not be able to eat at the next meal. This and many other factors must be taken in consideration in the development of fortified meals.

Satiety and fortified meals

When patients suffer from early satiety, it may interfere with their ability to adequately eat (25). This is one of additional considerations when planning the portion size and nutritional density. Studies have shown that a reduced food volume and dense foods served frequently may increase patient food intake (13,59,60). However, the satiating power is dependent on the amount of protein, carbohydrate, fat and fibre related to the post-digestive metabolic effects of food, thus indicating that not all nutrients will affect satiety in the same way (61). Classical laboratory studies have been conducted on the physiological effects of food ingredients and have shown that different foods with different macronutrients but equal energy have distinct effects on satiety. The results from these studies indicate a hierarchic classification to distinguish specific effects on satiety in the order of protein > carbohydrate > fat (62,63). High-protein food seems to deliver better satiety than food with lower protein, and the position of the satiety hierarchy is fairly accepted. In contrast, fat seems to be less satiating than carbohydrate and is placed lowest in the hierarchy. The immediate explanation is that fat delivers more than double the energy of carbohydrate and protein per unit, and the high-energy density determines the low satiety (61). Dietary fibre is another food ingredient that must be taken into consideration to promote satiety. Fibre is complex,

and it generally affects satiety in many ways depending on the fibre type. It has recently been shown that only the most viscous fibre had impact on the following meal (64).

Sensory components, such as taste, smell and texture, are closely connected to the experience of flavour and eating experiences. Thus, food texture seems to play a special role in satiety, which may be explained by the idea that viscous food is often related to hunger, while liquid is primarily consumed in relation to thirst (65). Solid and liquid foods seem to affect appetite differently, and studies have shown that liquid calories have weaker effects on satiety (66). Manipulating the viscosity in food has been investigated in several successful tests, for example, increasing the viscosity of a semi-solid chocolate pudding (67), thickening a “shaker” (68) and enhancing the thickness and creaminess of a yoghurt beverage (69). The results showed that chocolate pudding reduced the eating rate and increased satiety, the “shaker” reduced post-consumption hunger, and the yoghurt changed the perception of how satiating it was likely to be.

Taking a closer look at the phenomenon sensory specific satiety (SSS), it refers to the reduction in palatability during consumption that leads to decreases in ratings of pleasantness. SSS may appear independent from appetite sensations, which are not necessarily assessed (70). Studies have shown that changes related to the pleasantness of foods occurs immediately after consumption and do not increase over time (71). Given the possibility of various food conditions, it is shown that subjects consume greater amounts of food. This has been demonstrated in a study in which one group received hors d’oeuvres of one type in a single condition and another group had three types of hors d’oeuvres, different in appearance, flavour and texture. The study showed that subjects ate more when given a meal that consisted of an assortment of foods than when the meal consisted of a single food (72). The same tendency has been identified in a study that assessed varying flavour filling in sandwiches, which showed an increase in food intake of 15% compared to when offered a plain sandwich (73). Moreover, in a study that provided a four-course lunch as a varied meal with different foods in each course, in contrast to a plain meal with the same food in each course, the results showed an increase in food intake by 60% (varied meal) compared to the plain meal (74).

Evidence is limited on the effect of food variety and sensory satiety with respect to patients at nutritional risk. The studies referred to in the previous section have been performed in groups of healthy individuals; however, it might indicate future areas relevant for testing on patients in a hospital setting. A model has been developed for sensory quality to promote intake in patients at nutritional risk that incorporates eating related symptoms (75). The model is divided into three categories related to motivation to eat, pleasure, comfort and survival. Taking a closer look at the survival category, beverages and yoghurt are provided as examples of food to promote intake in combination with food sensory needs, such as texture, consistency, easy to eat and simple. The promotion of food intake in patients at nutritional risk is complex and

must be taken into consideration when new menus targeted patients at DRM are developed. Further studies might benefit from incorporating the previously discussed knowledge, which is primarily based on healthy individuals, with the knowledge from the motivation to eat model based on patients.

Effect of food based interventions in patients

In order to take a closer look at the effect of food based interventions for patients at risk of malnutrition, a systematic review of the literature was conducted. The aim was to summarize the evidence for the use of energy and/ or protein dense meals to increase energy and protein intake. The systematic review included studies regarding hospital inpatients and nursing home/ residential home dwelling patients. Nursing home/ residential home was included because of the similarity towards a relative high risk of malnutrition and public food service (76,77). The final literature search was completed on the 5th February 2019.

To identify all relevant publications between 2009 and 2019, the systematic literature search was conducted through PubMed and Cinahl data bases. The search was assisted by a medical librarian to ensure the most relevant keywords, search strategy and MeSH terms. A set of inclusion criteria were defined and included articles that reported use of energy and protein dense (fortified, enriched, modified) meals, snacks or beverages, to increase energy and protein intake within the target population. There were no restriction to the study design. Language was limited to Danish, Swedish, Norwegian and English. Conference abstracts were excluded due to the fact of possibility to enhance sufficient insight in methods and results. Studies involving the following, was also excluded: Fortifications with micronutrients only, and focus being on efficacy of combination with training exercise, combination with nutritional assistant, multi interventions and ONS only.

After the systematic search was completed, The PRISMA guideline (78) was used to evaluate the studies in order to obtain value of the reviews. The details of the search process are shown in figure. 4. Duplicates were removed and the titles of the articles were screened identified by the inclusion criteria. Following, all potentially abstracts were assessed for inclusion and full text was obtained for all included abstracts in order to complete the systematic search.

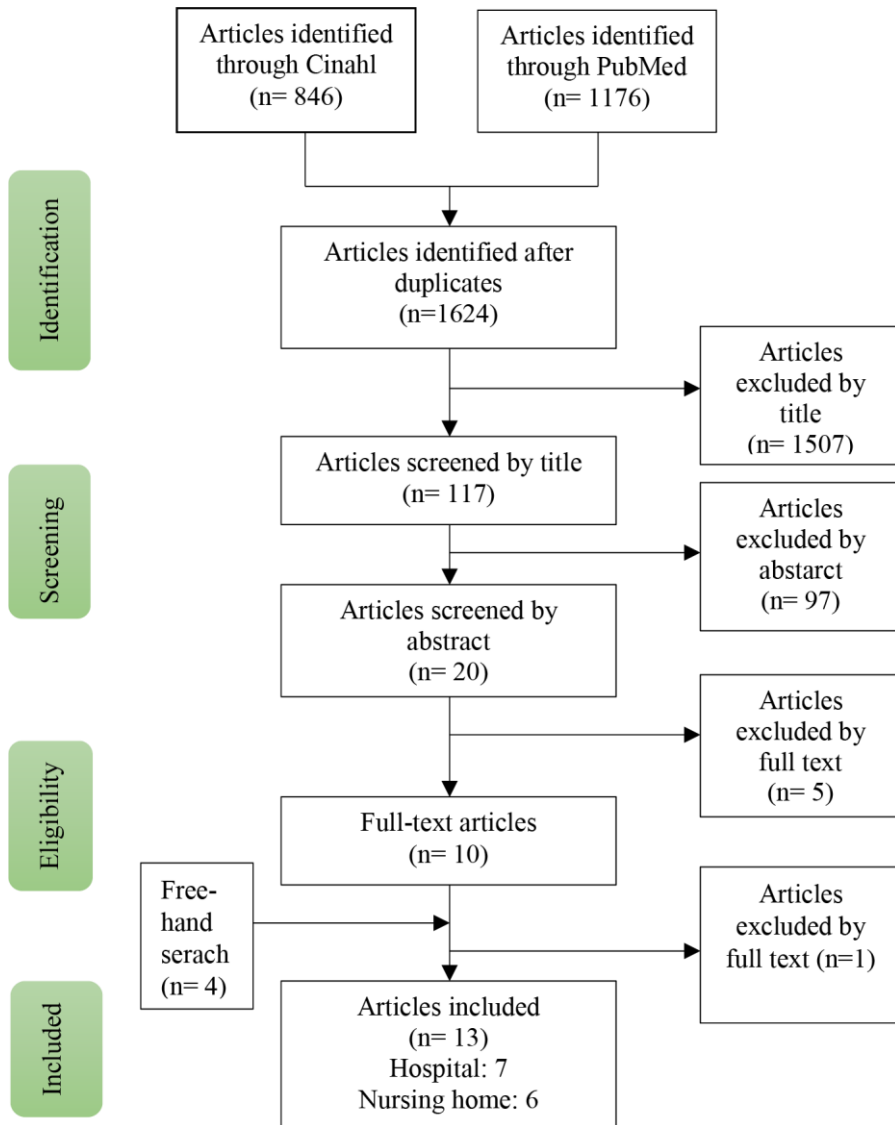


Figure 4. Article search flowchart

Review of studies related to fortified hospital food

Author/year/ reference	Subjects	Sample size	Design	Intervention (I) Control (C)	Areas of evaluation	Main outcomes
Beelen 2017 (60)	Patients admitted to Geriatrics/internal medicine or pulmonary medicine ≥65	147	RCT	I: Protein-enriched familiar foods and drinks menu C: Standard menu	a: Energy and protein intake b: Mean length of stay c: Hand grip strength	Energy and protein intake was significantly higher in the intervention group. No difference in length of stay or handgrip.
Beermann 2016 (79)	Patients admitted to the departments of heart and lung surgery and vascular surgery	62	Intervention study with a baseline and follow-up measurement	I: A protein enriched breakfast menu. Goal to increase protein intake at breakfast to at least 20g. Fortified with natural ingredients and with powder. C: Standard breakfast	a: Energy and protein intake	Total amount of protein intake for breakfast was increased from 14-20 g. Protein and energy intake at breakfast as well as total daily intake was significantly increased to meet recommended average level
Björkman 2012 (80)	Older persons in municipal nursing homes	106	RCT	I: Whey fortified juice 20g. Protein. Served with meals three times a day C: Regular fruit juice	a: Body composition	Increases bodyweight. Skeletal muscle index decreased in the control group however this difference levelled off at the re-examination

Castellanos 2009 (81)	Nursing home ≥60 years	33	Single-blind randomized cross-over	I: Enhanced lunch I: Enhanced breakfast incl. nutritional juice and lunch. Fortified with natural ingredients and with powder (juice) C: No meals enhanced	a: Consumed food weight b: Energy and protein intake	Smaller eaters increased energy intake when either breakfast or lunch were enhanced. Overall daily protein intakes were not increased
Collins 2017 (19)	Patients admitted to the department of geriatric	122	Non-blinded parallel controlled pilot study	I: Modified hospital food. Fortified with natural energy and protein dense ingredients C: Standard menu	a: Weight b: Hand grip strength c: Nutritional intake d: Satisfaction with the foodservice	No difference in weight. Significantly higher energy and protein intake among those receiving the intervention. Satisfaction with the foodservice was high. No difference in handgrip or nutritional intake.
Holst 2009 (20)	Patients admitted to the department of haematology, gastroenterology and infectious disease	276	Intervention study	I: A trolley serving bedside in-between meals varying in energy and protein. Fortified with natural ingredients. C: Standard in- between menu	a: Energy and protein intake b: Satisfaction with the in-between intervention c: LOS (length of stay)	No increase in total energy or protein intake. Overall patients expressed a positive attitude to the intervention. Reduced oral intake was not associated to LOS.
Ingadottir 2018 (21)	Patients diagnosed with	34	RCT	I: Snacks high in protein. Fortified	a: Energy and protein intake	Increase in energy intake in both groups.

