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NUTRITIONAL RISK IN GENERAL PRACTICE

PREVALENCE OF UNINTENDED WEIGHT LOSS; FACILITATORS, BARRIERS, AND THE FEASIBILITY OF AN EARLY PATIENT-INVOLVING NUTRITIONAL INTERVENTION AMONG PATIENTS WITH SUSPECTED MALIGNANT DISEASE

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BY
SABINA LUND MIKKELSEN

DISSERTATION SUBMITTED 2023



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by

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Preface

The work behind this thesis was conducted during the employment at Danish Nutrition Science Centre, Centre for Nutrition and Intestinal Failure, Department of Gastroenterology at Aalborg University Hospital from August 2020 to December 2023. The thesis consists of four studies reflected in four articles. Of these, three are published and one is submitted.

If we go back a few years. I got my bachelor in sports in 2017, and during the bachelor's I decided that I did not want a master in sports but in something else. I wanted to learn more about interventions that could benefit many people. Therefore, I started at the master's in public health at Aalborg University and graduated in 2019. During my master study, I worked with Mette Holst about nutritional risk in outpatient clinics at Aalborg University Hospital. I found the research field exciting, and therefore I applied for a company internship with Mette Holst after I graduated. Thereafter, I spent six months in the community training unit in Aalborg as a development consultant. However, I was not finished with the world of research, and I was offered a position as a research assistant from August 2020 with Mette Holst. During my first employment, I worked with nutritional risk in general practice, which was the starting point for my PhD. Thereafter, the health professionals and patients' perceptions of handling disease-related malnutrition as well as perceptions concerning a nutritional intervention in general practice were investigated (paper II and III). Finally, an early nutritional intervention was implemented in general practice towards patients at nutritional risk and referred to investigation at the hospital due to suspected malignant disease (manuscript IV).

Alongside my PhD, I have participated in other research fields concerning nutritional risk and disease-related malnutrition among hospitalized patients as well as intervention studies concerning nutrition and exercise in the municipality and in the participants homes. I think that this area concerning disease-related malnutrition is interesting, as it is known to have negative consequences on the course and outcome of the treatment. Therefore, there is a need for further research in this area.

The other research can be found through VBN ([Sabina Lund Mikkelsen — Aalborg Universitets forskningsportal \(aau.dk\)](#)) or ORCID ([0000-0003-2182-1601](#)).

Acknowledgements

I would like to thank participants in the studies, supervisors, colleagues, friends and family for the help and support throughout the thesis.

First, I would like to thank the patients and health professionals for participating in the four studies. The thesis would not have been possible without their positive collaboration and willingness to take part in the studies. Special thanks to the patients in the studies for participating and taking time for the interviews and follow-ups as well as inviting me into their homes.

I want to acknowledge and thank my supervisors for the help, support and guiding throughout the PhD process. Special thanks to my main supervisor Mette Holst for guiding, continuous support, believing and helping me throughout the PhD process. Furthermore, thanks to Mette for statistical and qualitative guiding in the four studies, I have really appreciated working with you. Thanks to Henrik Højgaard Rasmussen for sharing knowledge, constructive criticism, and encouragement during the PhD process. Thanks to Janus Laust Thomsen for sharing knowledge about general practice, feedback on the thesis and encouragement.

Many thanks to my colleagues at Danish Nutrition Science Centre, Centre for Nutrition and Intestinal Failure and Department of Gastroenterology at Aalborg University Hospital for sharing knowledge and support throughout the process.

I want to thank my family for never-ending support, listening and encouragement throughout the PhD process and for always believing in me. Thanks to my friends for both support and encouragement during the years and for giving me some funny breaks during the PhD. Without the support from family and friends, this PhD would not have been possible.

Finally, I would like to thank the foundations, which have contributed financial support to the individual studies, which together constitute the thesis. The funding is based on the “Helsefonden”, the “Ernæringspuljen” at Aalborg University Hospital, “Sundhedsinnovationspuljen” and “NordKap” (The North Jutland General Practice organization).

Summary

Background

Disease-related malnutrition (DRM) in both acute and chronic diseases is associated with increased negative consequences for the individual as well as the society. Early detection is fundamental to implement the most effective nutritional treatment to prevent reverse consequences related to DRM. General practice may be a good place for the early detection, as Danish citizens have free access to general practice, and visit general practice before any referrals for further investigation at the hospital. Early detection of patients at nutritional risk is proposed by the Danish Health Authority. In addition, the prevalence of nutritional risk is scarcely investigated in Denmark. Besides the lacking knowledge about the prevalence of nutritional risk in general practice, there is no data for managing nutritional risk in general practice.

Aim

The overall aim of this thesis was to evaluate nutritional risk in the general practice setting as well as test the feasibility of a relevant complex early intervention towards nutritional risk in a group of relevant patients.

Methods

The Medical Research Council (MRC) framework was used throughout this thesis, and the study was grounded in pragmatism. This thesis consisted of four studies. Study I was a questionnaire-based cross-sectional study performed in general practice aiming to investigate the prevalence of nutritional risk measured by unintended weight loss (UWL) and reduced food intake (RFI). Study II was a qualitative study using interviews with general practitioners (GPs) and general practice nurses (GPNs) with the aim to investigate their perception of how DRM was managed. Furthermore, the aim was to investigate their view of introducing an early intervention targeted patients at nutritional risk in the general practice setting. Study III was a development study, where a reanalysis of the interviews with the health professionals from study II was performed, and interviews with cancer patients were conducted. The aim with study III was to develop a relevant early nutritional intervention towards a particularly vulnerable group of patients, found in study I. Study IV was a feasibility study with a cohort study design. The study aimed to test an early nutritional intervention towards patients referred to investigation at the hospital due to suspected malignant disease. The intervention consisted of early nutritional guidance delivered by the GPNs in general practice. The participants were followed shortly after inclusion and the nutritional guiding session, and after one and three months.

Results and findings

The results showed that nutritional risk measured by using UWL and RFI occurs frequently among adult patients in general practice. Furthermore, UWL can be used as a relevant and feasible initial indicator for further nutritional assessment in general practice. In addition, UWL as initial indicator for DRM were to a low degree managed in general practice, as the health professionals found they rarely see patients with UWL. An early nutritional intervention may be relevant to implement in general practice, however possible facilitators and barriers must be considered before the implementation. Furthermore, recommendations were established related to a communication strategy, which can be included in the development of the intervention. The recommendations were: Strategy and preparation of health professionals, means of communication and forms of message. The early nutritional intervention was less feasible concerning recruitment of general practice and patients, however feasible concerning retention and in some degree feasible concerning outcomes. Furthermore, the intervention had a positive impact on the participants' health concerning an increase in dietary intake, muscle mass, and percent body fat from baseline to three months after inclusion.

Conclusion

This thesis revealed that nutritional risk measured by UWL and RFI is frequent in general practice. This was a concern for further investigation, as the problem was to a low degree managed at the moment by the health professionals. After training, the GPNs will be able to perform nutritional guidance to patients with UWL and therefore being in nutritional risk. An early nutritional intervention performed by the GPNs targeted patients referred to investigation at the hospital due to suspected malignant disease was likely feasible. However, the methods concerning the recruitment of general practice as well as the recruitment of patients by the GPs causes concern. If the intervention should be performed again, there is a need for further development of recruitment methods and focus on patients at nutritional risk in general practice.

Resumé

Baggrund

Sygdomsrelateret underernæring hos borgere med både akutte og kroniske sygdomme er forbundet med øgede negative konsekvenser for den enkelte såvel som for samfundet. Tidlig opsporing er nødvendig for at opnå den mest effektive ernæringsbehandling og reducere konsekvenser relateret til sygdomsrelateret underernæring. Almen praksis (AP) kan være et godt sted for tidlig opsporing, da danske borgere har fri adgang til AP, og borgerne skal besøge egen læge inden eventuelle henvisninger til yderligere undersøgelser på sygehus. Tidlig opsporing af ernæringsrisiko er desuden anbefalet af Sundhedsstyrelsen i Danmark. Derudover er prævalensen af ernæringsrisiko i AP sparsomt undersøgt i Danmark, og der er ingen data for håndtering af ernæringsrisiko i AP.

Formål

Det overordnede formål for denne afhandling var at evaluere forekomsten af ernæringsrisiko i AP. Formålet var derudover at teste gennemførligheden af en relevant kompleks tidlig intervention målrettet en gruppe af patienter med øget risiko for at være i ernæringsrisiko i AP.

Metoder

Medical Research Council (MRC) rammen blev brugt gennem hele afhandlingen, som teoretisk var baseret på pragmatisme. Denne afhandling bestod af fire delstudier. Studie I var et tværsnitstudie udført i AP, hvor et spørgeskema blev brugt til at undersøge forekomsten af patienter i ernæringsrisiko ved brug af uplanlagt vægttab og reduceret kostindtag. Studie II var et kvalitativt studie, hvor der blev gennemført interviews med praktiserende læger og konsultationssygeplejersker. Formålet var at undersøge deres opfattelse af, hvordan sygdomsrelateret underernæring aktuelt blev håndteret, og deres syn på at indføre en tidlig indsats målrettet patienter i ernæringsrisiko i AP. Studie III var et udviklingsstudie, hvor der blev foretaget en genanalyse af interviews med de sundhedsprofessionelle fra studie II, og der blev gennemført interviews med patienter med en kræftdiagnose. Formålet med studie III var at udvikle en tidlig ernæringsintervention til en gruppe af patienter, der i studie I var fundet med en højere forekomst af uplanlagt vægttab og derfor var i ernæringsrisiko. Studie IV var et feasibility studie med et kohortestudiedesign. Studiet havde til formål at teste en tidlig ernæringsintervention til patienter henvist til udredning på hospitalet på grund af mistanke om ondartet sygdom. Interventionen bestod af tidlig ernæringsvejledning givet af konsultationssygeplejersker. Deltagerne fik opfølgning kort efter inklusion og efter

at have modtaget undervisning af sygeplejerskerne, samt efter en og tre måneder.

Resultater og fund

Resultaterne viste, at forekomsten patienter i ernæringsrisiko målt ved uplanlagt vægttab og nedsat kostindtag var hyppigt forekommende blandt voksne patienter i AP. Ydermere kan uplanlagt vægttab bruges som en relevant og gennemførlig indikator før yderligere ernæringsvurdering i AP. Derudover blev uplanlagt vægttab, som tidlig indikator for sygdomsrelateret underernæring, ikke i tilstrækkelig grad håndteret i AP, da de sundhedsprofessionelle fandt, at de sjældent ser patienter med uplanlagt vægttab. En tidlig ernæringsintervention kan være relevant at implementere i AP, dog skal mulige facilitatorer og barrierer overvejes inden implementering. Desuden blev der opstillet nogle anbefalinger til en kommunikationsstrategi til brug i udviklingen af interventionen. Anbefalingerne var: Strategi og forberedelse af sundhedsprofessionelle, kommunikationsmidler og budskabsformer. Den tidlige ernæringsintervention var mindre gennemførlig med hensyn til rekruttering af AP og patienter, dog var den gennemførlig med hensyn til fastholdelse af deltagerne og i nogen grad med hensyn til dens resultater. Desuden havde interventionen en positiv indvirkning på deltagerne helbred med hensyn til en stigning i kostindtag, muskelmasse og fedtprocent fra baseline til tre måneder efter inklusion.

Konklusion

Denne afhandling fandt, at ernæringsrisiko, målt ved uplanlagt vægttab og nedsat kostindtag, forekommer hyppigt i AP, men de sundhedsprofessionelle håndterer i øjeblikket ikke i tilstrækkelig grad problemet. Konsultationssygeplejerskerne kan, efter undervisning, udføre ernæringsvejledning i AP målrettet patienter med uplanlagt vægttab, og som derfor kan være i ernæringsrisiko. En tidlig ernæringsintervention, udført af konsultationssygeplejersker til patienter henvist til udredning på hospitalet på grund af mistanke om ondartet sygdom, var til en vis grad mulig. Rekruttering af AP såvel som patienter vækker dog bekymring, og hvis interventionen skal gentages, er der behov for en videreudvikling af rekrutteringsmetoderne og fokus på patienter i ernæringsrisiko i AP.

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List of papers

The thesis is based on four research papers:

- I. Mikkelsen S, Geisler L, Holst M. Malnutrition measured by unintended weight loss among patients in general practice. *Nutrition*. 2022 Apr; 96:111554. doi: 10.1016/j.nut.2021.111554. Epub 2021 Nov 30. PMID: 35152153.
- II. Mikkelsen S, Geisler L, Holst M. Healthcare professionals' experiences with practice for managing disease-related malnutrition in general practice and proposals for improvement: A qualitative study. *Scand J Caring Sci*. 2022 Sep;36(3):717-729. doi: 10.1111/scs.13033. Epub 2021 Sep 19. PMID: 34541700.
- III. Matthiesen, S. S., Mikkelsen, C. L., Mikkelsen, S. L., & Holst, M. (2022). Communication about Disease-Related Malnutrition in the Perspective of Health Professionals in General Practice and Patients. *International Journal of Nursing and Health Care Research*, 5, [1349].
<https://doi.org/10.29011/26889501.101349>
- IV. Mikkelsen S, Rasmussen H, Thomsen J L, Holst M. Early nutritional intervention in general practice in case of suspected cancer – a feasibility study. *Health & Social Care in the Community*. Submitted 10.11.2023.

Abbreviations

| | |
|----------------|--|
| App: | Application |
| BFM: | Body fat mass |
| BIA: | Bioelectrical impedance analysis |
| BMI: | Body mass index |
| COPD: | Chronic obstructive pulmonary disease |
| DRM: | Disease-related malnutrition |
| EORTC QLQ-C30: | EORTC core quality of life Questionnaire 30-item |
| ESPEN: | European Society for Clinical Nutrition and Metabolism |
| EQ-VAS: | EQ-visual analogue scale |
| EQ-5D-5L: | The 5-level EuroQoL-5 Domain |
| EVS: | Ernæringsvurderingsskema (Nutritional assessment form) |
| FFM: | Fat free mass |
| GLIM: | Global Leadership Initiative on Malnutrition |
| GP(s): | General practitioner(s) |
| GPN(s): | General practice nurse(s) |
| HRQoL: | Health-Related Quality of Life |
| ID number: | Identification number |
| Kg: | Kilogram |
| MET: | Metabolic equivalent of task |
| MM: | Muscle mass |
| MNA: | Mini Nutritional Assessment |
| MRC: | Medical Research Council |
| MUST: | Malnutrition Universal Screening Tool |
| M0: | Baseline measurement in study IV |
| M1: | Measurement at month one in study IV |
| M3: | Measurement at month three in study IV |
| NIS: | Nutrition impact symptoms |
| NordKap: | The North Jutland General Practice organization |
| NRS-2002: | Nutritional Risk Screening-2002 |
| OR: | Odds ratio |
| PBF: | Percent body fat |
| REDCap: | Research Electronic Data Capture |
| RFI: | Reduced food intake |
| SF-12: | 12-item short-form health survey |
| UWL: | Unintended weight loss |
| WHO: | World Health Organizations |
| WHOQOL: | WHO Quality of life |
| 30s-CST: | 30 second chair-stand test |
| 95% CI: | 95% confidence interval |

Definitions

Malnutrition (or undernutrition): is defined as “a state resulting from lack of intake or uptake of nutrition that leads to altered body composition and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease” [1]. In this thesis, malnutrition is used as a synonym for undernutrition.

Malnutrition can be classified into: Disease-related malnutrition (DRM), e.g., associated to inflammation (chronic or acute i.e., chronic obstructive pulmonary disease (COPD), pneumonia, sepsis, cancer), malnutrition without inflammation (i.e., neurological disease) or malnutrition without disease (i.e., anorexia nervosa or starvation) [2]. In this thesis, malnutrition will be defined and classified once, but thereafter malnutrition is used as a synonym for DRM, malnutrition without inflammation and malnutrition without disease.

Diagnosis of malnutrition: can be made according to the Global Leadership Initiative on Malnutrition (GLIM) criteria (at least one phenotypic criterion and one etiologic criterion) and is always preceded by screening for nutritional risk [2].

Nutritional risk: The patients can be identified as being at nutritional risk based on validated screening tools and differs between settings [1]. In this thesis nutritional risk is used as a synonym for risk of malnutrition and risk of undernutrition.

Nutritional risk in hospitals: NRS-2002 is recommended as the internationally validated screening tool for screening of nutritional risk in hospitalized patients in Denmark [1,3,4].

Nutritional risk in general practice and in the community: Unintended weight loss (UWL) is recommended and at least one kilogram (kg) is regarded as significant by the Danish health Authority [3]. Nutritional assessment form (EVS=ernæringsvurderingsskema) is recommended for further assessment of nutritional risk and guidance for nutritional treatment [3,5,6].

Unintended weight loss (UWL): A weight loss experienced by people that did not come out of intendedly decreasing food-intake og excessing physical activity or other conscious actions explaining a loss of weight. The amount of weight lost defining UWL differs within screening tools and settings. If a patient has an UWL and is found to be at nutritional risk, then treatment of nutritional risk must be initiated [3].

Medical Research Council (MRC) framework: MRC framework can be used related to the development and evaluation of complex interventions. The MRC framework consists of four phases: development/identification of an intervention, feasibility, evaluation, and implementation. Furthermore, the framework consists of six core

elements, which should be included during the entire process: context, programme theory, stakeholders, key uncertainty, refinement of intervention and economic considerations [7,8]. The context is important to consider, and some dimensions can be considered such as physical, political, organizational as well as social and cultural functions. The programme theory is intended to help identify the different elements in the intervention and how these elements interact, and therefore how an intervention is expected to cause the effects and under which conditions. The programme theory is intended to be developed with relevant stakeholders and based on evidence as well as theory. Stakeholders can be patients and the public. The stakeholders can be individuals, which are targeted the intervention, individuals who are part of the development of the intervention or delivery as well as individuals whose interests are affected. During the entire research process, it is necessary to identify key uncertainties, and these can be identified during the development of the programme theory. A refinement of the intervention can be helpful to improve the feasibility and acceptability of the complex intervention. An economic evaluation can be made regard to the costs and consequences of the intervention compared to an alternative intervention as well as no intervention. An economic evaluation can be relevant for decision makers, if they for example should assess whether an intervention is cost-effective to implement in a larger setting [7,8].

1.0 Introduction

Disease-related malnutrition (DRM) in acute and chronically ill citizens is associated with increased negative consequences for the individual as well as for the society due to increased economic cost [9–15]. DRM including nutritional risk has been investigated among inpatients and outpatients, but it is sparsely investigated in general practice among adult patients.

During the recent years, the overweight and obesity problem has increased, and 52.6% of the adults are overweight or obese in Denmark in 2021 (Body Mass Index (BMI) ≥ 25 kilogram(kg)/m²) [16]. Due to the overweight and obesity problem, nutritional risk including unintended weight loss (UWL) can be difficult to investigate, and it has become more difficult to implement nutritional interventions targeted the problems. It can be difficult to get patients and citizens to take UWL seriously as a symptom if they have an overweight problem and want to lose weight. In addition, proper and enough nutrition can be a problem among hospitalized patients, as some patients first and foremost are hospitalized due to medical treatment for getting well. People are not accustomed to think of nutritional status and staying physically active as something necessary as a basis for getting the most out of medical treatment. Some patients even see a weight loss during disease as an easy way of losing weight or as something just natural when being ill. Most people are not aware of the risks associated with nutritional risk. Therefore, there is a need to investigate how to prevent and treat UWL and how nutritional interventions can be implemented in the Danish Health care system. This is also due to the fact that among patients with cancer as well as in other groups patients with acute and chronic diseases, it can be difficult to increase lost muscle mass (MM) and level of function as well as improve dietary intake after adaptation to less efforts [17,18]. Therefore, optimization of individual dietary intake in those at nutritional risk can improve outcomes if the efforts are carried out in due time.

Early detection and handling of nutritional risk has shown relevant for many disorders, such as cancer, pulmonary diseases, neurological disorders, and for many senior citizens. There is only limited data concerning the prevalence of nutritional risk in general practice in Denmark. In Denmark, general practice seems a very good place for early detection of nutritional risk, since all Danish citizens have free access to general practice. Furthermore, general practice is the place where citizens address symptoms of illness, and the place with responsibility for following the course of most chronically ill patients [19]. Besides the lacking knowledge about the prevalence of nutritional risk, there is no data for managing nutritional risk in general practice, including the health professionals' knowledge and competences towards implementation of nutritional interventions in general practice. Therefore, the overall aim of this thesis was to evaluate nutritional risk in the general practice setting as well as to test the feasibility of a relevant complex early intervention towards nutritional risk in a group of relevant patients.

2.0 Background

Malnutrition and nutritional risk

Malnutrition also known as undernutrition can be defined as “a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass (FFM)) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease” [1]. Malnutrition can be classified as DRM with inflammation, DRM without inflammation and malnutrition without disease [1]. This thesis has its primary focus on DRM with inflammation, as it primarily regards patients who seek their physician regarding symptoms of disease, and DRM with inflammation is triggered by a disease-specific inflammatory response [1]. However, this thesis first and foremost regards the early detection of nutritional risk, but the GLIM criteria are used in the last study, but no diagnosis is given at the timepoint where patients are seen in the studies.

Early identification of malnutrition is core since nutritional status often deteriorates throughout the course of disease and early intervention is needed regarding decreasing the negative consequences of malnutrition [3,17,20–22]. To detect whether a patient is malnourished, the Global Leadership Initiative on Malnutrition (GLIM) criteria can be used. The first step in the GLIM criteria is screening for nutritional risk by using validated screening tools [1,2]. Different screening tools can be used depending on the setting. European Society for Clinical Nutrition and Metabolism (ESPEN) recommends Malnutrition Universal Screening Tool (MUST) in the community, Nutritional Risk Screening-2002 (NRS-2002) at the hospitals and Mini Nutritional Assessment (MNA) for elderly both at the home-care programs, nursing homes and hospitals [1,23]. Common for all these screening tools is that they include the presence of UWL. The last step in the GLIM scheme is to assess whether the patient is malnourished or not. A patient should have at least one phenotypic criterion and one etiologic criterion or preferably all criteria, before the patient can be classified as malnourished [2]. A phenotypic criterion can either be an UWL, low BMI or reduced MM, while an etiologic criterion can either be reduced food intake (RFI) or assimilation, disease burden as well as an inflammatory condition. A patient can either be moderate malnourished or severe malnourished based on a phenotypic criterion: weight loss in percent of actual weight, low BMI, or reduced MM [2].