COPD admitted to the department of respiratory medicine	with natural ingredients. C: Oral nutritional supplements ONS	b: Weight change c: Body composition, fat mass, fat-free mass and muscle mass d: QoL	Protein intake was higher in the snack group, but no significant changes was found in the ONS group. Both groups increased body weight and fat mass while fat-free mass decreased. QoL score improved in both groups.
Ingadottir 2015 (82)	I: Energy increased hospital meals. Fortified with natural ingredients. C: Standard menu (study 2011)	a: Energy and protein intake	Increase in energy. No difference in protein intake.
Munk 2013 (22)	I: Energy fortified meals. Fortified with natural ingredients. C: Standard hospital menu	a: Energy and protein intake	No overall differences in energy and protein intake between the groups were found
Munk 2014 (83)	I: Protein fortified novel food service with protein powder C: Standard hospital food service	a: Energy and protein intake	Increase in overall protein and energy intake

Van Til 2014 (84)	Patients admitted to rehabilitation centre	34	RCT	I: Protein enriched bread and drinking yoghurt fortified with protein powder. C: Regular bread and drinking yoghurt	a: Protein intake	Increase daily protein intake
Van Wymelbeke 2016 (85)	Nursing home ≥ 70	111	RCT	I: Protein and energy enriched brioche. C: Oral nutritional supplement C: Standard breakfast	a: Energy and protein intake b: nutritional status	Increased energy and protein intake and improved nutritional status
Zaylan 2017 (86)	Senior residential centre	42	RCT	I: Protein-enriched bread and meals. Fortified with natural ingredients. C: Regular bread and meals	a: Energy and protein intake b: Acceptability of protein-enriched products	Increased protein intake, energy intake did not differ significantly between the groups

As showed in the review schema only 13 substantial articles were identified related to food based interventions and risk of malnutrition, and only seven were carried out in hospital settings. The studies differed in the way that enrichment was used, either by natural ingredients or by powder or in combination. Two studies focused only on energy enrichment, seven studies on protein, and four studies focused on both energy and protein. The two studies of Ingadottir and Munk (22,82) conducted only with energy enrichment did not show any differences in protein intake even though energy intake was increased in the study of Ingadottier.

Studies performed with protein fortification alone (54,73,74,75,81-84) showed an increase in both energy and protein intake, except for one study (86). Five of the studies used only natural fortifications. Of these studies, one (72) showed no difference in energy and protein intake, one (82) showed increase in energy and two

Three studies (76,77, 83)) used both energy and protein fortifications, with varying results. An explanation to the varying results might be different levels of protein used in the studies, in combination with different protein sources as natural dense food ingredients and protein powder, or used in combination.

Only two studies involved patient's preferences in the food development. One of them was the hospital breakfast study (79) included in this PhD, where new breakfast items were developed based on data on patients preferences. In this study energy and protein intake were increased considerably. The other study (81) was carried out in a nursing home setting, using data from three days of food recording to determine which foods to enhance. The resulted showed an increase in daily energy intake but not in overall protein intake.

One study (22) used former patients, in the development of a new hospital menu. However this elaborated method did not show any overall improvement in intake.

Summary: The studies included in the literature review, indicate that it is possible to increase energy and protein intake with fortified food items, in hospitalized patients at risk of malnutrition and in elderly living in nursing homes. However, some areas could likely be improved. It seems that, in order to increase protein intake, protein level must be increased in the food items, and fortification seem necessary to reach the recommended levels. Studies where only energy was increased, showed only improvement in energy intake and not in protein intake, which indicate a combination of both energy and protein enrichment is relevant. Studies that present food preferences in the development of new food items were limited, but might be beneficial for focus in future studies, based on the results from the breakfast study (79).

The missing gap

Although there are some studies conducted on energy and protein dense meals, menu planning in hospitals are often more based on years of experience and calculations that aim to meet official guidelines for nutrients rather than on the documentation of effects or data collected on patients' eating challenges and preferences. Good Nutritional Practice is recommended and implemented in many hospitals, but still DRM remains an undergoing problem in patients all over the world (4,5,7).

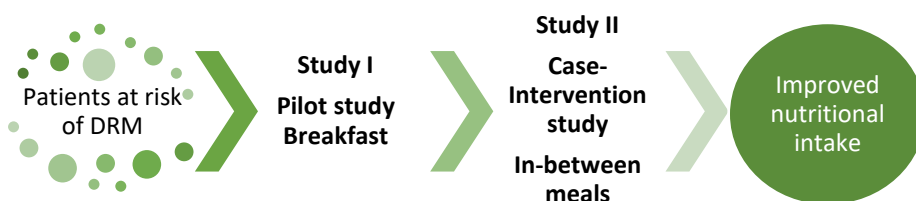
Energy and protein dense meals are a part of the nutritional care plan and must be developed to fit patients at nutritional risk. It is our belief that food production regarding patients is complex and demands more patient-near involving and knowledge than can be overseen from inside a hospital kitchen.

The missing gap to achieve a better nutritional status in risk patients may be found in the development of targeted hospital food by integration of interdisciplinary expertise in relation to food, nutrition, health and patient values.

RESEARCH METHODOLOGY

Overview of the study methods

The studies conducted in this PhD are based on a multimodal research strategy using the chain of development as the driving factor to improve energy and protein intake in patients at risk of DRM. A multimodal model, the Kulina-model, established on the basis of the MRC-guidance (17), has been developed and tested in two studies conducted in a hospital setting. The studies and related papers are illustrated in figure 5.



Paper I	Protein and energy intake improved by breakfast intervention in hospital
Paper II	An investigation exploring patients eating patterns, food, drinking and texture preferences, and appetite for in-between meals during hospitalization
Paper III	Catering for patients at nutritional risk using in-between meals – An evidence-based multidisciplinary menu planning approach
Paper IV	Protein and energy intake improved by in-between meals: A targeted intervention study in hospitalized patients

Figure 5. Illustrated overview of the studies and related papers

Presentation of the studies

The studies conducted in this PhD aim to generate action oriented insights for use in the development of targeted hospital food, by the introduction of the Kulina-model. The Kulina-model is developed, tested and investigated through two studies based on hospital meals – breakfast and in-between meals. Study I was designed as a pilot study focused on the development and testing of the Kulina-model. Study II was a case-intervention study that refined the methods used in the Kulina-model. In Table 1, an overview of the studies is presented in more detail.

Table 1. Overview of the studies

Study	Aim	Setting	Design	Outcome	Paper
I	<p>A: To develop a multimodal model, The Kulina-model, for nutritional improvement in patients at risk of DRM</p> <p>B: To examine if protein and energy dense breakfast can increase protein and energy intake in patients at risk of DRM by use of the Kulina- model.</p>	<p>Departments of Thoracic surgery and vascular surgery, Aalborg University Hospital.</p>	<p>A pilot-interventions study based on a multi modal approach, with a control group and an intervention group to measure nutritional intake (n=62) in combination with qualitative data: Semi-structured interview and food-image selection (n=10)</p>	<p>Primary outcome was to develop the Kulina-model in order to improve total energy- and protein intake, and specifically increasing protein intake at breakfast to least 20 g.</p>	<p>Paper I: <i>Protein and energy intake improved by breakfast intervention in hospital.</i> Authors: T. Beermann, M.N. Mortensen, L.B. Skadhauge, R.H. Høgsted, H.H. Rasmussen, M. Holst</p>

II	<p>A: To refine The Kulima-model in order to study:</p> <ol style="list-style-type: none"> 1. Eating patterns, food preferences and Appetite, and for in-between meals, in patients at risk of DRM 2. To develop high-protein and high-energy in-between meals, preferred by patients 	<p>Departments of Abdominal surgery and Lung medicine. Aalborg University Hospital.</p>	<p>A case-interventions study based on a multimodal intervention approach with a control group and an intervention group to measure nutritional intake in combination with qualitative data: Semi-structured interview and food-image selection.</p> <p>A: Case study conducted as a feasibility study based on: Semi-structured interview, food-image selection and measurement of appetite, processed descriptive and statistical. Targeted improvement from study I. (n=14)</p> <p>B: Intervention study conducted as a</p>	<p>Primary outcome was to obtain more systematic in depth data, by using a refined Kulima model, in order to develop high-energy and high-protein in-between meals, specifically targeted to and preferred by patients at risk of DRM, and by that to improve total energy- and protein intake in patients at risk of DRM.</p> <p>Secondary outcome was to test the refined Kulima-model according to</p>	<p><u>Paper II: An investigation exploring patients eating patterns, food, drinking and texture preferences, and appetite for in-between meals during hospitalization.</u></p> <p>Authors: M.N. Mortensen, A.K. Larsen, L.B. Skadhauge, R.H. Høgsted, J. Kolding, T. Beer mann, H.H. Rasmussen, B.E. Mikkelsen, M. Holst</p> <p><u>Paper III: Catering for patients at nutritional risk using in-between meals – An evidence-based multidisciplinary menu planning approach.</u></p> <p>Authors: M.N. Mortensen, A.K. Larsen, M. Holst, H.H. Rasmussen, L.B. Skadhauge, T. Beer mann, R.H. Høgsted, B.E. Mikkelsen</p>
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<p>at risk of DRM</p> <p>B: To examine if protein and energy dense in-between meals can increase protein and energy intake in patients at risk of DRM by use of the refine Kulina-model</p>		<p>feasibility study based on a multimodal intervention approach with a control group and intervention group measuring nutritional intake. (n=92)</p>	<p>usability and transferability</p>	<p><u>Paper IV: Protein and energy intake improved by in-between meals: An intervention study in hospitalized patients.</u> Authors: M.N. Mortensen, A. K. Larsen, L.B. Skadhauge, R.H. Høgstved, T. Beermann, M. E. Cook, H.H. Rasmussen, B. E. Mikkelsen, M. Holst</p>
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Project and study design

MULTIMODAL APPROACH

As previously discussed in the introduction of this chapter, a multimodal approach was chosen to accomplish the aim - *to increase energy and protein intake in patients at risk of disease related malnutrition by the development of a multimodal model – the Kulina-model based on the MRC-guidance*. This approach has been chosen aiming to solve a part of the multi-conditional facts, with respect to what causes undernutrition in hospitalized patients as previously described. It also addresses the complexity that is linked to a hospital setting and involves the individuality of the patients and staff, calling for methods that are workable to develop and evaluate complex interventions.

For this PhD project, the MRC-guidance has been chosen as framework (17). The MRC-guidance works with developing and evaluating complex interventions and updates the advice provided in the 2000 MRC (88). Figure 6 illustrate the key elements of the development and evaluation process in complex intervention.

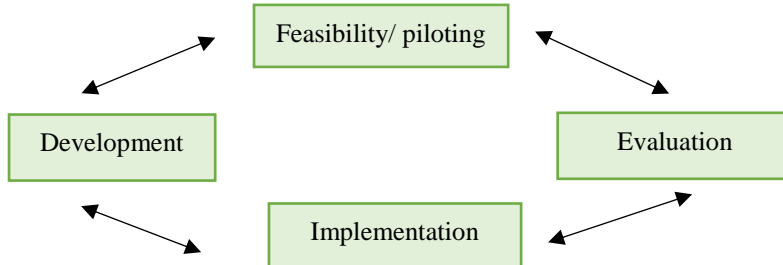


Figure 6. Key elements of the MRC–guidance of the development and evaluation process (17)

The use of this study design enables the use of different research methods and strategies, which is essential for all studies performed in this PhD. The best practice is to develop interventions systematically, starting with the best available evidence

and theory, in order to develop a set of pilot testing targeted the key uncertainties before ending up with a definitive evaluation (17).

To Clarify causal assumptions (why and how it works) and to improve the understanding of these elements that leads to effect a Logic model has been implemented and named the Logic model - The Kulina-model (table 2). A logical model illustrate connections between input/ resources and activities, output, results (outcome) and effect (impact) (88,89). Using a logical model brings transparency in to the project that is valuable for use in reproducing the project or for use in normal praxis.

As addition to the Logic model - The Kulina- model is illustrated in a flow chart in figure 7. The flow chart illustrate the content of study I and study II including a conscious mix of qualitative and qualitative methods, including literature reviews, nutritional risk screening, semi-structured interviews combined with and photographs of meals, design and development sessions and pretesting, and intervention. The green boxes in the illustration illustrate areas that have been refined from study I to study II. Details about the refining of the methods is described later in the section about the Kulina-model.