In 2022 the Danish Health Authority published a new recommendation regarding malnutrition, addressing communities, hospitals, and general practice. The recommendations concerns detection, treatment and monitoring of citizens and patients at nutritional risk within the three settings [3]. It is recommended that weighing can be used in the community, and if a citizen has an UWL at least one kg, then the nutritional assessment form (Ernæringsvurderingsskema=EVS) can be used to detect and assess if an adult citizen is at nutritional risk and need guidance for nutritional treatment. The

NRS-2002 is recommended to use among adult inpatients, while weighing should be used among adult outpatients. Among inpatients, NRS-2002 should be used within the first 24 hours of the hospitalization if the patient is expected to be admitted ≥ 48 hours. In general practice, weighing is recommended for adult patients to detect whether a patient has had an UWL and is at nutritional risk. In general practice, the detection can be done both opportunistically and systematically. The opportunistic detection happens, when a patient visiting general practice with a problem, which gives the general practitioner (GP) or other health professionals in general practice reasons to suspect that the patient may be at nutritional risk. The systematic detection happens when a patient visits general practice due to planned follow-up e.g., a planned controlled for a chronic disease as chronic obstructive pulmonary disease (COPD). A patient will be considered with a warning of nutritional risk if the patient had an UWL at one kg. Sometimes however a two to three kg UWL within three months or two kg within two months may be more relevant to use [3].

Frequency and consequences of malnutrition and nutritional risk

Malnutrition in acute and chronically ill citizens is associated with increased negative consequences for the individual patient and the society. Malnutrition has been associated with longer hospital stays, readmissions, depression, reduced quality of life, reduced physical ability, increased dependence on post-discharge care, among others [9–15]. These negative consequences pose a significant impact on the health economy. Studies have investigated the financial burden associated with malnutrition. Thus, a study found that the cost was \$1500-2000 higher for malnourished inpatients compared to well-nourished patients due to longer hospital stay and higher medical costs [13].

Malnutrition and nutritional risk have been investigated at the hospitals among both inpatients and outpatients. Among inpatients, it has been shown that 9.8-64.0% are malnourished [10,11,13,24–26], and 12.0-74.0% are at nutritional risk [24–29]. Some of the studies have used GLIM to investigate the prevalence of malnutrition, while other have used validated screening tools to investigate the prevalence of malnutrition as well as nutritional risk. So, the prevalence is depending on the definitions in the tools, which have been used. Some use different gradings, while others only use one term, as the nutritional interventions are equal. Two recent Danish studies have investigated the prevalence of nutritional risk among adult inpatients, and found that 53.2% and 63.0% were at nutritional risk [12,30]. Other studies in Denmark investigated the prevalence of nutritional risk among older patients and found 56.0-98.0% at nutritional risk [31–34]. The difference in the prevalence of both malnutrition and nutritional risk depend on both the population and the used screening tool and whether the GLIM criteria have been used too. Based on Danish as well as international studies, some patient groups had higher risk of being at nutritional risk and therefore increase the risk of experience some the related consequences. The patient groups are acutely

ill patients, patients with comorbidities, the elderly and patients with some types of cancer [9,15,31,35–37].

In the hospital outpatient setting, nutritional risk differs between 13- 28% depending on diagnosis and amount of weight loss used to define UWL [38–42]. In Danish outpatients with COPD, 13.4% were found with five % weight loss within two months. This was reflected in length of stay on hospitalizations and worse quality of life within one year [43], while patients with pulmonary fibrosis and being at nutritional risk had higher risk of hospitalizations and mortality [44].

General practice and the role in the Danish healthcare system

All Danes have free access to general practice and most of the services provided in general practice are free [19,45]. Almost all the income in general practice comes from public funds, as the GPs receive fee-for-service payment for the services they provide [19,46]. Most GPs are self-employed working alone or in collaboration sharing facilities and/or patient lists. There are a smaller number of clinics owned by the Danish regions or private companies with hired GPs. Different groups of professionals are employed in general practice, but as a minimum a GP and very often a general practice nurse (GPN). Many general practices also have secretaries, medical laboratory technologist, and sometimes physiotherapists and dietitians are among the employees [19]. The GPNs' task as well as the GPs' can be different depending on the organizational structures in the general practice. Normally, the GPNs' tasks include wound care, annual controls of chronic diseases, birth control pills, fear of sexually transmitted diseases, consultations regarding respiratory infections, pediatric examinations, vaccinations, and rashes. The GPs' tasks include acute care and newly developed symptoms as well as patients with polypharmacy and multimorbidity. The GPs are first line of treatment and act as gatekeeper concerning further diagnostic investigations and treatment with referrals to the hospital, physiotherapy, or municipal health service [45,47]. Furthermore, the general practices have telephone-, video-, and e-mail-consultations during the day. GPs and GPNs work in close collaboration in the everyday work [19]. In 2022, the number of contacts to general practice was 42,950,531 [48], which means that the average contact with general practice was 7.3 per citizens, since 5,873,420 lived in Denmark in 2022 [49].

Malnutrition and nutritional risk in general practice

Malnutrition and nutritional risk are sparsely investigated in general practice. Studies internationally have found that 3.5-58.0% are malnourished in general practice [50–56], while 2.2-83.0% are at nutritional risk [51–55,57–59]. In Denmark, only few studies have investigated malnutrition and nutritional risk. Among +65 years old patients in general practice, 38% were at nutritional risk [60], and among >70 years old

patients 17.5% had an UWL and could be at nutritional risk [61]. A study from UK found that a patient diagnosed with malnutrition by the patient's GP had increased cost compared to patients without malnutrition with £1003 within six months due to increased health resources (e.g., consultations with GPs) and increased hospitalizations [62].

Internationally, malnutrition and nutritional risk have been investigated among older adults. In a population of older adults attending their GPs for an annual health assessment, nutritional risk was identified among one in six. One third of the patients in at risk had a BMI in the overweight or obese category, however BMI was significantly lower among the patients at nutritional risk compared to the patients not at risk [57]. Since one third of the patients at nutritional risk had a BMI ≥ 25 kg/m² [57], and another study found that overweight and obesity were problems in general practice [63], this highlights the need for systematic screening of nutritional risk, rather than relying on the visually obvious. The systematic screening is supported by other studies, arguing that older patients neglect UWL and had limited awareness of the benefit of good nutrition [58,61]. Therefore, a systematic screening can prevent further UWL as well as facilitate communication about good nutrition and the benefit of this as well as the consequences of poor nutritional status. Studies has found, that malnutrition was found as a secondary concern since the identification of malnutrition is usually secondary compared to other clinical issues [63,64]. Furthermore, a qualitative study from Ireland found, that GPs feel they do not know who is responsible for the managing of malnutrition in the community setting, lack knowledge and professional support to effectively monitor and treat malnutrition [63]. This highlighted the need for systematic screening in general practice as well as teaching in malnutrition in general practice to increase the health professionals' knowledge about nutrition and their options in community.

Intervention targeted nutritional risk in general practice

During the last 15 years, the length of hospitalization has decreased, and the number of outpatients increase [65]. Since the length of hospitalizations are going to be shorter and shorter, the opportunity to give nutritional treatment and improve the patients' nutritional status at the hospital is diminishing. A systematic review has showed that the nutritional status among inpatients gets worse during hospitalization among previously well-nourished patients [66]. Therefore, the patients being discharged from hospital may have a worse nutritional status compared to before the hospitalization. This can lead to that the GPs and the municipalities need to deal with these patients and their poorer nutritional status.

Optimization of individual energy and protein intake, in those at nutritional risk, improves outcome if the efforts are carried out in due time [67,68]. Studies in patients with cancer have shown that the negative consequences are directly proportional to

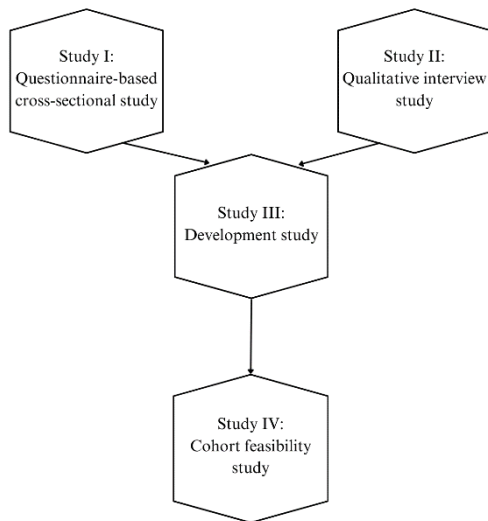
the degree of weight loss [69,70]. A study found that patients with head and neck cancer and had normal nutritional status had better treatment tolerance and survival rates if they had received early nutritional counseling compared to late or no counseling [71]. Furthermore, among cancer patients early detection of nutritional risk and interventions should be initiated with the aim to reduce weight loss and the risk of being malnourished [15,72,73]. For cancer patients as well as in other groups of acute as well as chronic ill patients, it is difficult to reverse lost MM and level of function. At the same time, it can be very difficult for the individual to improve dietary intake and physical activity after adaptation to less efforts [17,18]. In the recommendations from the Danish Health Authority, there are clear recommendations for how patients at nutritional risk should be managed at the hospital, outpatient clinics, general practice, and communities with the purpose to improve their nutritional status. In general practice, the health professionals can e.g., give nutritional guidance, initiate another form of nutritional treatment or refer the patient to municipal guidance [3]. However, not many studies have implemented nutritional interventions in general practice. One of the few studies used GP in the nutrition follow-up home visits after hospitalization, which was less successful, as the GPs compliance to the study intervention was very low [74]. One study of “GP surgeries”, investigated the economic impact of the implementation of the Malnutrition Pathway, which consist of early screening and nutritional support if the older patients were at nutritional risk based on the screening. The study found that managing the problem significantly reduces healthcare use with e.g., reduced hospital admissions, length of hospital stay and visits in general practice, which reduced the cost [75]. Due to the lack of data regarding prevalence of UWL and handling of UWL in general practice, there is a need to investigate nutritional risk in general practice in Denmark.

3.0 Aims

The overall aim of this thesis was to evaluate nutritional risk in the general practice setting as well as to test the feasibility of a relevant complex early intervention towards nutritional risk in a group of relevant patients.

This thesis consists of four studies. The relations between the studies are illustrated in Figure 1.

Figure 1: Illustration regarding the four studies in the thesis



Study I:

The overall aim of study I was to investigate the prevalence of nutritional risk using UWL and RFI among patients ≥ 18 years of age attending general practice and whether UWL and RFI are relevant as initial indicator for further assessment.

Study II:

The overall aim of study II was to investigate GPs' and GPNs' perceptions of how they manage malnutrition, and their view on introducing an early intervention targeted patients at nutritional risk in general practice.

Sub-aim: Clarify how GPs and GPNs detect and treat malnutrition as well as gain knowledge about their available resources, opportunities as well as tools to manage malnutrition.

Sub-aim: Clarify the GPs' and GPNs' view on introducing an early intervention in general practice as well as facilitators and barriers concerning implementation of an early intervention targeted patients at nutritional risk.

Study III:

The overall aim of study III was to develop a complex early nutritional intervention towards a relevant group of patients in general practice.

Sub-aim: Identify elements necessary related to an intervention targeted patients with UWL as initial indicator of malnutrition in general practice and based on this knowledge present recommendations to a communication strategy.

Sub-aim: Develop an early nutritional intervention targeted patients with UWL as initial indicator of malnutrition based on the recommendations to a communication strategy and literature.

Study IV:

The overall aim of study IV was to test a complex early nutritional intervention towards a relevant group of patients at nutritional risk in general practice.

Sub-aim: Investigate the feasibility of a complex early nutritional intervention in ten general practices among patients with UWL and referred to hospital due to suspected malignant disease.

Sub-aim: Explore the impact of the early nutritional intervention on the participants' health concerning dietary intake, MM, and strength as well as health-related quality of life (HRQoL).