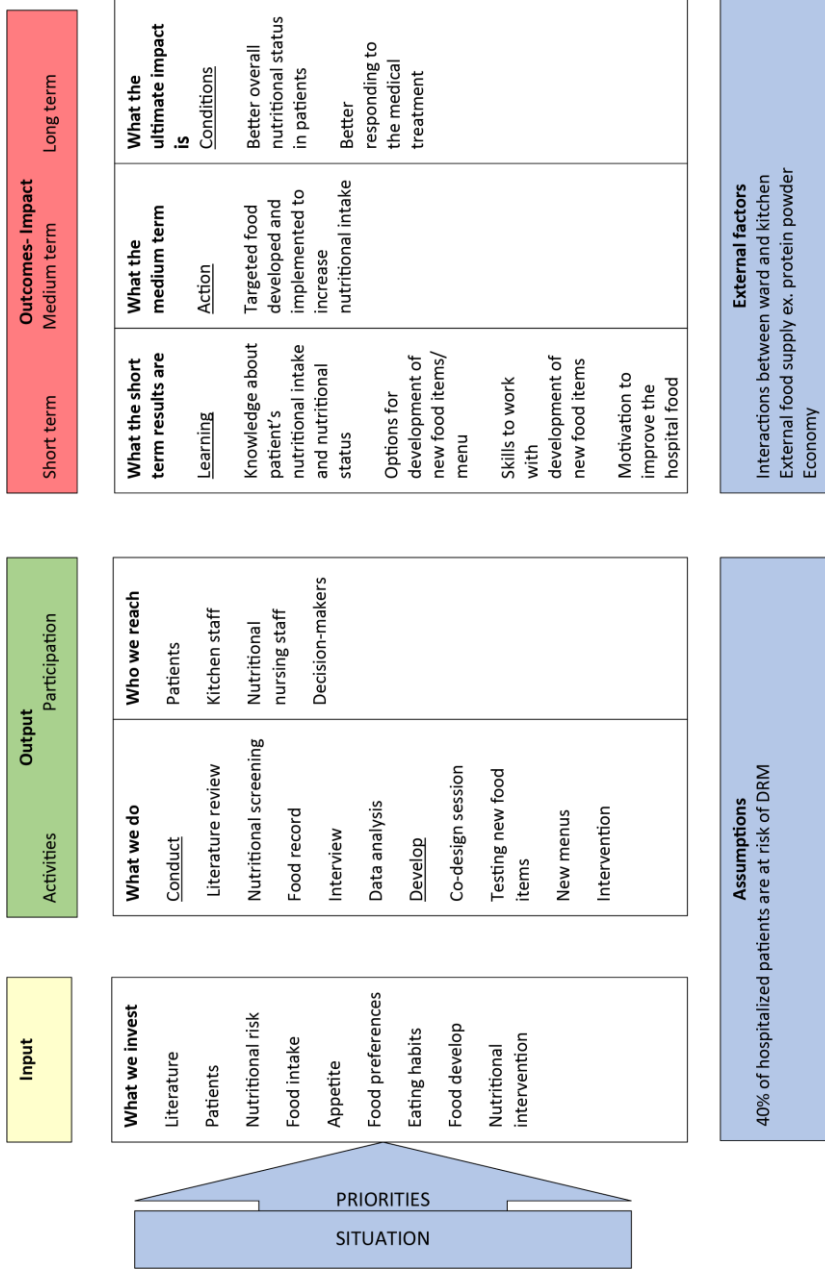


Table 2. Logic model- The Kulina model illustrating input, output and outcome-impact

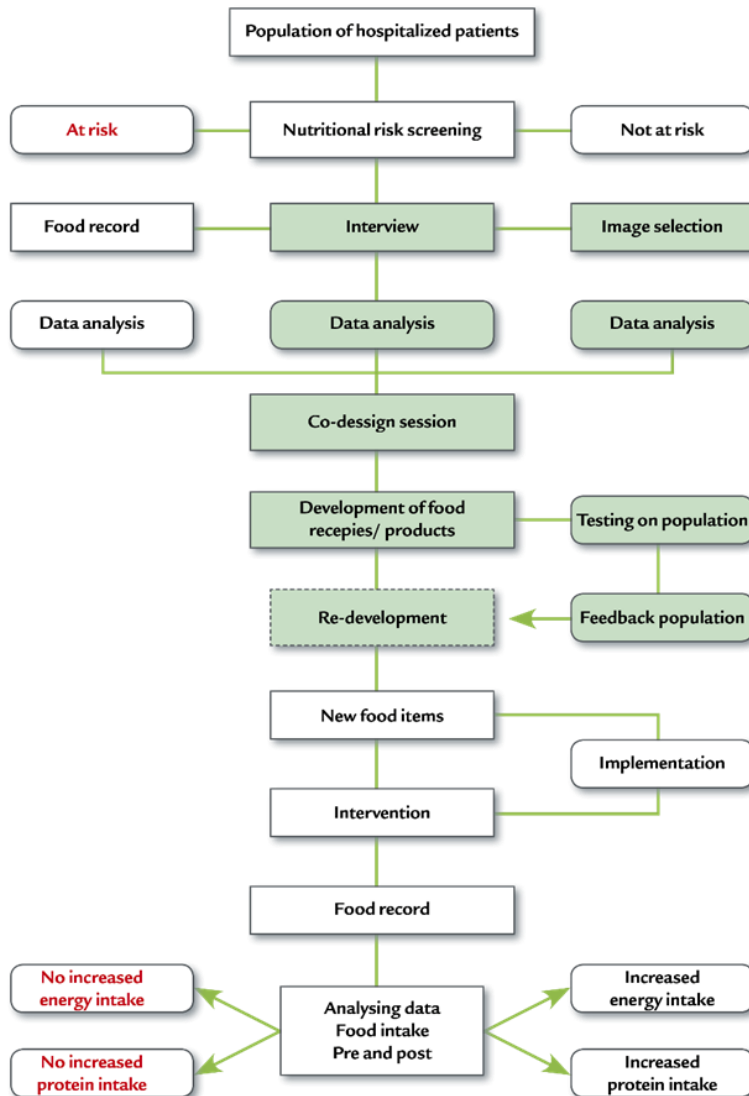
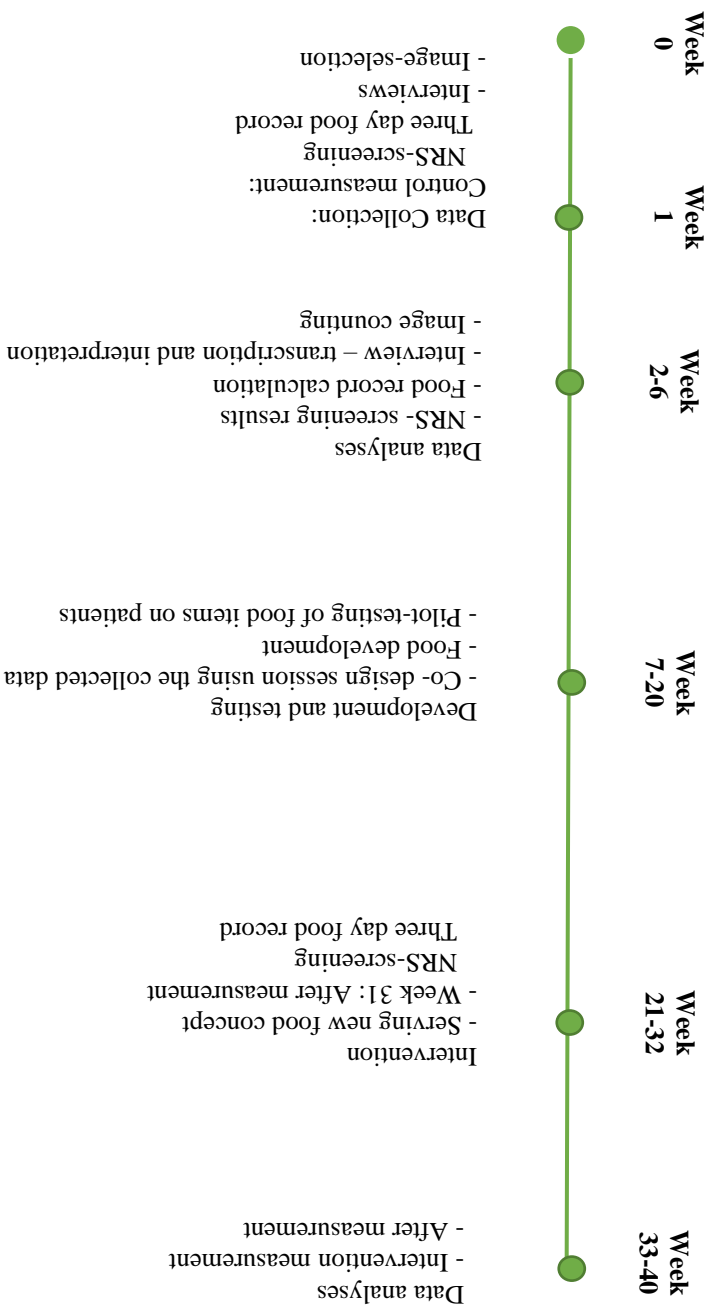


Figure 7. Flow chart- The Kulina-model – To increase of energy and protein intake in patients at risk of disease related malnutrition. Areas illustrated with green has been refined from study 1 to I to study II

STUDY-TIMELINE

In the study-timeline, an illustration of time and performed processes is provided. The time that was given to each study was based on my experiences from earlier studies to allocate the right amount of time for each phase in the studies. The Study-timeline presented in figure 8 illustrates studies I and II, performed over a period of 40 weeks each.

Figure 8. Study timeline for the respective studies



PARTICIPANTS

Study participants were selected from the surgical and medical departments at Aalborg University hospital. *Study I* included patients admitted to the departments of thoracic surgery and vascular surgery. *Study II* included patients admitted to the departments of lung diseases and abdominal surgery. Both departments were located at Aalborg University hospital section south. The selected intervention group in study I was based on a request of a homogenous intervention group to minimize errors associated with using patients from both medical and surgical departments. The choice of including both medical and surgical patients in study II was implemented to investigate the applicability in an un-homogenous group of patients.

The inclusion criteria for study participation were as follows: Patients hospitalized >48 h and identified to be at nutritional risk by NRS-2002 screening, age 18 years or older who can eat orally and do not rely on enteral and/ or parenteral nutrition. The qualitative data collection depended on the feasibility on the day when the data were collected. The exclusion criteria included patients diagnosed with cognitive dysfunction, patients suffering from progressive terminal illnesses, as well as patients with language barriers and patients on special diets. The exclusion criteria in study IV did also include patients diagnosed with diabetes mellitus on a special diet.

STUDY SETTINGS

Aalborg University Hospital is the largest hospital in the North Denmark Region. The hospital handles highly specialized regional functions and has 755 beds with approximately 77.000 discharges per year and 680.000 ambulatory treatments. The meals served in the hospital are produced in the main kitchen by cook-chill and cook to serve. The food delivery is organized to fit two different types of ward settings, with small or large receiver kitchens. Food delivered for wards with small kitchens have the food delivered in a food trolley ready to serve, three times per day. Wards with large kitchens have the food delivered once per day in components prepared for cooking and arrangement of serving. The meals are served from a buffet in the wards by the nursing staff or service staff. The meals are based on a two week menu plan with four seasonal changes. In addition to the menu plan, a range of special diets are individually prepared. Protein and energy levels in the menu are higher than recommended for healthy individuals, as they follow the recommendations for hospital food (3). The meals are distributed and served as three main meals and two in-between meals. In addition to the meals, a selection of extra frozen and cold food and drinks are available in the wards.

Data collection and outcome

Data collected in the two studies were based on the Kulina-model, which was refined throughout the studies and modified for the targeted meals. The Kulina model has been illustrated in Figure 8 to provide an overview of the process levels – data collection, development and intervention phases in the two studies.