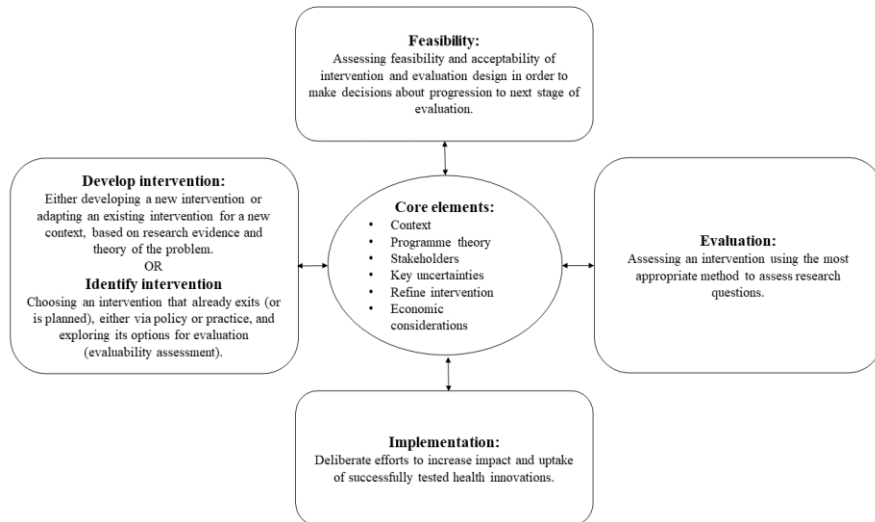
4.0 Methodological and theoretical reference framework

4.1 Medical Research Council framework

Regarding development and evaluation of complex interventions, the Medical Research Council (MRC) framework can be used by researchers and stakeholders. Complex interventions are characterized by having different interacting elements, different targets, and target groups, as well as being flexible and interacting at different organizational levels.

The MRC framework consists of four phases, which are briefly described in the following and illustrated in Figure 2. The core elements should be considered early in the research process but also during the entire process as well as during all phases, to assess whether it is possible to move to the next phase or repeat the present phase or move back to the previous phase [7,8].

Figure 2: The MRC framework with inspiration from [8]



MRC: Medical Research Council

Developing or identifying a complex intervention:

In the developing or identifying phase, a new intervention can be developed, or an existing intervention or idea can be used. Whether a new intervention should be developed or an existing intervention should be identified, the core elements are key considerations in this phase [8]. Regarding this thesis, a systematic literature search was performed in the beginning of the process. Based on the literature search, no nutritional and physical activity intervention have been implemented in general practice targeted patients at nutritional risk. Therefore, it was necessary to develop a new intervention, and the guidance on intervention development was used in the development phase [8,76]. The first step was to identify whether nutritional risk was a problem in GP including the size and relevance of the problem and to investigate whether the problem is a priority in general practice [76]. Therefore, study I was performed, as the aim was to investigate whether nutritional risk was a problem in general practice, where nutritional risk was measured by using UWL and RFI. Thereafter, study II was performed to investigate, which contextually elements should be considered regard to the development of the intervention. Based in the guidance on intervention development, stakeholders should be involved [76]. In the development of the questionnaire used in study I, GPs and GPs were involved to pose questions relevant to their practice. Both GPs, GPNs and patients were relevant stakeholders and by interviewing them (study II and III), it was possible to identify elements to be caretaken in the development of the intervention, define the context as well as possible obstacles to the intervention. Furthermore, other stakeholders were included in the development phase, which were an advisory board group with both the PhD. student, supervisors, patients, GPs, physicians at the hospital, a leader from the North Jutland General Practice organization (NordKap) and finally a clinical dietitian.

After the design and refinement of the intervention, the end of the development phase was reached, and it was possible to move on to the next phase, the feasibility phase.

Feasibility:

The aim with the feasibility phase was to assess whether the evaluation design would be feasible. To investigate the feasibility of the evaluation design, the following aspects were included [7]: Recruitment of both general practices and patients, retention of participants and outcomes used in the intervention.

Furthermore, the effectiveness was considered regard to the outcomes of the intervention [8]. Self-reported data and physical measurements were collected to investigate the effectiveness of the intervention related to the participants' health. The data collected in the feasibility study were decided together with the advisory board group. The intervention itself related to e.g., acceptability, cost effectiveness or optimal content and delivery [8], are not evaluated in this thesis, as no data was collected related to that part.

Before moving to the next phase, a recommendation should be made related to whether the intervention was feasible or not [8]. In this thesis, success criteria were established concerning recruitment, retention, and outcomes of the feasibility study (study IV).

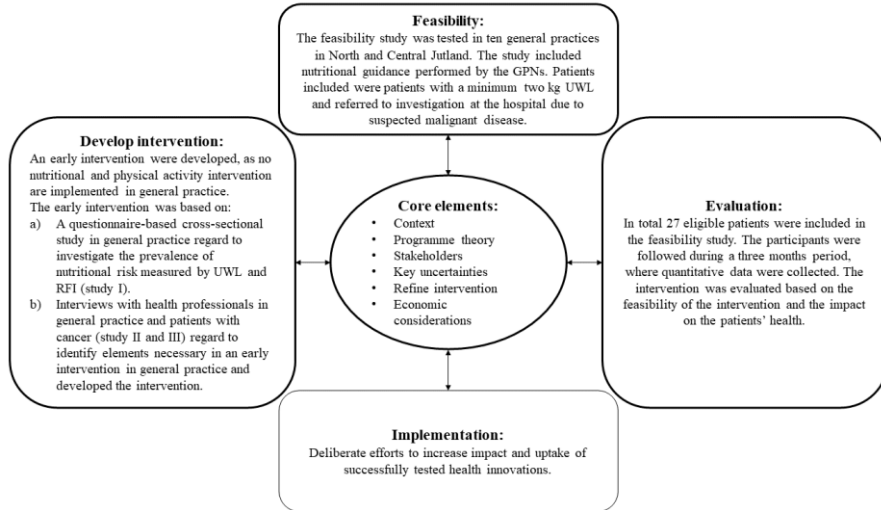
Evaluation:

In the evaluation phase, an evaluation should be made regard to whether the intervention works, how the intervention interacts with the context as well as how the intervention changes the system [8]. In this thesis, the intervention was evaluated concerning the feasibility as well as impact on the participants' health based on quantitative data. Therefore, it was the effectiveness that was evaluated in this phase. In the evaluation phase, stakeholders should be included to assess which outcomes will be most important to use [8]. Depending on the evaluation of the intervention, it is possible to move to the next phase or move back to the previous phases.

Implementation:

In the implementation phase, the intervention developed or adapted, tested, and evaluated can be implemented in a real-world setting. It is necessary to consider the implementation throughout the research process and especially if the intervention should be adopted and maintained in the real world [8]. The MRC framework related to the thesis is illustrated in Figure 3 concerning the development phase, feasibility phase and evaluation phase. The implementation phase is not described further in this thesis.

Figure 3: The MRC framework related to the thesis with inspiration from [8]



MRC: Medical Research Council, UWL: Unintended weight loss, RFI: Reduced food intake, GPNs: General practice nurses.

4.2 Pragmatism

The approach used in the selection of methods was based on the scientific theoretical orientation applied in this thesis, namely pragmatism. Pragmatism is further described in this section as it is interpreted in this thesis.

Pragmatism arose in USA and the essential representatives were Charles Sanders Peirces, William James and John Dewey [77]. Pragmatism contributes to a dynamic paradigm [78], as the scientific understanding in pragmatism is based on the fact that we cannot find an eternal and unchanging truth about the world, as the world is characterized by constant change and the understanding is contextual [77,79]. What is found to be the truth today can be false tomorrow [80]. Therefore, in pragmatism the traditional dualisms are rejected e.g., subjectivism vs. objectivism, facts vs. values, and instead looks at moderate versions of philosophical dualism [80]. Furthermore, reality and knowledge are based on a social consensus, which means that reality and knowledge are constructed and based on how we experienced the world [77–81]. Hence, knowledge can be a relationship between actions and the consequences of those [79]. Therefore, the scientific investigation begins, when something makes one wonder, which leads to hypotheses that are possible explanations for the phenomenon,

the researcher had observed in a given time and in a given context [77]. The researcher will through scientific work test these hypotheses and the work process will be called abduction, as the data collection as well as the analysis are flexible and adaptive [77,78]. Therefore, induction and deduction are used to complement each other, but without rules for how they should be used [77]. The researcher needs to understand the characteristics of both, so the researcher can use them correctly [80]. In pragmatism the topic or phenomena determines, which methodological approaches are most appropriate [77,78,81]. Therefore, the researcher have the opportunity to choose the method(s) or technique(s) that fit the purpose and give the best chance to achieve the most useful answer or solution of the problem [78,80,81]. Within pragmatism there is an interconnectedness between experience, knowing and acting, where acting is a key principle [78]. Therefore, it enables the use of different methods during the data collection [78]. This means, that pragmatism is characterized by an undogmatic approach, where it is not important to comply with abstract rules but what the researcher does will work [77]. Within the pragmatism, there is a focus on the transferability of the research regarding how the research is applicable to other contexts or settings [78].

As described in section 4.1 regarding the MRC framework, an early systematic literature search was performed, and thereafter a questionnaire-based cross-sectional study was necessary to perform. The results were that nutritional risk measured by using UWL and RFI was a problem (study I). Then the new wonderment was, even though nutritional risk was prevalent in general practice, it seemed to be a neglected problem in literature as well as in practice (study II), so how could the problem be dealt with. The next step was to perform interviews with both health professionals and patients (study III). Based on the findings from the two studies, an early nutritional intervention was developed, and we choose the methods that should be most suitable to use to answer whether the intervention was feasible or not (study IV). Therefore, this thesis was grounded in pragmatism, which is underlined by the way the four studies build up on new existing knowledge and thereby questions from one study to the other. In addition, the methods in the four studies were chosen based on the scientific theoretical orientation.

5.0 Methods and Materials

In this chapter, the overall study design is explained. Furthermore, descriptions of the four different studies are explained including the four individual study design, data collection, sampling as well as data analysis. Finally, the ethical considerations are described in detail.

5.1 The overall study design

The overall study design is a multiple method study, as none of the methods or results as well as findings are mixed or integrated [80]. The different study designs and methods related to the four studies in this thesis are illustrated in Table 1.

Table 1: Overview of the methods related to the four different studies in this thesis

| | Study I | Study II | Study III | Study IV |
|-------------------------|--|--|---|--|
| Design | Questionnaire-based cross-sectional study. | Qualitative interview study. | Development study. | A cohort feasibility study. |
| Study population | Patients visiting general practice. | GPs and GPNs. | GPs, GPNs and patients. | Patients referred to investigation at the hospital due to suspected malignant disease. |
| Setting | General practice. | General practice. | General practice with the health professionals. Hospital, telephone or at the patients' homes. | General practice and in the participants' homes. |
| Study period | 26/8 2020 – 8/10 2020. | 2/9 2020 – 19/10 2020. | 2/9 2020 – 15/3 2021. | 1/10 2022 – 30/6 2023. |
| Methods | Questionnaire. | Individual interviews with GPs and focus group | Individual interviews with GPs and patients and | Questionnaire, BIA, the app EnerDia, 30s-CST, |

| | | | | |
|------------------------------|---|-----------------------------------|---|--|
| | | interviews with minimum two GPNs. | focus group interviews with minimum two GPNs. | EQ-5D-5L during a three-month period. |
| Data analysis | Descriptive statistics, χ^2 tests, simple and multi-variable logistic regression analyses. | Qualitative content analysis. | Interpretive thematic analysis. | Descriptive statistics, χ^2 tests, paired t-tests and Wilcoxon signed rank tests. |
| Data analysis program | SAS. | NVivo. | NVivo. | STATA. |
| Paper | Paper I and published [82]. | Paper II and published [83]. | Paper III and published [84]. | Manuscript IV and submitted. |

GPs: General practitioners, GPNs: General practice nurses, BIA: bioelectrical impedance analysis, the app EnerDia, 30s-CST: 30 second chair-stand test, EQ-5D-5L: the 5-level EuroQoL-5 Domain.

5.2 Study I: Questionnaire-based cross-sectional study

In this section, study I is described regarding study design, data collection, sampling of general practices and patients, as well as statistical analysis.

5.2.1 Study design

Study I was a questionnaire-based cross-sectional study design with only quantitative data. In this study, the results were based on the general population of patients affiliated to five different general practices in North Jutland, Denmark. The study design was required to determine the prevalence of nutritional risk by using the surrogate measurements UWL and RFI at a given time point in a sufficient sample of patients and by representation of different types of general practices. Furthermore, the study design was used to investigate associations between the selected outcomes and exposures [85], and the outcomes and exposure-variables were collected at the same time [86].

5.2.2 Data collection

In this section, the data collection and the materials used in the data collection are described. The collection of data lasted for four days in each of the included general

practices.

Collection of empirical evidence

Patients were recruited in the waiting room right after they checked in for the consultation. The patients were informed about the study and asked if they would like to participate. If the patient accepted to participate, they were invited to a quiet and more shielded place in the waiting room or to a room just next to the waiting room, where the weighing scale and a height measuring scale was placed. The patients' weight and height were measured if the patients have not weighted themselves the particular day and/or the patients' height was not measured within one year. Then the patients filled in the printed questionnaire by themselves, or the investigator/the PhD student helped the patients fill in the questionnaire, sitting next to the patients.

Materials

To collect data a questionnaire was developed and inspired by literature search and questionnaires used in resent studies in outpatient settings [39–41], as there are no standardized questionnaires for this purpose or setting. GPs and GPNs from included practices discussed and validated the questionnaire before data collection, and a minor change was made.

In total the questionnaires consisted of eight questions (also illustrated in Appendix 1 and used in paper I [82]):

1. Gender.
2. Age (years), weight (kg) and height (cm).
3. Your visit in general practice today is to: GP and/or GPN and/or blood tests (The patients could fill in more than one answer at this question).
4. Reason for visit the general practice today: newly emerged disease and/or new injury and/or follow-up on chronic physical illness e.g. annual check-ups and/or chronic pain and/or newly emerged pain and/or visits for prescription renewal and/or virus/flu symptoms and/or mental discomfort e.g. anxiety, depression or control and/or fatigue and/or suspicion of serious illness and/or skin problems and wounds and/or pregnancy examination and/or general health check and/or medical certificate e.g. driving license and/or vaccination and/or other (The patients could fill in more than one answer at this question).
5. UWL within the past two months: yes or no. If yes, what was the amount of weight loss (kg). A limit value was one kg was chosen according to recommendations from the Danish Health Authority [87,88].
6. RFI within the past week compared to usual [4]: yes or no.

7. Intended weight loss: yes or no. If yes, what was the amount of weight loss (kg). A limit value of one kg was chosen according to recommendations from the Danish Health Authority [4,88].

If the patients answered “yes” in question 5 and/or 6, the patients answered the following question:

8. Nutrition impact symptoms (NIS): nausea and/or pain and/or worries and/or swallowing problems and/or lack of appetite and/or constipation and/or lack of help for cooking/shopping and/or do not like eating alone
(The patients could fill in more than one answer at this question).

5.2.3 Sampling procedures

In this section, the sampling procedures are explained due to the sampling of general practices and patients. Furthermore, the inclusion and exclusion criteria regard to general practices and patients are presented.

Sampling of general practices

A set of criteria were established regard to the sampling of general practices in this study, which were:

- All kinds of general practices should be included: traditional multiple physician practices, license clinic and partnership clinics.
- The practices should be widely geographically located with large city, smaller city and countryside represented.
- The practices should be both small and big practices.

Single physician practices were excluded due to the risk of getting too few participants in the study. Based on the criteria for the general practices, different general practices were contacted via e-mail and invited to participate in the study. The main supervisor had contact to one person in one multiple physician practice and in a partnership clinic, but the other practices were recruited via e-mail. The sampling techniques used to recruit general practices were snowball sampling and voluntary response sampling [89–91]. General practices were recruit in June and July 2020.

In total, five different general practices were recruited, and the included general practices had a minimum of two or more GPs and GPNs as well as minimum one secretary. The general practices included had different internal organizations and were widely geographically located, as both country and city were represented.

Sampling of patients

The method used to recruit the patients in study I was consecutive sampling, as the aim was to recruit all patients visiting the general practice the specific day and met the inclusion and exclusion criteria (see Table 2). Consecutive sampling is a non-probability sampling method, as the patients were recruited over a period in each practice, and all patients were asked for participation in the study [92]. The patients were recruited from 26. August 2020 to 8. October 2020.

Table 2: Inclusion and exclusion criteria in study I

| Inclusion criteria | Exclusion criteria |
|---|--|
| <ul style="list-style-type: none"> - ≥ 18 years. - Willing to participate in the study. - Speak Danish or English or have a relative who could speak Danish or English and was willing to help the patients. | <ul style="list-style-type: none"> - Relatives to a child < 18 years and thus did not have a consultation themselves. - Wheelchair users who were not able to stand safely on the weighing scale. - Not able to understand the given oral information i.e., due to mental impairment. |

5.2.4 Statistical analysis

The collected data were entered and stored in Research Electronic Data Capture (REDCap), which is hosted by Aalborg University Hospital. Before the data analysis, the data was double-checked with the aim of avoiding typing errors, and 999 was used in case of missing data. Missing data were excluded from the association analyses and the logistic regression analyses. Data were analyzed in SAS (SAS Inc., Cary, NC, USA, version 9.4 for Windows). Descriptive statistics were performed and presented as filled-in replies (N) and percent (%). Normality of distribution was examined using Shapiro Wilk Test [85], and based on these analyses, median and range were performed. Chi² tests, simple and multivariable logistic regression analyses were used to investigate the association between the dependent and independent variables, as the dependent variables were binary [85]. UWL and RFI as well as UWL and RFI combined were the dependent variables. Independent variables were sex, which general practice, age, BMI, the health professional the patients visited, the reason for visit as well as RFI.

Multivariable logistic regression analyses were performed with the purpose of adjusting the associations between UWL, RFI as well as UWL and RFI combined regard to the health professional the patients visited, reason for visit in general practice and RFI. The variables used to adjust with were sex, age, BMI, and general practice. A

significance level of 0.05 ($p < 0.05$) were used, and a 95% confidence interval (95% CI) was calculated in relation to the odds ratio (OR) [85]. The group with the most answers were applied as reference group in the analyses. Some patients were duplicated, as they could fill in more than one answer in question 3, 4 and 8.

In this study, no power calculation was performed, as the study design was a questionnaire-based cross-sectional study. BMI was calculated based on the World Health Organization's (WHO) definition of BMI groups [93].

5.3 Study II: Qualitative interview study

In this section, the study II is described in terms of the study design, data collection, sampling of health professionals and the qualitative data analysis.

5.3.1 Study design

The study design was a qualitative interview study with GPs and GPNs from the five general practices, which also were included study I. The study design was used to investigate how the health professionals' experienced a given phenomenon and getting their subjective attitudes towards the phenomenon [94,95]. In this case, the interviews should clarify how the health professionals detect and treat malnutrition as well as to gain knowledge of their available resources, opportunities, and tools for handling malnutrition. Furthermore, interviews should help clarify facilitators and barriers regarding implementation of a nutritional intervention in general practice.

5.3.2 Data collection

The data collection is described in this section regarding the interviews as well as the interview guide used to the health professionals.

Collection of interviews

The data collection consisted of both individual interviews as well as focus group interviews. Individual interviews were performed with one GP, while focus group interviews were performed with a minimum of two GPNs (one general practice only had two nurses). All interviews were made by prior agreement, so the health professionals had the possibility to spare time for the interviews.

The focus group interviews with the GPNs were chosen as the aim was to investigate perceptions, ideas and obtain discussions about malnutrition, the management related

to malnutrition as well as facilitators and barriers toward an intervention [95–97]. During the focus group interviews, the PhD student and the co-authors participated as moderators, presented the themes and facilitated the interviews [97]. The focus group interviews with the GPNs were performed in lunch breaks. Due to logistical reasons, individual interviews were chosen with the GPs, as it was easier to perform the interviews in between the patients and in some cases in the lunch breaks. However, it was still possible to obtain information about the GPs’ experiences about a given phenomenon and their individual experiences towards malnutrition [95,97]. The individual interviews were also performed by the PhD student and the co-authors. The PhD student and the co-authors were all experienced with performing interviews with both patients and health professionals.

An Olympus Dictaphone WS-852 were used to record the interviews, and the interviews were transcribed verbatim after performing each interview by the PhD student. As no new topics occurred in the last individual and focus group interviews, data saturation was achieved [95,98].

The GPs and GPNs were not paid for the participation in the interviews, and the individual interviews lasted from 11 to 30 minutes, while the focus group interview lasted from 18 to 40 minutes.

Interview guide to health professionals

A semi-structured interview guide was developed to the health professionals’ interviews, as the aim was to have flexible interviews but still obtain the perceptions of the phenomenon [94,97]. The interview guide was developed based on literature [63,99]. The semi-structured interview guide consisted of the following topics (see Appendix 2):

- Health professionals’ roles and responsibilities regarding early detection and treatment of malnutrition
- Opportunities and tools available regarding management of malnutrition
- Cooperation and communication with other sectors
- Barriers and facilitators for implementation of nutritional intervention in general practice

The interview guide was tested and validated on health professionals in one general practice. No corrections in the interview guide were made, and the interview was included in the data analysis. The interview guide was used to both the individual and focus group interviews with GPs and GPNs respectively.

Questions in the interview guide

The interview guide started with briefing and ended with debriefing. The aim with briefing was to inform the health professionals with the aim of the interviews, the use of the dictaphone, obtain written sign of consent and ask if there were any questions before the interviews start. The aim with the debriefing was to end the interviews and hear if the health professionals have anything to add or ask about after the interviews [97]. Before the interviews started, the health professionals were asked whether they were employed full-time or part-time, but also how many years of experience they had in general practice. This is to be able to make a descriptive description of the health professionals afterwards. Furthermore, the interview guide consisted of following types of questions: Starting up questions, structuring questions and specifying questions. Additionally, the following types of questions were used during the interviews: follow-up questions, direct questions, and interpretative questions. Silence and breaks were used to give the health professionals the possibility to reflect and eventually elaborate their replies [97].

5.3.3 Sampling procedures

In this study, the sampling method was purposeful sampling, as the health professionals were recruited as they could provide with in-depth and detailed information about the given phenomenon [90,91,100]. The health professionals participating in the study were invited to the interviews during/or after study I. The leader in each of the five general practices recruited the GPs and GPNs, but as a minimum one GP and two GPNs should participate in the interviews from each general practice. The interviews were performed from the 2. September 2020 to 19. October 2020.

5.3.4 Data analysis

The transcribed interviews were analyzed in the program NVivo 12.2.0. A qualitative content analysis was used to analyze the transcribed interviews, as a qualitative content analysis can be used to systematically describe meanings [101]. The qualitative content analysis consisted of; reading the interviews, condense and code meaningful quotations, group codes with the same content into subcategories and thereafter created main categories based on the subcategories. Thereafter, the themes were created based on the main categories [95,97,102]. The PhD student performed the content analysis and thereafter interpreted and discussed the findings with the co-authors. Eventual disagreements were discussed until consensus were reached. Each health professional got an identification number (ID number), and each quotation were described with the ID number. After performing the analysis, each health professional got the opportunity to read through the findings, so they got the possibility to reflect

over the findings [97]. The health professional did not have any comments.