CONTROL GROUP DATA AND INTERVENTION GROUP DATA

The control group and the intervention group data collected in studies I and II included: department, gender, age, BMI, NRS-2002 scores, calculated nutritional need and dietary recording. A daily follow-up was performed throughout the baseline and follow-up periods consisting of three days each.

NUTRITIONAL RISK SCREENING

All included patients were screened with the nutritional risk screening tool NRS-2002 (90). Nutritional requirements were calculated in the hospital IT system based on a standardized, modified scale of the Harris-Benedict equation. Protein requirements were calculated in the programme as 1.3 g/kg/d, as recommended by the National Danish Board of Health (3).

DIETARY RECORDING

Nutrition intake was recorded for three consecutive days (control group and intervention group) using a registration schedule. Drinks were registered in approximate decilitres, and meals were registered as pieces or approximate quartile portion sizes by the patient, nursing staff or project team (Food consultant, Food science assistant or the main researcher) depending on the patient's abilities. Translation of the portion size and nutritional intake were processed in an electronic calculation programme used in clinical practice at Aalborg University Hospital based on premeasured meal- and drink-portions for protein (grams) and energy (calories, kcal). The results were registered in the electronic patient record and Microsoft Excel (91).

INTERVIEWS

Patient interviews (performed on the control group- appendix A and B) were conducted in a semi- structured face to face format, investigating the patients' eating

patterns, preferences for food and appetite. Questions were open-ended and constructed based on the researchers previous experiences and non-fiction literature (92). The interviews were performed in relation to the serving time of the investigated meals (Study I between 9:00 and 10:00 and study II at 10:00, 15:00 and 20:00). The interview questions for study I and II are presented in table 3. The interview questions from study II was added additional questions which and can be seen in appendix B.

Table 3. Semi-structured interview guide – study I and II

Study I
How do you experience the breakfast served at the hospital
What does breakfast mean to you
Can you tell me about your feeling of appetite and hunger in the morning when hospitalized
How do you experience the service and the servings from the food-trolley for breakfast
How is your appetite and desire for breakfast affected by the serving for breakfast
Does the breakfast fit in to your expectation in relation to taste, texture and appearance?
Study II
What does food mean to you
How would you say your diet is, and do you eat as you did three months ago
How is your appetite right now on a scale from 1-10
Have you had anything to eat for late morning, afternoon, and late evening to day, and do you expect to have a serving
What do you normally eat for late morning, afternoon and late evening
What have you eaten for late morning, afternoon and late evening when hospitalized
How do you experience the in-between meals for late morning, afternoon and late evening, that have been served for you during this hospitalization
If you had something for late morning, afternoon or late evening, how was it offered to you
Is there something you would have preferred or liked to eat for late morning, afternoon or late evening
Do you know oral nutritional supplements – have you been offered oral nutritional supplements

The interviews from both studies were audio recorded, transcribed verbatim in Microsoft Word and analysed, in order to generate knowledge about the patient's experiences, as well as barriers and opportunities related to the breakfast and in-between meals.

Study I: Ten patients were interviewed. The interview guide consisted of six open ended questions with no further elaborate questions (appendix A). The interviews were used as an inspiration for the future work in developing a new breakfast concept, and content analysis was performed.

Study II: Fourteen patients were interviewed. Eight research questions were conducted with 10 interview open ended questions and 18 related elaborate questions (appendix B). The transcribed interviews were analysed, with the aim to obtain a better and varied understanding of eating patterns, appetite and preferences using coding and categorization. Categories were chosen in advance that represented the interview questions (92). In addition to the interview, appetite was measured using a numerical rating scale with fixed points from 1-10, which ranged from no appetite to best imaginable appetite (93)

In both studies, the patients were recruited by a nutrition nurse specialist in collaboration with the nursing staff at the wards, in consideration of the inclusion criteria and the patients' physical and psychological wellbeing at the time of the day.

FOOD-IMAGE SELECTION

The interviews were combined with a visual method in which still images of food items related to the investigated meal were used. Images were selected from google search on the Internet by the researchers, based on a set of criteria developed for the studies. In both studies I and II, the following criteria were included:

- All five basic tastes should be represented in the total selection of images of in-between meals (salt, sweet, sour, bitter, and umami)
- The consistency should be mixed of hard and soft textures (ex. hard = cracker/buns and soft = Brownie/ gel)
- Mix of cold and hot meals
- Colorful and lightly colored
- Traditional and modern meals/ food items
- Beverages (hot and cold)

Thirty-nine images were included in study I (Appendix C), with 59 images in study II (Appendix D). The images were shown to the study population in relation to the interview, which was timed around the serving of the investigated meals (Study I: between 9:00-10:00 and study II at 10:00, 15:00 and 20:00.). Each patient was asked to sort the images in order of what they preferred to eat at the time of day. The images chosen by each patient were counted, and the data were stored in Microsoft Excel. The chosen images from each patient were made into moodboards – photo illustrations (Figure 9 and 10). In study I, the moodboards were used as an inspiration

tool with no further data analysis. In study II, the moodboards were analysed together with the interview, using descriptive and statistical analyses to obtain deeper insights into the patient's food preferences and frequencies of food choice.



Figure 9. Examples of patient's moodboards – Breakfast



Figure 10. Examples of patient's moodboards- In-between meals

CO-DESIGN SESSION

In the co-design sessions, the results from the data collected from the control group (nutritional risk screening, dietary recording, interviews and image selection/moodboards) were used to develop new menu concepts – breakfast and in-between meals. A team of professionals, including the researcher, culinary experts and hospital kitchen staff, participated in the co-design sessions for the development of the new menu.

Study I: Breakfast menu

The breakfast menu was based on a week plan to minimize the amount of food items and secure a high quality in each food item. The menu (Appendix E) is planned to provide different categories of food items with various tastes, textures and nutritional levels. In table 4, an example of the breakfast menu is shown.

Table 4. Menu example- Breakfast

Monday	Bread Rye bread and white bread Cold cuts Pate and ham Cheese Selection of soft and hard cheese Jam Homemade Soft boiled eggs Garnish Carrots and green peppers Dairy Shun with cream and honey roasted granola Porridge Oatmeal porridge cooked with full cream milk topped with rhubarb compote and brown sugar Drink Coffee, tea, milk, juice and nutritional drink
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Study II: In-between menu

In the development of the new in-between meals menu, a model of food sensory quality was used to promote intake in patients at nutritional risk (75), together with the findings from the baseline measurements. By implementing the model, it was possible to incorporate eating related symptoms in the development of food for DRM patients. The model is illustrated in the matrix in table 5. The model is divided into three categories related to motivation to eat, including pleasure, comfort and survival. The categories are linked to food choices to promote intake, sensory needs, perception and eating ability.

Table 5. Model of food sensory quality to promote intake in patients at nutritional risk (75)

Food Choice	Examples of existing foods to promote intake	Elaborate and garnished meals with varied side-dishes	Soup, porridge, yoghurt, fresh fruit ice lolly, cola, traditional dishes	Oral nutritional supplements, beverages, yoghurt
	Food sensory needs	Appearance, aroma, taste, variety	Refreshing, thirst quenching, gastrointestinal comfort, pleasantly, satiating, familiar	Texture and consistency, easy to eat, simple
	Food sensory perception and eating ability	Mild eating symptoms (e.g., lack of appetite, early satiety)	Desired positive post-digestive response, desire to return to eating normally	Severe eating symptoms (e.g., anorexia, dyspepsia, nausea, emesis, xerostomia, dysgeusia, dysphagia)
		Pleasure	Comfort	Survival
Motivation to eat				

The framework for the new in-between meals menu was divided into the three categories pleasure, comfort and survival as in the model. The in-between meals were developed to fit into the categories inspired by the food examples: Pleasure = hard texture (h), comfort = lightly soft texture (ls) and beverages (b) and survival = highly soft texture (hs) and beverages (b), provided in the model and the sensory needs,

perceptions and eating ability. The texture levels were categorized subjectively by the researcher.

The in-between menu (Appendix F) is based on a week plan to secure the same criteria as in the breakfast menu. Table 6 shows an example of a day’s menu.

Table 6. Menu example – In between meals

		Late morning	Afternoon	Late evening
Monday	Pleasure	Fresh fruit (h)	Crisp bread with cheese and jam (h)	Chocolate cake (ls)
	Comfort	Super drink (b)	Chocolate cake (ls)	Pizza bun (ls)
	Survival	Protein drink (b)	Apple-/cinnamon crème (hs)	Lemon mousse (hs)

DEVELOPMENT OF NEW FOOD ITEMS

Following the co-design session, the development of new products/menu occurred. The developments were targeted fixed nutritional goals for energy and protein, as recommended by the Recommendation for the Danish hospital food (3) and based on the calculations from the results of the measurements of nutrition intake, with a special focus on energy and protein. The goal for breakfast was calculated as 5 g of protein pr. portion with a total goal of 20 g for the combined meal. In-between meals were calculated as 700-1200 kJ/ 167-287 kcal and 10-15 g of protein pr. serving. Food items naturally high in protein were selected in combination with protein enrichment. Protein was used in the breakfast menu to increase the protein level. In the development of the in-between meals, whey was the first protein source selected for testing. Based on the sensory tests, whey protein was evaluated for acceptability and if the whey negatively affected the products, collagen or pea protein were tested.

The food items developed in study I were developed and tested in the kitchen in a non-systematic way. The food items developed in study II were developed together with patients admitted to the respective wards to qualify the chosen food items. The

sensory test (tables 7 and 8) was performed continuously throughout the development on patients and kitchen staff aimed at the adjustment of taste, smell and texture to promote the most preferred food items. The scheme developed for the sensory test was inspired of a guideline developed for use in kitchen food production (94) , based on that the “panel” of patients were untrained.

Table 7. Scheme applied by the team in the sensory testing of new developed in-between meals

Describe the in-between meal		
Assign the in-between meal a number from 1 to 5		
5 = Very satisfactory	Visually	
4 = Really good	Aroma (Scent)	
3 = Good	Taste	
2 = Criticisable	Mouth feel and consistency	
1 = Not for eating	Overall rating	

Table 8. Questions employed for verbal sensory testing of newly developed in-between meals with patients

What do you think about the product's Colour? Scent? Mouth feel and consistency? Taste?
Would you eat the product again? Yes/No
Which tastes did you find the best? (When two or more taste varieties were available)

In the following pictures, examples of newly developed food items and servings are shown.

Breakfast



In-between meals



DATA ANALYSES

The studies conducted in this PhD are based on descriptive methods, and in connection to this, descriptive statistics were employed to examine data for comparability and variation. Due to the non-existing studies on this specific area, a relevant strength calculation could not be performed. The studies were thus undertaken as feasibility studies and included patients' feasibility for consecutive inclusion during a period of three days before and after intervention.

Study I: The two groups (control and intervention) were compared by a t-test in order to compare differences between the two groups. Fisher's exact test was used to test differences in energy and protein intake. Data were analysed for normal distribution by a qq-plot test.

Study II: Ranked descriptive analysis was performed of all selected images and between departments and gender across time.

Differences in median appetite scores during the day (10:00, 15:00 and 20:00/ average over time) for each patient were analyzed using non-parametric Friedman test. A boxplot was used to investigate texture in relation to appetite score, which was done by dividing the images in three categories: hard texture, soft texture and liquid, inspired by standard categories developed for use in hospital food production (3). Each patient was assigned to a texture category, based on the highest category score.

A t-test (age and appetite score) and Fisher's exact test (setting and gender) was used to analyze texture preferences in relation to age, gender, setting and appetite score. The texture categories were reduced to two, hard and soft/liquid in order to obtain sufficient data for meaningful analysis.

The two groups (control and intervention) were compared by an unpaired t-test in order to compare differences between the two groups. Chi2 test was used for testing differences in energy and protein intake.