5.4 Study III: Development study

In this section, study III is described in terms of the study design, data collection, sampling of health professionals and patients, and the qualitative data analysis. Furthermore, the material developed based on the findings is described at the end of the section.

5.4.1 Study design

The study design was a development study based on qualitative interviews with patients and health professionals. The aim was to develop a complex early nutritional intervention towards a relevant group of patients in general practice based on interviews with patients and a secondary analysis of the health professionals' interviews from study II. The study investigated which elements are necessary for early management of UWL as initial indicator of malnutrition in general practices perceived by patients and health professionals. Based on the elements, it should be possible to provide some recommendations and use these in an effective communication strategy. The recommendations should be used in the development of the nutritional intervention targeted patients with UWL as initial indicator of malnutrition in general practice.

5.4.1 Data collection

The data collection will be described in this section concerning the collection of the interviews as well as the interview guide.

Collection of interviews

Collection of interviews with the health professionals

The collection of interviews with the health professionals were performed as part of study I. Further description of the collection is described in study II in section 5.3.2.

Collection of interviews with the patients

Individual semi-structured interviews were performed with patients, which had experienced an UWL, when the patients visit the GPs before referral to hospital for further investigations. The interviews were performed by the PhD student and one of the co-

authors. The patients had the opportunity of being interviewed at home, at the hospital or by telephone, and this was chosen by the patient.

An Olympus Dictaphone WS-852 was used to record the interviews, and the interviews were transcribed after performing each interview by the PhD student. The aim was to achieved data saturation, which was achieved, as no further information was forthcoming in the last interview [97,98]. The patients were not paid for participate in the interviews, and interviews lasted from 15 to 50 minutes.

Interview guide

Interview guide to health professionals

The interview guide used to the health professionals was semi-structured. It was the same interview guide used to both the GPs and the GPNs. Further description of the interview guide and the questions used in the interview guide are described in study II in section 5.3.2.

Interview guide to patients

The interview guide to the patients was semi-structured, as the aim was to have flexible interviews but still obtain the perceptions of the phenomenon [94,97]. The phenomena were patients experiences with handling UWL as initial indicator of malnutrition in general practice as well as the patients' perception towards management opportunities early in general practice. The interview guide consisted of following topic (also see Appendix 3):

- Experiences with the weight loss and their reflections on if and eventually how weight loss had affected their life though the course of disease.
- Experiences with handling their weight loss in general practice.
- Options for managing and preventing further weight loss.

A pilot interview was performed of one patient for test and validate the interview guide. No changes were performed, and the patient was included as an informant.

Questions in the interview guide

The interviews started with a briefing to inform the patients about the aim with the interviews, sign the consent form, and the purpose with recording. Before the interviews started, the patients were asked whether they had any questions before the dictaphone was started. The interviews ended with a debriefing to clarify whether the

patients have any questions or any additions [97].

Demographic information regarding age, diagnosis, weight loss in total, the course of the treatment and marital status were collected. The interview guide consisted of Starting up question about the patients' weight loss related to the diagnosis, as well as structuring questions and specifying questions. During the interviews the following types of questions were used: follow-up questions, direct questions and interpretative questions as well as the use of silence and breaks [97].

5.4.2 Sampling procedures

Sampling procedures with the health professionals

The sampling method used to recruit health professionals to the interviews was purposeful sampling [90,91,100]. Further description is described in study II in section 5.3.3.

Sampling procedures with the patients

The patients were recruited by dieticians and ward nurses at different wards at Aalborg University Hospital. The sampling procedure was purposeful sampling, as these patients had specific knowledge and experiences with the problem [90,91,100]. The patients were recruited from 30. November 2020 to 15. Marts 2021. The inclusion criteria were: patients with an initially UWL at minimum five % of their bodyweight within the last three months when they visited general practice as well as willingness to share their experience with handling UWL in general practice.

5.4.3 Data analysis

A secondary data analysis

As part of the secondary analysis, the transcribed interviews were reread and reanalyzed by using a systematic process [103]. This second analysis made an in-depth analysis with special focus on the nurse-patient communication about nutrition and other topics they found could be equated with nutrition communication, the use of written material during communication, and their experiences and thoughts on the use of applications (apps) among their patients. Furthermore, the analysis sought what was reflected around existing knowledge about nutrition among the health professionals, regarding especially the GPNs and the need and preferences for training within the field of nutrition.

Data analysis based on the interviews with the health professionals and the patients

All the transcribed interviews with both the health professionals and the patients were analyzed in NVivo 12.2.0. The interviews with the health professionals and patients were analyzed through an interpretive thematic analysis with the aim to achieving a rich and detailed description of the data [104]. The thematic analysis strategy was an inductive analysis strategy and consisted of five phases [104]: 1. Be familiarized with the data, 2. Generate codes initially, 3. Search for themes, 4. Themes should be reviewed, and 5. Define and name the themes. The first two authors analyzed independently the transcripts with the aim to identify the themes separately, which thereafter were discussed with the other co-authors.

Theory used in the data analysis

To explain the findings from the thematic analysis, the motivation theory self-determination theory, the health belief model, and communication theory were used. Self-determination theory was used to understand the informants' action and motivation for make some changes as well as maintain behavior [105]. The health belief model was used to understand and explain the informants' behavior and participation in health promotion and disease prevention [106,107]. Regarding the communication theory, some concepts framed the communication theory, which were patient involvement [108], patient-centered communication [109], empowerment [110,111] and health literacy [106,112]. Patient involvement deals with the involvement of patients and their knowledge in the healthcare system at both the organizational and individual level [108]. Patient involvement specifically refers to patients' rights to and the benefits of having a central position in their disease process [113]. In patient-centered communication, there is a mutual and equal exchange of information between the patient and the health professional [109]. The health professional can thus gain an insight into what is important to the patient in relation to the disease and possible treatment. The health professional supports and advises the patient in making decisions and mastering illness and treatment [109]. A crucial goal for patient-centered communication is thus to achieve empowerment of the patients. Empowerment aims to give patients the ability to act, have control and ownership related to decisions that affect their lives and health [110,111]. Patient involvement, patient-centered communication and empowerment require that health professionals can adapt health information to the individual patient's health literacy. Health literacy can be described as individuals' ability to read, understand, acquire and use health-related information, as well as individuals' opportunities to participate in the healthcare system and make informed choices regarding their own health [106,112]. These concepts are mutually dependent, when implementation in practice is in focus [111,114].

The communicative theory complements the health belief model and self-determination theory by clarifying how UWL as initial indicator of malnutrition is approached

and solved through a communicative strategy, which should end with some recommendations for future intervention in general practice. In the communication strategy, it is also necessary to consider the approach strategies [115], the form of appeal (including ethos, logos and pathos) [116] and communicative tools (including syntax, lexis and layout) [117]. In this study, the communication strategy will be presented, which can describe both specific objectives, messages and media as well as timing [118,119].

5.4.4 Findings from the qualitative analysis

Based on the health professionals' statements, suggestions were found to support the implementation in general practice, where minimum one GPN should be especially affiliated to the study, receive a more extensive training, and give the nutritional guidance to the patients.

5.4.5 Developed materials based on findings

In this section, the materials developed to implementation in the complex intervention are described. The section is divided into two parts, the written materials, and the app.

Based on the findings from the qualitative analysis from the interviews with the patients and health professionals in study II and III and the results from study I, the intervention was targeted patients referred to investigation at the hospital due to suspected malignant disease. Furthermore, as described in section 5.4.4 minimum one GPN should give the guidance to the patients after receiving training concerning nutrition.

The written materials

The written materials were developed based on scientific literatures and the qualitative analysis in study III.

The written materials were a pamphlet about the study, a pamphlet about diet and physical activity, a diet overview chart, a more detailed diet chart, a training program, and an inspiration catalog for meals. In addition, an instruction document to both participants and GPNs were developed with the aim of guiding them in the use of the app EnerDia. Furthermore, an inspiration paper to the GPs regard to, what they could tell the patients was developed as well as a reminder paper that could hang in the GPs' office (see Appendix 4.1 and Appendix 4.2).

The app EnerDia

Based on the findings from study II, an app was included in the complex intervention. The app EnerDia was chosen (<https://apps.apple.com/de/app/enerdia/id1621690916>), as the app was used earlier in another study. In the previous study, the app was called NutriDia and was used to prevent weight loss in cancer patients. Based on the previous study, the app proved very helpful in order to prevent weight loss and for motivating patients, however the app was introduced to the patients after the start of treatment [120].

Before study III, the app was updated and adjusted toward a more general population not only including cancer patients, and for foodstuffs as well as information about NIS and advice to eat more if users/patients experience problems with eating. The app functions are described in the following.

Functions in the app EnerDia

Weight registration as well as energy and protein requirements: The app consists of a weight-registering module with the purpose to show the weight development over time. Based on individual information of height and weight, the app will calculate individual requirements for energy and protein. The energy requirement is calculated by multiplying 25 kcal with the entered weight, and the protein requirement is calculated by multiplying 1.2 gram protein with the entered weight [3]. It is possible to adjust the energy and protein requirements, if the users/patients have a BMI < 18.5 kg/m² or BMI > 30 kg/m², then the energy and protein requirements will be calculated corresponding to BMI = 25 [3]. Furthermore, adjustments can be made if the user/patient for instance shows to have extensive metabolism and thereby loses weight even though goals are met.

Food registration: The app had a food and dietary registration module. Furthermore, the app consisted of instructions about the correct individually dietary intake, and what the user/patient could eat to improve dietary intake. The users/patients could also follow, how close they were to meet energy and protein requirements for the specific day. Not reaching requirements was illustrated by a red arrow, which turned yellow when goal was near and then green when goal was achieved. It was possible to perform registration back in time if the users/patients forgot the food registration or wanted to do it later than the actual meal.

Nutrition impact symptom registration: The app consisted of a NIS module, where early satiety, diarrhea, mouth sores, lack of appetite, pain, constipation, swallowing problems, changes in taste, fatigue, and nausea could be scored from one to ten. The colors green to red indicated no problems or worst thinkable symptoms. It was

possible to perform registration back in time if the users/patients have forgot to perform the NIS registration.

Activity registration: The app included a physical activity module, where it was possible to monitor the activity at three different levels and how much time spent during the day from 0 minutes to 120 minutes. The three levels were: low activity (1.5-3 metabolic equivalent of task (MET)), medium activity (3-6 MET) and high activity (6-9 MET). It was possible to perform registration back in time if the users/patients have forgot to perform the activity registration.

Information library: The app consisted of an information module, where the users/patients had the opportunity to obtain knowledge about weight loss due to a disease, different nutritional opportunities (food, oral nutritional supplements, enteral nutrition, and parenteral nutrition) as well as find a description of different types of NIS and non-medical advice on what the patient can do against each NIS. Additionally, the users/patients could find the references used in the information library [3,121,122].

Opportunity to share information with health professionals: User/patients used the app for motivational usage, and it was possible to share the entered data with health professionals or relatives aiming at shared decision making on nutrition. Based on the previous study, this function performed the basis for a dialogue about nutrition and overall symptoms between the patient and professional, which enhanced early symptom handling and nutritional intervention initiatives [120].

Legal considerations regarding the app

The user/patient creates a profile in the app and enters information about current height and weight, name, and an e-mail. The user/patient decides for whether an existing e-mail is used, or if the user/patient want to create an email just for this purpose. Information about illness or social security number is not entered and the use of the app is not tracked. The app is intended to serve as motivation and decision support between user/patient and professional regarding nutritional status, but can as in this case, also be used to share information and get support on weight, dietary intake and physical activity in a development program or research. In that case, the user/patient presses a button “connect” and get a four-digit number, which the user/patient tells or write to the receiver using another media. Then the receiver can log into the data the user enters in the app and thereby discuss the entries and the progress. It is possible to add a new connection, and then the procedure is repeated, and another number is achieved. If the user/patient only wants to use the app for own motivation and information, this is also possible. Then the user/patient simply refrains from inviting anyone to see the data. All data will be deleted when the user deletes the profile.