Statistical significance was predetermined as $p < 0.05$.

DISCHARGE OF DATA

Registration schedules of nutritional intake with missing data were excluded. The definition of missing data was as follows: If breakfast or more than one food serving (meal, drink, in between meal) was missing or was unclearly registered on the schedules.

Ethical considerations

Protocols for study I and II was put forward to the local ethic committee, which did not find full submission to the committee necessary, according to Danish law of ethics for intervention studies. Prior to inclusion, the patients were given written and oral information about the study. The participants were informed that they could withdraw from participation at any time during the study. The study was conducted according to the rules of the Helsinki Declaration of 2002.

RESULTS

In the following section, a summary of the main findings from studies I and II is presented.

Study I

Interview

Ten patients (six women and four men) with a mean age of 66 years participated in the study exploring patient's appetite and expectations related to breakfast. The age ranged from 58-82 years (mean age 66).

For the new breakfast-menu, 17 food products were developed and served in combination with a selection of bread, cold cuts, cheese and garnish.

In the development of the breakfast-menu, protein was integrated in two different ways, including natural-based on food products high in protein and density, such as egg and shun (a protein rich, low fat, fermented dairy product), and protein powder supplementation (WPI: whey protein isolate). Table 9 presents examples of protein fortified breakfast meals with weight and the content of energy and protein specified in portion sizes.

Table 9. Examples of protein fortified breakfast meals.

Breakfast					
Recipe/product	Weight/ por/g	Energy/ por/kJ	Energy/ por/kcal	Protein/ por/g	*WPI/ g
Skyr mixed with whipped cream, vanilla and honey roasted granola	60	631	151	5.7	-
Homemade yoghurt with cherry	75	493	118	6.1	3.5
Soft-boiled eggs	60	287	69	5.5	-
Omelette with cheese and ham	100	569	136	12.8	-
Oatmeal porridge cooked with whole milk, rhubarb compote and brown sugar	180 25	617 150	147 36	12.4 0.1	7
Smoothie	150	732	175	7	-
Protein juice – Nutridrink juice style	150	1335	319	4	-

WPI: Whey protein isolate

Intervention

Forty patients were assigned to standard breakfast (control group), and thirty-four patients were assigned to the protein-fortified breakfast concept (intervention group). Of these patients, 62 patients completed the study (control n= 32 and intervention n=30), including 127 food intake registrations.

The control group was comparable to the intervention group in gender and BMI; however, the patients were significantly older in the intervention group (years: 66 ± 8 vs. 72.6 ± 8 , respectively, $p = 0.01$).

Table 10 shows the results from the control group and the intervention group. Overall, the protein-fortified breakfast concept had a significantly positive impact on the protein and energy intake compared to the standard breakfast served at the hospital. The protein-fortified breakfast delivered, on average, 22% of the individual daily requirements of protein and 24% of the energy; thus, the recommended levels for minimum requirements were met.

Table 10. Protein and energy intake at breakfast and daily total mean, (SD)

Intake related to individually measured requirements ^a	Control	Intervention	p-value ^b
Protein, breakfast %	13.7 (7.2)	21.3 (9.4)	<0.001
Protein, daily total %	65.6 (19.9)	76.7 (23.3)	0.048
Energy, breakfast %	17.5 (6.9)	24.2 (12.9)	0.013
Energy, daily total %	77.8 (22.4)	96.6 (27.1)	0.004
Energy, breakfast, kJ/kcal	1632/389 (658)	2116/504 (1017)	0.029
Protein, breakfast, g	13,5 (7,3)	20.0 (8.5)	0.002
Energy, 24 h, kJ/kcal	7191/1712 (1872)	8470/2017 (2192)	0.016
Protein, 24 h, g	63.4 (18.4)	71.9 (20.1)	0.087

^a>75% of requirements.

^bFisher's exact, $p \leq 0.05$

The average total amounts of energy consumed per breakfast serving increased from 1632 kJ to 2116 kJ/ 390- 506 kcal, and the average total amount of protein consumed per served meal increased from 13.5 g to 20 g.

Study II

Interview

Fourteen patients (eight women and six men) participated in the study exploring eating patterns, food preferences and appetite for in-between meals during hospitalization. Ten patients completed all three interview-visual method sessions (10:00, 15:00 and 20:00), resulting in 38 interviews and 37 visual method sessions. The age ranged from 23-92 years (mean age 67.5).

Over half of the patients did not have anything to eat between breakfast and lunch during hospitalization. In the afternoon, most of the patients were served an in-between meal. During the late evening, approximately half of the patients had something to eat or expected to eat something.

Not all patients were used to eating in-between meals at home, particularly between breakfast and lunch. Two-thirds of the patients always or sometimes had an in-between meal in both the afternoon and the evening.

Some of the meals that were indicated as most preferred by the patients included fruit, apple pie and bread in various forms.

Nearly half of the patients reported that their appetite and eating patterns had changed during the last three month.

Ranked descriptive analysis on image selection regard preferences

No overall tendency towards preferred in-between meals were found (figure 11). All 59 images were chosen at some point. However, all beverages are placed in “top 25”. Some differences were seen between the departments, even though a majority of the images were selected equally. A number of images were chosen more frequently by patients from Pulmonary Medicine, which were meatball w. potato salad or bread, dark bread w. cold meat or cheese, soup, pork crackling, pierogi, fruit gel, mousse au citron, brownie, cookies, pastry, chocolate covered marshmallows and swiss roll. Patients from Abdominal Surgery chose vegetable w. dip, pretzels, ice coffee, homemade protein shake, milk and water more frequently. In general, patients from Pulmonary Medicine chose more images than the patients from Abdominal Surgery (figure 12).

Differences were also seen in image selection between gender. In general, 33 images were chosen more often by men than by women. The image most often selected by men were; dark bread w. cold cuts, tuna mousse, dates w. bacon, sausage roll,

croissant stuffed, bliny, mini pizza, fruit gel, sandwich, lemon mousse cold butter milk soup, pancake w. ice-cream, and milk coffee. Females preferred; butter milk horn (typical Danish bun-like cake), nuts, pretzel, muffins, oral nutritional supplement drink, smoothie, and crackers w. cheese or butter. The images which were equally selected by both gender were pork crackling, short pastry, cookies, creampuff, pretzel shaped pastry (figure 13).

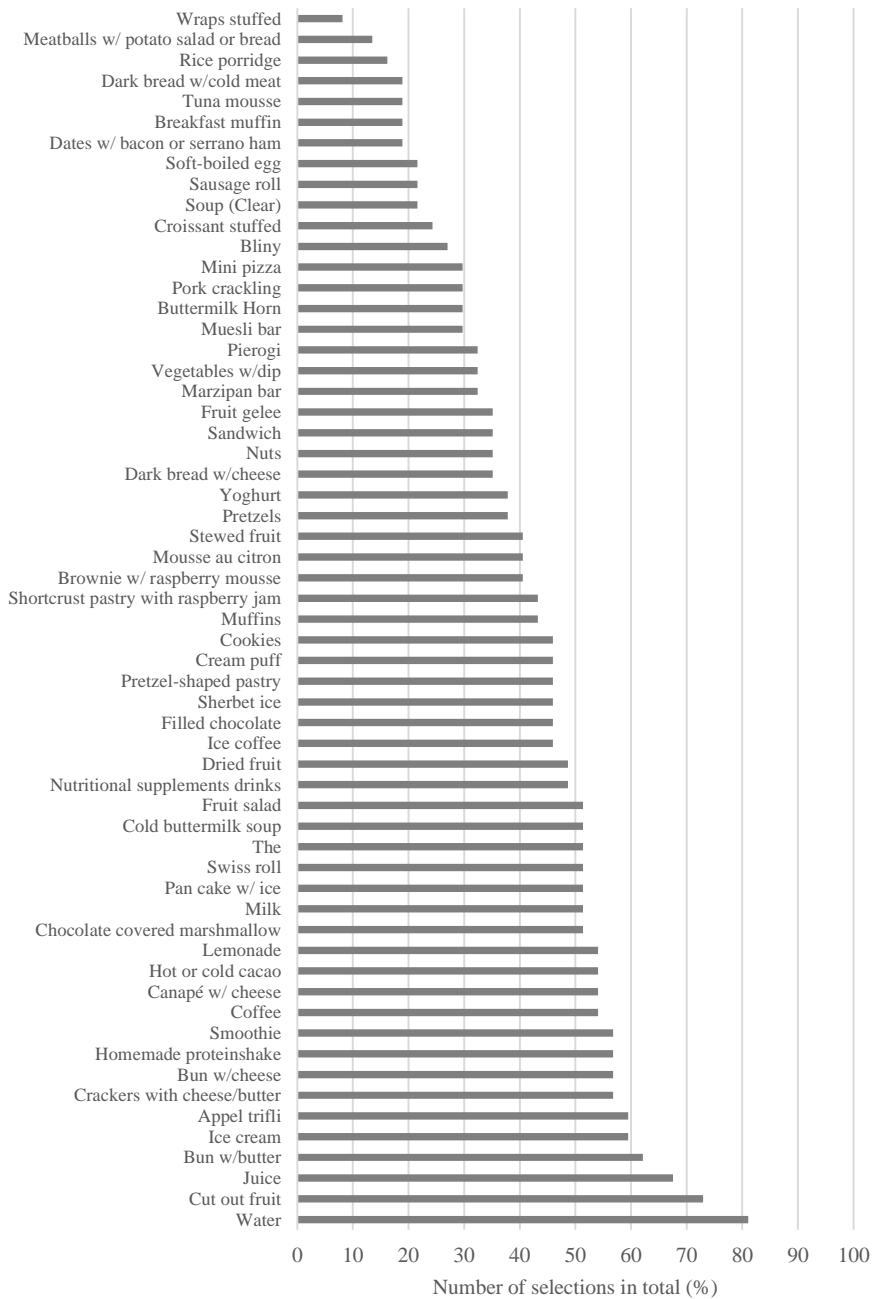


Figure 11. Ranked descriptive analysis of all selected images (10:00, 15:00 and 20:00) N=14.