The system thereby fully complies with all regulations for GDPR. CE marking has been applied for the program so that it can be used with medical data if desired, but it is optional and not yet fully developed. The app is free to use for all in the Apple app database and in Google Android database.

5.5 Study IV: Feasibility study

In this section, study IV is described related to study design, data collection including the measurements, sampling of general practices and the participants as well as the statistical analysis.

5.5.1 Study design

Study 4 was a feasibility study with a cohort study design. The aim was to investigate the feasibility of the intervention concerning recruitment of both general practices and patients, retention and outcomes [7,123]. Furthermore, the aim was to investigate the impact on participants' health after received an early nutritional intervention in general practice.

5.5.2 Data collection

In this section, the recruitment of both general practices and participants will be described as well as how feasibility is assessed in the study. In addition, the materials and measurements performed in the feasibility study will also be described.

Recruitment of general practices and participants

Recruitment and retention of general practices

Ten general practices were included. These were distributed on countryside and city, had different organizational structures and were from two different regions. Further description of the recruitment of general practices are described in the following section: Sampling of general practices.

Before the intervention started, all included practices received an introduction about the problem, the results and findings from study I-III as well as the early nutritional intervention. If it was possible all GPs, GPNs and secretaries participated in the introduction. All included practices should have at minimum one GPN to participate in a half day training day about nutritional risk, the consequences of malnutrition, the material and the recruitment and guidance process. The practices could send more than

one GPN, but they only received financial compensation for sending one GPN. The GPN who participated in the half training day, should be the one to provide the nutritional guidance to the participants.

During the nine-month intervention, monthly updates were sent to all included general practices from either the PhD student or the main supervisor. The practices were offered a follow-up meeting halfway through the study. The practices with few recruited patients or none were contacted more often regarding the offer of having a follow-up meeting compared to the practices with a higher recruitment rate.

Recruitment of participants

The participants were recruited by the GPs, if a patient had an UWL at minimum two kg within the last three months, had other symptoms and was referred to investigation at the hospital due to suspected malignant disease. The GP gave the initial introduction to the patient about the study. The GP could also give the patients a pamphlet about the study. If the patient was interested in the study, the patient booked a new appointment with the GPN.

The GNP further explained the implications of the study to the patient. Before the patient received the nutritional guidance, an informed consent had to be signed at the GPNs. The patients had the opportunity to take the informed consent form with them home and think whether they wanted to participate before they sign the form. After signing the consent form, the participant received information about the importance of keeping the weight stable as best as possible and preventing decrease in MM and muscle function. In addition, the participant was introduced to the app EnerDia and other written material. The amount of written materials was individualized to each of participants by the GPNs. The GPNs were taught that they should choose how much and which material and information each individual participant should receive during the half training day. This was chosen with the purpose to make the guidance targeted to the individuals state of mind at the time and competencies, based on the findings from study II and III. The general practices received financial compensation for each included participants, who signed the written consent form.

As explained in the section: The written materials, the GPs were provided with at an inspiration paper, they could use, when recruiting patients. Later in the intervention, an inspiration paper was developed for the GPNs, which the GPNs could use, when they gave the participants the nutritional guidance. The inspiration paper to the GPNs was developed due to the low number of recruited patients, and the GPNs may also need something they could be inspired by like the GPs (see Appendix 4.3).

Feasibility

The primary aim of this study was to investigate the feasibility of the early nutritional intervention in general practice. Therefore, the aim was to investigate “Can this study be done in practice?” [123]. To investigate the feasibility of the intervention recruitment, retention and outcomes were used [7,123]. Concerning recruitment, both the recruitment of general practices and the GPs ability to recruit patients were investigated. Concerning retention, the follow-up rates as well as the reasons for dropout were investigated. In relation to outcomes, missing data during the data collection, duration of follow-ups, the reasons for postponing follow-up as well as reasons for changing some physical follow-up to telephone follow-ups were investigated.

A set of success criteria were established concerning the feasibility of the intervention:

- A recruitment rate of >60% of general practices.
- Minimum 50 participants recruited within the nine-month intervention.
- Retention rate of >80% during the nine-month intervention, excluding participants without a cancer diagnosis.
- Only two participants with missing data at each follow-up timepoint.

Materials and measurements

After the participant received the nutritional guidance by the GPNs, the sign of consent form was sent to the PhD student with contact information such as name, telephone number, address, and e-mail. The PhD student contacted the participant to arrange a follow-up meeting at the participant’s home or another place chosen by the participant. The PhD student gave the participant additional help by using the guidance materials and the app if needed. The participants were followed at M0, M1 and M3 after inclusion. Data collected were physical measurements and self-reported data. No personal sensitive information such as social security numbers (CPR) were collected, and participants solely decided what information to give to the PhD student other than the initial and the follow-up measurements. All participants were followed until they had received the results from the investigation at the hospital, and if the participants did not have a cancer diagnosis, the follow-ups were stopped. However, all were followed at M0 and M1.

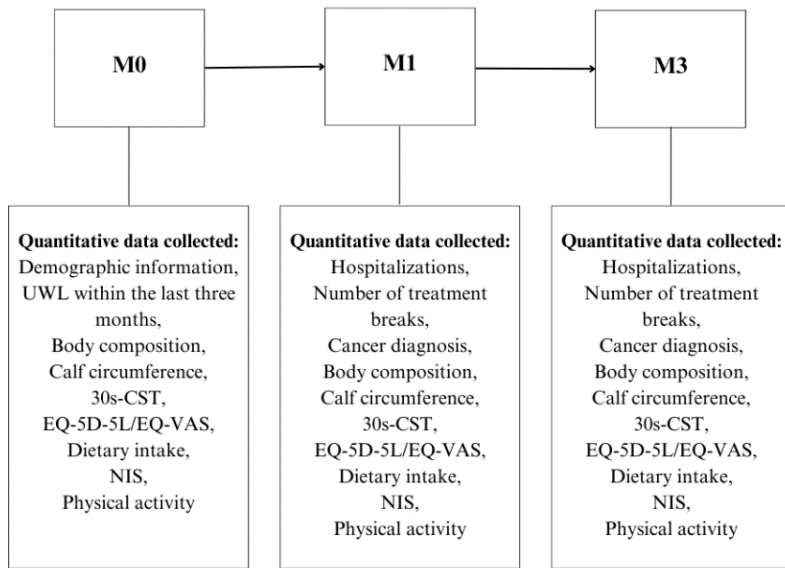
The data collection consisted of:

- A questionnaire concerning demographic and cancer and hospitalization information.
- The EnerDia app concerning dietary intake, NIS, and physical activity.
- Bioelectrical impedance analysis (BIA) concerning body composition.

- The 5-level EuroQoL-5 Domain (EQ-5D-5L) concerning HRQoL and EQ-visual analogue scale (EQ-VAS) score.
- 30 second chair-stand test (30s-CST) concerning lower body strength and power.

Data collected at the different follow-up timepoints are presented in Figure 4 and described in the following sections.

Figure 4: Data collection and follow-up period



M0: Baseline measurement, M1: Measurement after one month, M3: Measurement after three months, UWL: Unintended weight loss, 30s-CST: 30 second chair-stand-test, NIS: Nutrition impact symptoms

Demographic and cancer information

The questionnaire used to collect demographic and cancer information were developed based the questionnaire used in study I (see Appendix 5 for the questionnaire used at M0 and for the questionnaire used at M1, which have the same structure at M3).

Demographic information: The demographic information was collected at M0, and the demographic information was:

- Gender (Male, female or other)
- Age (years)

- UWL within the last three months (kg).
- Other symptoms besides UWL: Nausea and/or pain and/or worries and/or swallowing problems and/or lack of appetite and/or other
(The participant could fill in more than one answer at this question).
Co-morbidity/co-morbidities: COPD and/or diabetes and/or kidney disease and/or liver disease and/or heart problems and/or other co-morbidities and/or other
(The participant could fill in more than one answer at this question).

Cancer and hospitalization information: The cancer information was collected at M0 and M1 as well as M3 depending on how far the participants were in the investigation. The following information concerning cancer was collected, however some of the questions were only asked at M1 and M3 (see Appendix 5):

- Cancer diagnosis: yes or no. If yes, “What was the cancer diagnosis” and if no, either “Haven’t gotten that far in the investigation” or “No cancer diagnoses” or “Other illness”.
- If the participant had a cancer diagnose, the following questions were asked:
 - o Is the participant started with the cancer treatment? Yes or no. If yes, the following questions were asked:
 - Which cancer treatment gets the participant? Operation and/or radiation and/or immunotherapy and/or chemotherapy (intravenous and/or through pills and/or other)
(The participant could fill in more than one answer at this question).
 - Had the participant had any treatment breaks? Yes or no. If yes, how long was the break?
 - o Is the participant not started with the cancer treatment, but the treatment is planned? Yes or no. If yes, the following questions were asked:
 - Which cancer treatment was the participant going to have? Operation and/or radiation and/or immunotherapy and/or chemotherapy (intravenous and/or through pills and/or other)
(The participant could fill in more than one answer at this question).
- Any acute and/or planned hospitalization since last follow-up? Yes or no. If yes, “Number of acute and/or planned hospitalization” and “Number of days per hospitalization”.

Body composition and function measures

The body compositions and the function measures were performed at M0 and M1 as well as M3 depending on how far the participants were in the investigation. Body composition was measured by BIA (Inbody 270) as well as calf circumference.

BIA: Weight (kg), height (cm), MM, Body Fat Mass (BFM), percent body fat (PBF), BMI as well as segmental lean analysis were measured. Based on the measurements, FFM was calculated by $FFM = \text{Weight (kg)} - \text{BFM (kg)}$ [124]. PBF was grouped based in the limit values from Inbody 270, which were 10-20% and 18-28% for males and females respectively [125–131].

Before the measurement the participants fasted two hours, the participants had no exercise the last eight hours, and the participants had emptied the bladder maximum 30 minutes before.

The participants were not allowed to wear jewelries, watches, or belts. If possible, the participants were standing 10 minutes before the measurement. The legs and arms should not touch each other or the torso, respectively. If the participants had edema/ascites, this was noted. Only weight and height were measured, if the participants had pacemakers [132], even though the BIA has been cleared for use in this group of patients/participants, but the local guidelines has not confirmed this [133].

Calf circumference: The calf circumference was used as a second measurement of the participants' anthropometry. Calf circumference is also recommended as surrogate assessment for MM cf. phenotypic criterion within the GLIM criteria, when a direct measurement cannot be made [134,135]. Calf circumference was measured at the right calf while the participants were seated. The calf circumference were measured in different places on the calf to find the maximal calf circumference, which was included [134].

If the BMI was not within 18.5–24.9 kg/m², corrections were made. The corrections were +4 cm if BMI < 18.5 kg/m², -3 cm if BMI were 25-29 kg/m², -7 cm if BMI were 30-39 kg/m² and -12 cm if BMI ≥ 40 kg/m². Thereafter, it was possible to assess whether the participants had low calf circumference and the severity as well. Males had moderately or severely low calf circumference if the calf circumference were 34 cm and 32 cm respectively. Females had moderately or severely low calf circumference if the calf circumference were 33 cm and 31 cm respectively [134].