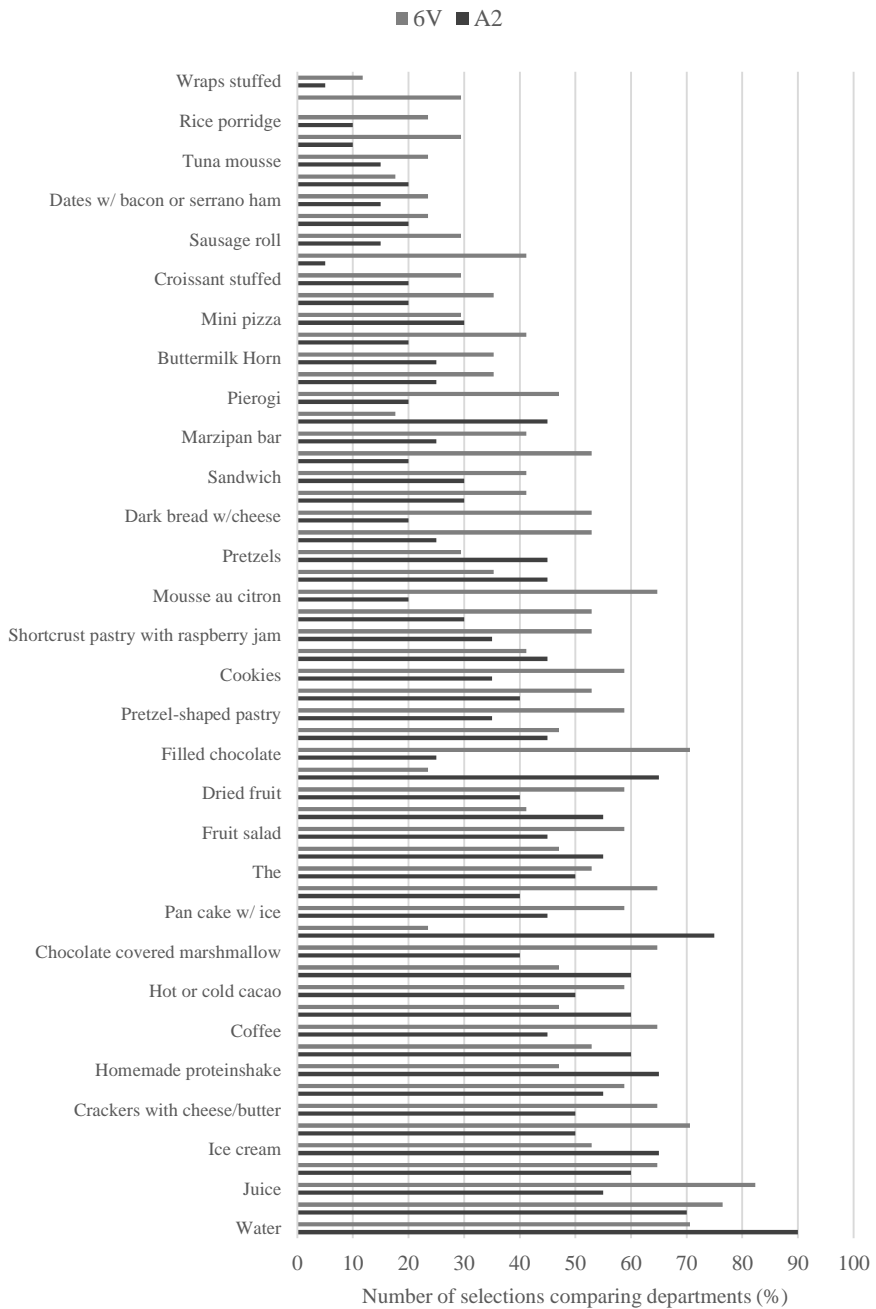


Figure 12: Ranked descriptive analysis between departments of all selected images (10:00, 15:00 and 20:00) N=14.

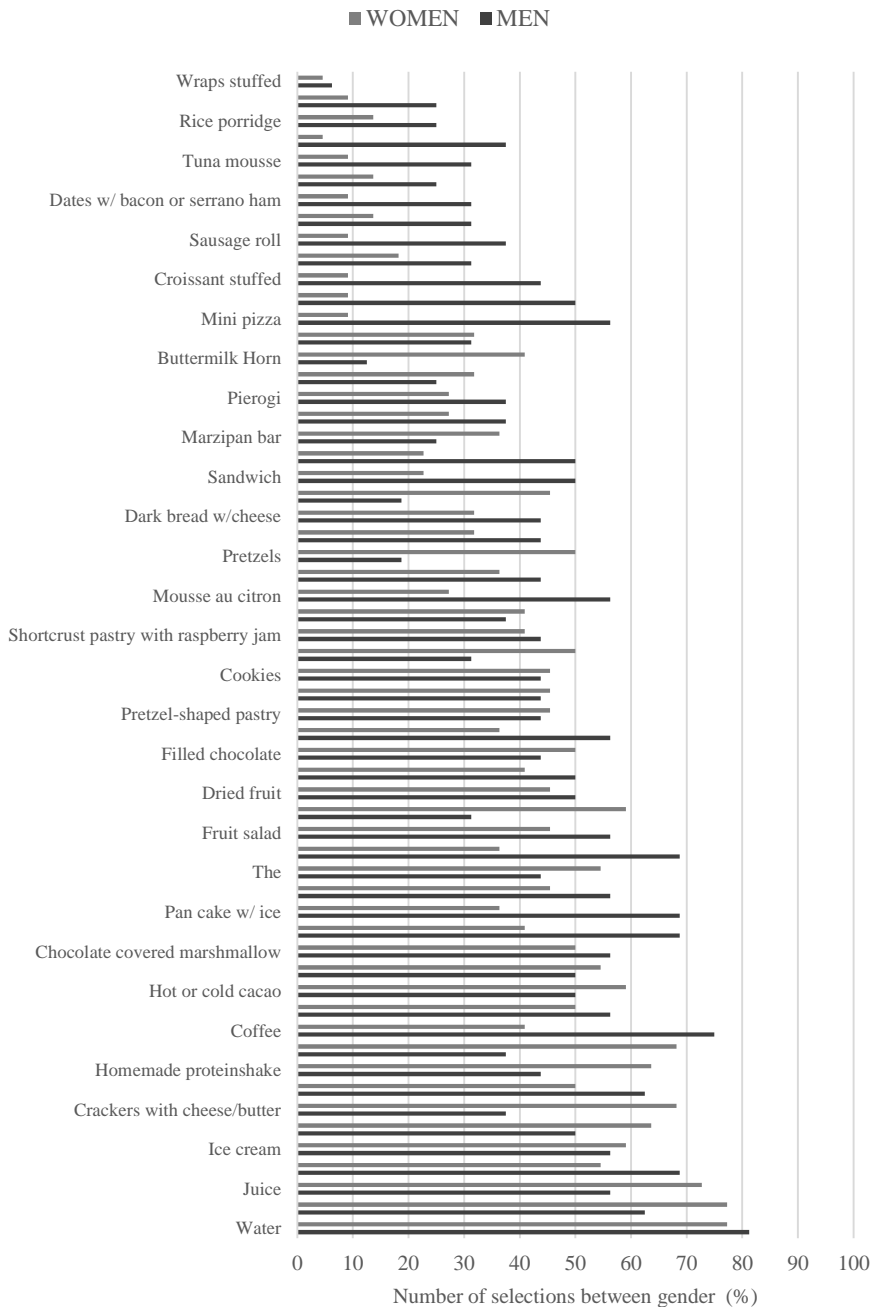


Figure 13: Ranked descriptive analysis between all women and men of all selected images (10:00, 15:00 and 20:00) N=14.

Appetite score

The appetite scores barely differed throughout the day. The results were: Morning median 5.0 [range 3.5-5.5], afternoon median 4.5 [3.3-5.0] and evening median 5.0 [3.0-6.0]; ($p=0.65$). No statistical differences were found between appetite scores at 10.00, 15.00 and 20.00.

A tendency towards an association between higher appetite score and desire for harder food texture, and lower appetite score and desire for softer food texture and liquids (beverages) was seen (figure 14).

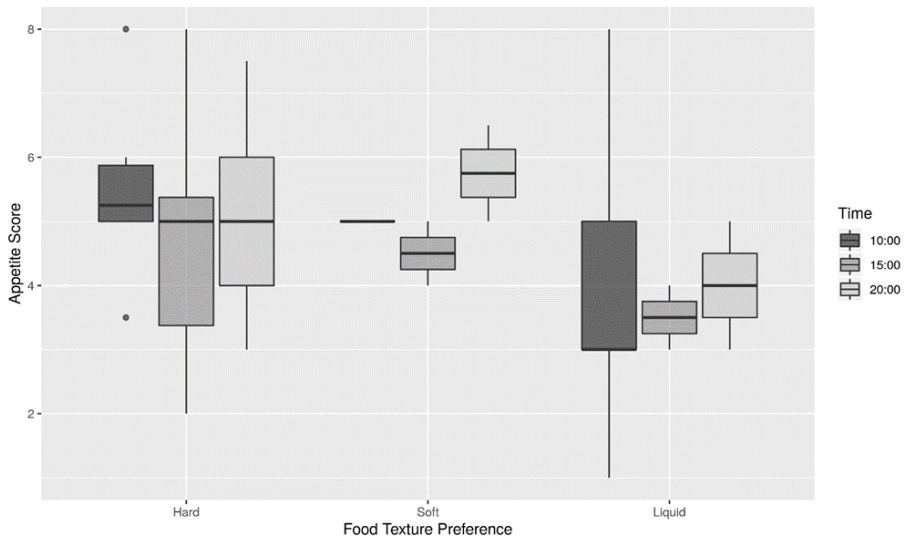


Figure 14. Appetite score vs food texture preference. N = 14/ 36 scores.

Statistical analysis on texture (hard, soft/liquid) preferences in relation to age, gender, setting and appetite score for the three time settings (10:00, 15:00 and 20:00), showed a lack of sufficient data at the time points 15:00 and 20:00 and therefore these were excluded from further interpretation. The analyses from the time setting 10:00 (N=13), did not show any significant differences in the comparison of texture preference (hard, soft/liquid texture) and the parameters age, gender, setting and appetite score.

Based on the latter results, 35 new in-between meals were developed, and out of these, 23 were selected for the new menu. A mix of natural-based food products high in protein density, such as cream, egg and cheese, and powder supplements (collagen, pea, whey) were used in the development of menu for the in-between meals.

The new in-between meals menu had an average level of 9.7 g of protein and 721 kJ/ 172 kcal pr. serving. Table 11 provides examples of the fortified in-between meals with weight and the content of energy and protein specified in portion sizes.

Table 11. Examples of protein fortified in-between meals

In-between meals							
Recipe/ products	Size g/ por	Energy kJ/ por	Energy Kcal/ por	Protein g/ por	Collagen g	Whey g	Pea g
Milkshake – orange	150	856	205	16	7.6	7.1	-
chocolate cake	56	662	158	7.6	2.87	2.6	-
Pizza bun	40	332	79	6	1,0	1.0	0.6
Fruit salad	65	535	128	8.4	3.8	3.8	-
Bun	40	435	104	4.9	-	1.34	0.8
Cheese crackers	10	158	38	1.4	-	0.7	0.5
Sandwich - ham	40	464	111	5.3	-	1.0	-
Jelly - apple and cream	50	515	123	9.5	5.5	-	-

Intervention

Forty-six patients were assigned to standard in-between meals (control) and forty-six patients were assigned to the protein-fortified in-between meal concept (intervention). Of these patients, 62 patients completed the study, including 187 food intake registrations (7 discarded in the control group and 15 discarded in the intervention group – due to insufficient registrations).

The quasi-experimental control group was comparable to the intervention group in gender, age and BMI.

Table 12 shows the results from the control group and the intervention group. Serving a protein-fortified in-between meal concept (three servings per day) significantly increased the protein and energy intake compared to the standard in-between meals

served at the hospital. The average energy intake improved from 55% to 118%, and protein intake improved from 30 to 112% of requirements. The average total amounts of energy consumed per in-between meal serving increased from 385 kJ/ 92 kcal to 886 kJ/ 211 kcal, and the average total amount of protein consumed per in-between meal increased from 2.6 g to 10.3 g.

Table 12. Mean energy- and protein intake during in-between meals

Average nutritional intake % (Range)	Control	Intervention	p-value
Total daily energy intake	74 (10 - 137)	109 (40 - 165)	0.001
Total daily protein intake	49 (11 – 101)	88 (30 - 167)	0.001
Energy intake from in-between meals ^a	55 (0 - 176)	118 (21 – 232)	0.001
Protein intake from in-between meals ^a	30 (0 - 144)	112 (9 - 231)	0.001

^a 30% of total daily requirements.

SUMMARY OF THE OVERALL RESULTS

Paper I: Protein and energy intake improved by breakfast intervention in hospital

This study aimed to compare food intake in a group of surgical patients at nutritional risk from the departments of Thoracic Surgery and Vascular Surgery, before and after development and implementation of a new breakfast concept conducted on the basis of a multimodal model. The results (N=62, mean age 69) showed an increase in protein intake from 14% of individual requirements to 22 % ($p<0.001$) and energy intake increased from 18% to 25% ($p=0.01$) for breakfast. Total amount of protein intake for breakfast was increased from 14 to 20g ($p<0.002$). Total daily protein intake increased from 64% to 77% ($p=0.05$) and total energy intake from 76% to 99% ($p<0.01$) of requirements. In conclusion, our results showed a significant increase in energy and protein to meet recommended average level for minimum individually measured requirements at breakfast as well as daily intake in a population of patients admitted to two surgery departments.

Paper II: An investigation exploring patients eating patterns, food, drinking and texture preferences, and appetite for in-between meals during hospitalization.

This study aimed to investigate eating patterns, food and drinking preferences and appetite in patients at nutritional risk from the department of Lung Medicine and Abdominal Surgery. The result showed (N=14, mean age 67.5) in general, that the participants did not eat in-between meals neither at home or at the hospital except in the afternoon. The findings from the image selection showed a broad individual variation of food preferences independent of the time of the day, gender and department, identifying the need for all tastes and consistencies in the menu. The appetite score indicated a moderately affected appetite with no differences in median appetite scores during the day. A tendency towards an association between lower appetite score and desire for softer texture and liquids were seen, which may indicate that especially soft and fluid consistencies may be useful in the most affected patients.

Paper III: Catering for patients at nutritional risk using in-between meals – An evidence-based multidisciplinary menu planning approach.

This study aim to develop high protein and high energy in-between meals for patients at nutritional risk from the department of Lung Medicine and Abdominal Surgery, using a multimodal menu planning approach, involving different fields of expertizes such as nutrition specialist, nurses, chefs, food scientist and patients.

The result showed that average minimum of requirements of energy and protein for an in-between meal was 700 KJ and 10g of protein. A tendency towards preferences for drinks, either hot or cold, were seen and soft texture were chosen more than hard texture. Time of serving did not significantly influence the participants' preferences ($p < 0.001$). Three categories of servings were chosen by analysis according to the results from a former Danish study and the results given in paper II; pleasure, comfort and survival and incorporated in nine in-between meals per day. The serving at 10:00 were chosen to be a high protein energy drink. Twenty-three new in-between meals were developed and tested by a team of different professionals (food scientist, nutrition specialist, food preparation, menu planner and a supply manager) and patients, with an average content of 721 KJ and 9.7 g protein pr. serving (standard in-between meals: 653 KJ and 2.3 g protein). In conclusion, the use of a multimodal menu planning approach resulted in development of high energy and high protein in-between meals targeted abdominal surgery patients and patients with lung diseases.

Paper IV: Protein and energy intake improved by in-between meals: An intervention study in hospitalized patients.

This study aimed to compare food intake in a group of surgical and medical patients at nutritional risk from the departments of Lung Medicine and Abdominal Surgery, before and after development and implementation of a new in-between meal concept conducted on the basis of a multimodal model. The results (N=92, mean age 69) showed an increase in protein intake per in-between meal from 2.6g to 10.3g. In total, daily protein intake increased from 49% to 88% of individually measured requirements ($p < 0.00$) and total energy intake from 74% to 109% ($p < 0.00$) of requirements. In conclusion, the result showed a statistical as well as clinical significant increase in protein and energy intake, and recommended average level for individually measured requirements was reached.

THE KULINA-MODEL - DEVELOPING TARGETED HOSPITAL FOOD

The development of the Kulina-model resulted in a multimodal model based on both quantitative and qualitative methods. The model was initially designed with seven levels, inspired by the MRC-guidance: 1. Data collection-baseline, 2. Data analysis, 3. Development, 4. Intervention, 5. Data collection-Intervention, 6. Data analysis-intervention, and 7. Comparison of data- baseline and intervention. These levels were maintained through study I and II. When study I was completed, the model was evaluated for value and practicability. The evaluation resulted in a refined version of the levels and the model was named the Kulina-model as shown in Table 13.

Table 13. Development of the Kulina-model in study I and II

Study I	Study II
<p>1. Data collection-pre</p> <ul style="list-style-type: none"> • Population: Homogeneous • Screening: (NRS 2002) • Food record (three days Manuel registration schedule) • Interview (semi-structured - interview guide) • Image- selection 	<p>1. Data collection-pre</p> <ul style="list-style-type: none"> • Population: Non-Homogeneous • Screening: (NRS 2002) • Food record (three days Manuel registration schedule) • Interview (expanded semi-structured interview guide, appetite score) • Image- selection (expanded criteria)
<p>2. Data analysis-Baseline</p> <ul style="list-style-type: none"> • Screening: Gender, age, BMI, nutritional requirements • Food record: Food intake • Interview: Transcription and used for inspiration • Image: Moodboards as inspiration 	<p>2. Data analysis-Baseline</p> <ul style="list-style-type: none"> • Screening: Gender, age, BMI, nutritional requirements, requirements for in-between meals • Food record: Food intake • Interview: Transcript and analysed • Image: Moodboards analysed descriptive and statistical

<p>3. Development of food</p> <ul style="list-style-type: none"> • Frame: Recommendation of the Danish institutional meals • Protein sources: <ul style="list-style-type: none"> - Natural ingredients - Why powder • Food development/ sensory test: By kitchen staff in a non-systematic way 	<p>3. Development of food</p> <ul style="list-style-type: none"> • Frame: Recommendation of the Danish institutional meals. Model of food sensory quality to promote intake in patients at nutritional risk (75). • Protein sources: Natural ingredients. Why, pea and collagen powder. • Food development / sensory test: By kitchen staff and patients in a systematic way.
<p>4. Intervention</p> <p>Three months</p>	<p>4. Intervention</p> <p>Three months</p>
<p>5. Data collection-Intervention</p> <ul style="list-style-type: none"> • Screening: (NRS 2002) • Food record (three days manual registration schedule) 	<p>5. Data collection-Intervention</p> <ul style="list-style-type: none"> • Screening: (NRS 2002) • Food record (three days manual registration schedule)
<p>6. Data analysis-Intervention</p> <ul style="list-style-type: none"> • Screening: Gender, age, BMI, nutritional requirements • Food record: Food intake 	<p>6. Data analysis- Intervention</p> <ul style="list-style-type: none"> • Screening: Gender, age, BMI, nutritional requirements • Food record: Food intake
<p>7. Comparison of data – Baseline and intervention</p> <p>Nutritional intake, age, gender, and BMI</p>	<p>7. Comparison of data – Baseline and intervention</p> <p>Nutritional intake, age, gender, and BMI</p>

DISCUSSION

The main *aim* for this PhD project was to increase energy and protein intake in hospitalized patients at risk of disease related malnutrition by the development and pilot testing of a multimodal model based on the MRC-guidance, the “Kulina-Model”, for menu-planning targeting preferences for meals and challenges to appetite.

This was done by an interactive process, by constantly improving the menus and targeting food options to the specific needs and variety of the hospitalized population. By systematic development and refining the Kulina-model through study I and II improvement in both energy and protein intake were seen. Although the model has provided sufficient results, the model needs to be tested in sufficiently sized samples and long-term interventions to establish the effectiveness of the Kulina-model. In the below section, important areas from this thesis will be discussed.

Literature study

In the literature study we excluded studies regarding fortifications with micronutrients only, combination with training exercise, combination with nutrition assistants, and interventions using ONS only. It is possible that some relevant knowledge could have been found in some of these studies, and that our studies could benefit from these perspectives, but at the same time there might be a risk of not being able to conclude the effect of the food intervention it selves.

The time line of our systematic review was 10 years. This limitation was based on a purpose of identifying the newest literature in the field. Using a time limitation excludes older studies that might be relevant. In order to remedy this, the search was added a freehand search with no limitation on years. In the free hand search only 4 studies were found to have been excluded based on publication year. It is possible that some relevant data could have been used in the development of our studies, and it seems relevant to take a closer look before planning further tests or implementation. But what about the quality of the studies identified in the review, and how do they differ from the studies performed in this thesis? Looking at the studies performed with the use of natural ingredients high in energy and protein only, five studies were found with varying results for energy and protein intake (19,21,22,82,87). Only one study increased both energy and protein intake by using naturally ingredients (19), compared with eight studies (56,75-77,83-86) using a combination of natural ingredients and protein powder.

These findings indicate that it can be difficult to increase energy and especially protein intake without adding protein powder. Based on these findings our studies were conducted with new food recipes developed with a combination of ingredients naturally high in energy and protein and adding protein powder. The reason for not adding protein powder in all the recipes and using different amounts, is that protein powder is difficult to incorporate in some recipes because of a high sensory impact that often leads to changes in taste, smell, appearance and texture. The studies from the review and our studies can thus be difficult to compare. Only one study (85) was

conducted as a breakfast intervention. This intervention was based on serving enriched brioche and oral nutritional supplement drink. The food options in that study is limited compared to our study (I) performed with a menu with several different choices, and that the ONS may have had huge impact on the result. Taking a look at the studies performed in in-between meals or snacks, also here only one study was found (80). This study was based on snacks high in protein fortified with natural ingredients, with no significant changes in protein, however with increased energy intake. However in our study II the recipes of in-between meals were based on a calculated average level of energy and protein from the nutritional records and requirements collected from the retrospective control group.

Another explanation to the positive results of our studies (I, II) might be found in the design of the studies, and especially the part investigating patient's food preferences and barriers related to eating. None of the studies have collected these data in hospitalized patients, and none have involved patient preferences in the development of new food recipes as we did in study II.

The Kulina-model and the MRC-guidance

A multi-modal model, the Kulina-model, has been designed in this thesis, to promote nutritional intake in patients at nutritional risk. The effect of the model has been successfully tested in both pilot studies I and II. Study I showed clearly improved results despite the very small sample. The use of the same model, including modifications in study II, was tested for practicability in the new settings.

However, several questions remain to be answered. Can the model be used in larger samples, and in larger settings, where the researcher does not have the same insight into the organization as was the case in these studies? Can the model work in other areas of hospital settings or nursing homes, as well as in other countries? Would patients keep eating the sufficient amount of protein and energy if presented to the developed food in a longer term setting, i.e. rehabilitation hospitals?

As the effects of the model have been demonstrated in both surgical and medical patients, the findings indicate that the model is robust to handle different groups of populations. The mean age (approximately 70) was relatively high in the studies, as is common in hospitalized patients in general, which also indicates that the model might be suitable for use in nursing homes. With respect to the applicability of the model for use in other countries, some corrections will be relevant regarding specific eating traditions and eating patterns that might differ from the Danish food-culture.

The choice of using a multimodal approach was based on the fact that food and eating in a hospital setting is affected by many connecting factors, as the environment, individual food preferences and different diseases. Factors that must be taken in consideration when designing food studies involving patients at hospitals. However, using a multimodal approach leaves a risk of not reaching in depth because of the many areas and levels that must be investigated. However, the multimodal approach provides strengths and value towards understanding implications which may not be achieved using quantitative methods only. By implementing the MRC-guidance

defined by the English medical research council in the Kulina-model, the possibility of an iterative process has been established with continued interaction between methods where qualitative and quantitative methods is used to identify the health professional and the patient's perspective in order to gain new knowledge and to develop based on evaluations and tests.

The use of the MRC-guidance in the development of the Kulina-model and the focus on patient involving fit very well into the clinical practices, where focus the recent years has been on placing the patients at the center of health care, in order to improve their experience and the health care services. Patients involvement is in focus in high-quality clinical care, but also in research studies involving Patients-Reported Outcomes (PROs) by the use of Patient-Reported Measurers (PROMs), tools or instruments often based on self-completed questionnaires (patient's) related to functional status, quality of life and symptoms (95). The Kulina-model includes PROMs with regard to patient's appetite, food preferences and eating behaviour, performed as interviews and questionnaires. This simultaneous with implementing elements from Good Nutritional Practice (GNP) as identifying risk patients by the use of nutritional risk screening followed by nutritional assessment and a nutrition plan (including also new menus) as well as a follow-up strategy, gives strength in to the studies performed in this thesis, and to the results.

Population

In study I, a population of only surgical patients was selected. The choice of only including one group of patients was based on the fact that no similar studies have been performed earlier. The study was designed as a pilot study to determine whether the Kulina-model worked in a relatively homogeneous group of patients before testing in a more heterogeneous group (surgical and medical) as performed in study II. To my knowledge, this is the first time a food related study has been tested in two interventions with different sets of populations. However, the data collection methods were refined from study I to study II. Although there was a wide spreading in the population, there is a possibility that the results could be different if the study was carried out in other groups of patients with, e.g., cancer or neurological diseases. Positive results have been seen in some other patients groups as in a study from Herlev Hospital, Denmark, which included oncology, orthopaedics and urology patients, using protein supplemented food with a positive effect on intake, however the interventions were not based on PROMs (14). Similarly, studies conducted in elderly geriatric patients and nursing homes have been able to show improvements of energy and protein intake (55, 84). However, not all studies conducted on patients or elderly individuals have been able to show positive or only small changes in nutritional intake (13,22,96,97), which might be explained by the lack of patient involvement in the development of the food and focus on the protein level.

Dietary intake

The aim of the project was to increase nutritional intake in hospitalized patients at risk of malnutrition. For this approach, monitoring of nutritional intake was used. In the dietary records, drinks/supplements were registered in approximate decilitres and meals in approximate quartile portion sizes of the patients, nurses or project team. This set up may be associated with errors regarding differences in the estimations of food and drinks served and eaten. However, this method is used in clinical practise on a daily basis, and was tested in an earlier study towards a 24-hour recall dietary interview and weighed method and shown to be sufficiently sensitive for clinical practices, as well as research purpose (91). Moreover, it is possible that the differences in individuals/staff who made the registrations may have affected the results; however, based on the fact that the data were pooled and the average level of intake was used, the errors are considered limited. Weight measuring of served food and eaten food could be a more precise way of measuring the food intake, but this method is extremely time-consuming, and does not suite the bulk serving of hot meals. The accuracy might also depend on how easy the plate leftover of food is to separate when doing the measurements. New developments have been done in the field of measuring food intake using the Dietary Intake Monitoring System (DIMS). The DIMS is an electronic device developed for capturing patients food choice, food intake and plate waste by the use of a camera and a digital weight scale (98). According to our knowledge this device has not been commercialised yet, but might be relevant in order to secure more precise data of food intake in the future.

Interview

The conduction of the interviews in study I were subsequently shown to be too shallow, and needed extrapolation. According to Kvale et.al, it may be useful to compose two interview guides, one guide with the project thematic research question and one guide with the interview questions to be asked, in regard to the thematic and dynamic dimensions (92). This approach might eliminate the risk of using theoretic language in the interview questions. In study II, this approach was applied in the development of the interview guide in combination with pre-defined elaborated interview questions; thus, the Kulina model was refined.

The use of a numerical rating scale (NRS) with fixed points that ranged from 1 to 10 to indicate no appetite to best imaginable appetite might not be the most commonly used tool for measuring appetite, as the visual analogue scale (VAS) has been widely used in appetite research. Despite this fact, a comparison of different scales measuring pain showed that the NRS scale had better compliance in elderly individuals and the VAS scale was reported as more complicated (99), with fewer missing values (100). Furthermore, the NRS scale has been shown to be useful in other research questions involving patient perspectives, such as in quality of life measurements (101). Based on the knowledge from pain studies and the relatively high mean age (69) measured in the baseline, the numerating scale was employed. We found this approach very giving because all patients were able to answer the questions on appetite using the 10 point scale, without questions to the investigator. In light that our patients are screened

for and found with risk of malnutrition (4,5,7) and the fact that lack of appetite is often associated with poor nutritional intake (53,104,105), it was expected to find that many patients had reduced appetite and that the average level of appetite score was low. Despite the expected outcome, it gave us unique opportunities to compare appetite scores with patient's food preferences, and an indication of what patients with low appetite preferred with regard to texture, as formerly indicated by Sorensen et al (70). In future studies investigating appetite in hospitalized patients it could be relevant to apply the SNAQ- Simplified nutritional appetite questionnaire. The SNAQ questionnaire is developed to assess appetite and to predict weight loss based on appetite, and has among other been investigated and validated in gastroenterology patients and in elder patients with liver cirrhosis (106,107).

Image selection

Using images from google search provides access to many different types of pictures for selection. It also reduces the work and costs of preparing the image selection, instead of taking the photos yourself, and no limits related to the type and number of food items must be taken in consideration. The number of images selected in studies I and II were based on a set of criteria defined for each study; however, no exact limits for the number of images were defined. Previous experiences have shown that patients get tired and unfocused when too many pictures are used, which might be explained by the fact that some patients might suffer from tiredness or exhaustion, which is associated with malnutrition (108).

The quality of the pictures used in the two interviews varied regarding clearness and set up because of the variety of the quality from private and professional photographers, respectively. Using Google images also gave the opportunity to select a variation of home-like pictures and set-up pictures, and may diminish the risk of presenting only very glamorous looking meals, with an image-catalogue made especially for the studies with the same type of pictures and quality. The use of images to assess individuals' preferences for food is relevant and has been well demonstrated in a study by Simmons et.al. (109), which indicated that images appear to activate property inferences for food tastes and rewards in the brain, and the gustatory system produces taste responses to images of food and not only to actual foods.

The image selection results might be specific for Danish food tradition and might appear different if the study was conducted in another country, other age groups or healthy individuals.

The choice of using 39 (study I) and 59 (study II) was based on the goal to obtain wide knowledge about the patients preferences, and the set of pictures therefore included both traditional meals and more untraditional meals for the time of serving. The idea was based on that eating preferences might change during illness and hospitalization. A relative high number of pictures presented for the patients, can be a bias, based on that the patients can lose focus and concentration also defined as response fatigue (110). This bias was however not investigated.

Co-design session

In the co-design session, new menu concepts were developed on the basis of the data collected in the baseline measurements. Based on the refining of the Kulina- model, a model of food sensory quality to promote intake in patients at nutritional risk (75) was incorporated in the co-design session together with the findings from the baseline to promote a more targeted menu concept, which holds as many aspects related to patients' food preferences as possible. This model was not a part of study I, which might leave some areas from the model unused. With respect to the food sensory needs in the model and the examples of food, study I might have benefitted from a more systematic approach in the development of the menu, as indicated in study II where the menu concept is divided and targeted into three categories, pleasure, comfort and survival, to embrace different categories of patients nutritional needs, barriers and preferences. In study II all food items/ images was chosen, and showed a wide preference for food. The choice of doing a cut off on the most preferred meals was based on a realistic approach considering the time allocated to the development from the food production in the hospital.

Development

The protein level was specified to be 5 g of protein per item (20 g per served meal) for breakfast and 10 g per served in-between meal. The energy level was only set for the in-between menu to a level of at least 700 kJ/ 167 kcal. The reason for only putting in a specific goal for protein and not for energy for breakfast was that especially requirements for protein has shown difficult to achieve in former studies. Furthermore, the level of protein intake has shown to significantly influence recovery after surgery (111–113).

In study I, whey protein was chosen as the only enrichment source because the protein is known as a high quality protein, rich in essential amino acids, and fast digestion (114). Fortifying the breakfast with the use of whey showed several limitations in some food items, regarding sensory quality. In particular, changes in the texture of buns and porridge occurred; however, changes regarding appearance were also identified. As the goal was to refine the Kulina-model from studies I to II, the protein sources were expanded in study II to eliminate limitations and provide more opportunities for the development. The expansion of using collagen and pea protein was based on a previous food experiment and the functionality of the proteins. The selection of collagen as a protein source was compromised to develop a clear liquid as the “super drink”, which was served late morning, while no other protein, according to our tests and knowledge, can provide clear liquid. The pea protein was used in baking because of a better backing capability. The use of protein sources with a lower quality demands thoughtfulness with regard to meal composition and distribution to secure the existence of all essential amino acids in the amounts required in daily food intake (115). In the development of study II sensory testing was conducted by both kitchen professionals and patients. The sensory testing was performed with two schemes, one developed for the kitchen professionals and a verbal scheme developed for testing on patients. The choice of using more simple tools than often seen in food

development and in the industry (116), was to make a model that could fit into a kitchen where many different food items are produced every day, without sensory facilities and specially trained staff. We wanted to still make food created in a kitchen, without leaning too much towards a laboratory thinking. The testing on patients was done in the wards at the bedside, which requires a simple form of testing, because of a lot of interfering aspects in the bedroom and the ward, but also the condition of the patients. The setting/ surrounding where the food is tested could be claimed as a bias to the results, but in our opinion we see it as a realistic testing, that will be a part of the meal and meal serving afterwards.

The cost of nutrition

An economic estimation of cost (unpublished data) has been made in study II, on the cost of the new in-between meal menu compared to standard in-between meals. The time used in the production and handling of the new in-between meal concept increased by a factor of approximately 3. The total price of the new in-between meal concept increased 20% in cost compared to usual in-between meals, or 0.67 euro more per bed per day.

The calculation was based on data collected over a period of three months before the intervention and three months during the intervention. The data collected included the price of ingredients, preparation and cooking time, packing and handing time and dishwashing.

It might seem as a high cost, but compared to the cost of malnutrition in Danish hospitals which was estimated to reach approximately 800 million euro in 2014, it seems relevant to look at all possible ways to enhance even the smallest economic savings (117).

Although the model has provided fine results in nutritional intake in hospitalized patients, long-term interventions are required to establish the effect of the Kulina-model.

CONCLUSION

The *overall aim* of the research presented in this PhD thesis was to increase energy and protein intake in patients at risk of disease related malnutrition by the development and introduction of a multimodal model, the Kulina-model, which aims to provide knowledge for development of targeted hospital food based on knowledge of patient's eating patterns, food preferences and appetite. The conclusion that can be drawn from these studies are as follows:

A multimodal-model approach has been developed and tested in study I, based on quantitative (food record) and qualitative methods (interview, image-selection) and food development. A refined version of the model named the Kulina-model has been tested in study II.

- 1) Seventeen new food products high in protein were developed for the new breakfast menu, targeted an average content of 20g of protein in total pr. serving, based on patients preferences.
- 2) By implementing a multimodal modal it was possible to increase energy and protein intake significantly for breakfast in a population of surgical patients from the departments of heart and lung surgery and vascular surgery, to meet average recommended level for minimum requirements at breakfast as well as daily intake.
- 3) Over half of the patients were not served in-between meals between breakfast and lunch. A tendency towards a moderately affected appetite with no difference during the day was found. A broad individual variation of food preferences was seen, however a tendency towards association between lower appetite and desire for softer food texture and liquid was found
- 4) Twenty tree new in-between meals were developed targeted patients preferences and barriers for eating, with an average level of 9.7g of protein and 721 kJ/ kcal pr. serving.
- 5) By implementing the Kulina-model it was possible to increase energy and protein intake significantly for in-between meals in a population of surgical and medical patients at nutritional risk from the departments of lung disease and abdominal surgery.

PERSPECTIVE

Society and healthcare treatment is in progress and outpatient treatment as well as home treatment are becoming increasingly common. In Denmark, new hospitals are currently being built, designed to fit into this development.

When patients are treated outside the hospital in private homes, nutrition is handed over to the patients. Evidence indicates that a good nutritional status provides substantial effect on the results of treatment, and that this burden cannot be handed over to the patients alone. In the future, it is more important than ever to establish nutritional support for patients who are not treated inside the hospital. Supporting these patients includes recommendations and guidelines to inform patients about nutritional needs related to their illness and provide recommendations for food choice and recipes to fit these needs

However, the question is; can the Kulina-model fit into this development, and will it make sense to use it in outpatient settings?

My answer to this question is “yes I think so”. The use of this model requires no material that cannot be carried out in other hospitals and settings as a nursing homes or private homes. Employment of the model in a private setting makes it possible to promote even more individually personalized data that may be used in patient treatment. Individual recommendations and menu plans may be supported by recipes high in energy and protein.

For patients who receive meals from an authority kitchen or private kitchen, a close collaboration must be established to secure a connection between the knowledge obtained from the patients and the food delivered. In some authority kitchens, a nutrition support team visits the patients to establish whether a nutritional plan is required. It could be interesting in the future to determine whether the Kulina-model could be adapted in a local authority kitchen.

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