Lower body strength and power function: The lower body muscle strength and power function was measured by 30s-CST. The participants were encouraged to raise and sit down with the arms folded across the chest as many times as possible within 30 seconds. Only a chair and a stop watch were needed to perform the test [136,137]. If the participants needed support by had a hand at a table, this was allowed and noted. This was noted, so the participants used support at the next follow-up.

The app EnerDia

The app EnerDia was used to calculate the participants dietary intake (both energy (kcal) and protein (gram)). If the participant used the app, the last 24 hours dietary intakes, NIS and physical activity/activities were noted on a paper. If the participant

did not use the app, then the PhD student performed a 24-hour recall interview with the participant by using the app simultaneously regarding dietary intake, NIS and physical activity/activities and noted the information on a paper. The function and further information about the app see section: The app EnerDia. The 24-hour recall interview has been investigated in hospitalized patients regarding dietary intake and was found sufficiently sensitive for use in clinical practice [138]. This was considered sufficient as the method was used at all timepoints within the participant and dietary intake, NIS and physical activity/activities were neither the primary endpoint for this study. Dietary intake, NIS and physical activity/activities were monitored at M0 and M1 as well as M3 depending on how far the participants were in the investigation.

Health-related quality of life

The EQ-5D-5L questionnaire was used to measure the participants' HRQoL. This version was introduced in 2009. EQ-5D-5L consisted of five dimensions, which are mobility, self-care, usual activities, pain/discomfort and finally anxiety/depression. Each of the five dimensions consists of five problem levels, which are extreme, severe, moderate, slight and no problems [139]. When the participants have completed this part, it is possible to describe the health state with five numbers such as 11111, which indicate perfect health status. Thereafter, the participants filled-out the EQ-VAS regarding the self-related health from 0 to 100, where 0 is the worst health the participant can imagine, and 100 is the best health the participant can imagine [139]. Based on the health state such as 11111, a value, which is an expression of HRQoL, was estimated based on a Danish value set for the questionnaire EQ-5D-5L [140]. HRQoL and EQ-VAS were monitored at M0 and M1 as well as M3 depending on how far the participants were in the investigation.

5.5.3 Sampling procedures

Both the sampling of general practices and patients are explained in the following sections as well as the inclusion and exclusion criteria.

Sampling of general practices

The three criteria explained in study I were also applied in study IV regarding the sampling of general practices, but additional criteria were added:

- The practices should have one or more GPs and GPNs.
- The practices including GPs were willing to participate in the introduction to the intervention.

- Minimum one GPN should participate in the half training day.

In the feasibility study, all types of general practices were included: individual practice, multiple practice, partnership clinics and license clinic and therefore different internal organization structures were represented. Additionally, the general practices were recruited across two regions (North and Central Jutland) as well as being widely geographically located.

In total, ten general practices were recruited, where four of the practices included in the study also participated in study I, II and III. The further included general practices were recruited by advertising through phone calls, repeated newsletter to general practice and individual e-mails. The sampling techniques were snowball sampling, voluntary response sampling and purposeful sampling [89–91,100]. General practices were recruited from June 2022 to March 2023.

Sampling of patients

Consecutive sampling was used in the feasibility study concerning recruitment of relevant patients based on the inclusion and exclusion criteria (Table 3). The consecutive sampling strategy is a non-probability technique [92], as the patients were recruited by the GPs in the included general practices. The patients were recruited from 1. October 2022 to 30. June 2023.

Table 3: Inclusion and exclusion criteria in study IV

| Inclusion criteria | Exclusion criteria |
|--|---|
| - UWL of minimum two kg within the last three months. | - Lack of interest in receiving follow-up. |
| - Referred to investigation at the hospital due to suspected malignant disease. | - Not able to sign the written consent form due to other reasons i.e., mental impairment or lack of interest. |
| - Have a smartphone or tablet. | - Not able to receive nutritional guidance due to mental impairment. |
| - ≥ 18 years. | - Referred to hospice or a palliative care unit. |
| - Willing to participate in the study. | |
| - Speak Danish or had a person in the household who spoke Danish and who was willing to help (all the materials were in Danish). | |

UWL: Unintended weight loss, kg: Kilogram

The inclusion criterion was revised three months after the intervention started, and the criterion “Have a smartphone or tablet” was dropped and a new criterion was added “Referred to investigation at the hospital due to suspected malignant disease or had a cancer diagnoses one week before recruited to this study”. The criteria were revised based on the feedback from some of the included general practices, as some of the GPNs had experienced that some patients were not included, as they did not have a smartphone or tablet, but they were able to achieve the nutritional guidance and the written materials.

5.5.4 Statistical analysis

The collected data were entered and stored in REDCap. Before the data analysis, the data were double-checked, and 999 indicated missing data. Data were analyzed in STATA (version 18.0. Stata Corp, College Station, TX, USA), where descriptive statistical, normal distribution statistic, paired t-tests, Wilcoxon matched-pairs signed-rank tests were performed.

The descriptive statistics were performed either as number of filled-in replies and percent and presented as N (%), if the data were dichotomous or categorical [85]. Mean and standard deviation or median and range were performed, if data were numerical and presented as mean \pm standard deviation or median (range) [85]. Mean was performed, if data was normally distributed, while median was used, if data was not normally distributed, which was tested by using Shapiro-Wilk Test.

To investigate the difference in dietary intake, MM, PBF, weight, 30s-CST, HRQoL and VAS score from M0 to M1 and from M1 to M3, paired t-tests or Wilcoxon matched-pairs signed-rank tests were performed depending on whether data were normally distributed [85]. A significant level at 0.05 was chosen.

General practices were grouped depending on their location in city or country. BMI was grouped based on the definition from WHO [93]. No power calculation was performed for this feasibility study.

5.6 Ethics and Ethical considerations

Study I-IV were compliant to the Declaration Helsinki 2002 about medical research involving human subjects [141,142] as well as to the International Declaration on the Human Right to National Care (Vienna Declaration) signed by international clinical nutrition societies in 2022 [143]. Study I-IV were exempt from full application to the science ethical committee based on the Danish legislation, as the North Jutland regional ethic committee was approached regarding the studies. Furthermore, the data

protection agency approved study I, II and III with the registration number 2020-061, and the registration number for study IV was 2021-022.

In study I, the patients did not sign a consent form, and the patients' participation was anonymous and not related to any other health data or follow-ups. The patients got a personal ID number with the purpose to anonymize the patients, so no information could be brought back to the patients. Before the interviews in study II and III, the patients and health professionals signed a written declaration of consent. The participation in the interviews was voluntary, and the interviews were anonymized as each participant received a personal ID number.

In study IV, all included general practices signed a cooperation agreement concerning the study, confidentiality and ownership, publication, responsibility and insurance, timetable and recruitment, payment, data protection, duration of the agreement, and choice of law and court of jurisdiction before the intervention started. The cooperation agreement was developed together with the contract unit at Aalborg University Hospital. Furthermore, the patients signed a written consent form before they received nutritional guidance from the GPNs.

6.0 Summary of the results and findings

In this section, the results and findings will be presented based on the three published papers I-III and the submitted manuscript IV. Further results and findings are described in detailed in the papers I-III (Appendix 6-8 and [82–84]) and manuscript IV (Appendix 9).

6.1 Paper I: Published

The aim was to collect data regarding the prevalence nutritional risk measured by using UWL within the last two months as well as the RFI within the last week in five general practices in North Jutland. Furthermore, the aim was to investigate the relevance of UWL and RFI as initial indicator for further assessment in general practice.

The results showed that among the 1087 included patient, 14.2% and 12.9% of the patients had an UWL and RFI, respectively. Among 62% of the patients with UWL had experienced RFI, while about 69% of the patients with RFI had a UWL.

Simple logistic regressions showed that patients 18 to 39 years of age and ≥ 80 years of age (UWL: OR=1.68 [95% CI: 1.09-2.59] and OR=2.54 [95% CI: 1.48-4.38], RFI: OR=1.68 [95% CI: 1.06-2.66] and OR=2.29 [95% CI: 1.27-4.12]), underweight patients (UWL: OR=2.69 [95% CI: 1.17-6.21], RFI= OR=3.72 [95% CI: 1.60-8.66]) had significantly higher odds for experienced UWL and RFI.

Multiple logistic regressions showed that patients visiting the general practices for chronic pain (UWL: OR= 3.68 [95% CI: 1.97-6.87], RFI: OR=3.16 [95% CI: 1.70-5.90]), mental discomfort (UWL: OR=2.98 [95% CI: 1.47-6.02], RFI: OR=3.62 [95% CI: 1.85-7.08]), and suspicion of serious illness like cancer (UWL: OR=10.17 [95% CI: 4.63-22.35], RFI: OR=4.22 [95% CI: 1.95-9.14]) had significantly higher odds for experienced UWL and RFI.

In conclusion, a high prevalence of UWL and RFI was identified among adult patients in general practice. The results indicated that UWL can be relevant and feasible to use in general practice as an initial indicator for a further assessment. Therefore, further research is needing regard to investigate, whether UWL can be used in general practice as initial indicator for further assessment and nutritional treatment.

6.2 Paper II: Published

The aim was to investigate how GPs and GPNs manage malnutrition, and their perception of an early intervention targeted patients at nutritional risk in general practice. The nine GPs and 21 GPNs were recruited from the five general practices in North Jutland, which were included in paper I.

Based on the interviews, the health professionals in general practice rarely see UWL among patients, which can be used as an indicator of malnutrition, and the health professionals did not have any tradition for detect malnutrition. It is limited how much nutritional guidance the health professionals have given patients, but they do not have material and the knowledge to performed nutritional guidance.

Based on the interviews, the health professionals make suggestions for a nutritional intervention implemented in general practice target patients at nutritional risk, which could be folders or pamphlets about nutrition as well as an overview and pictures with food products. Furthermore, some of the health professionals express that an app as well as an individual approach could be an opportunity to a nutritional intervention. Furthermore, the health professionals expressed some barriers and facilitators regarding implementation of an intervention in the general practices. Some of the barriers were: lack of time and lack of education opportunities and skills among the health professionals in general practice. Some of the facilitators were: individualized intervention to the structure in each general practice and financial incentive.

In conclusion, UWL as initial indicator of malnutrition was to a low degree managed in general practice, as the GPs and GPNs rarely see patients with UWL. A nutritional intervention in general practice will be relevant based on the health professionals' statements, and they highlighted some suggestions for a nutritional intervention. In addition, barriers and facilitators were explained, which should be considered if a nutritional intervention should be implemented in general practice. Therefore, there is a need for further research regarding development and implementation of materials to an intervention targeted patients with UWL in general practice.

6.3 Paper III: Published

The aim was to identify elements necessary related to an intervention targeted patients with UWL as initial indicator of malnutrition in general practice. Based on this knowledge, recommendations to a communication strategy were presented, which could be included in the development of a complex intervention targeted patients with UWL in general practice. Both patients and health professionals were included in this study, where a second analysis were performed based on the interviews with the health professionals from paper II. All the included patients had a cancer diagnosis.

Based on the interviews with the patients, they had not received any nutritional guidance from GP regard to their UWL, only if the patients asked about it. Furthermore, some of the patients indicated, that information about the negative consequences related to UWL during a cancer course would have been lovely to receive. Both patients and health professionals point out the need of written materials related to nutritional guidance. Furthermore, the GPs express that GPNs are those who have the skills to give patients nutritional guidance in general practice, but the GPNs found they lacked sufficient education about nutrition and required little training before the start of an intervention.

Regarding the communication strategy, following recommendations should be considered regarding development and implementation of a nutritional intervention in general practice:

- ‘Strategy and preparation of health professionals’ regarding education of health professionals in the material as well as making the nutritional guidance as a fee-based task.
- ‘Means of communication’ regarding making the nutritional guidance individual and give the patients both verbal as well as written guidance.
- ‘Forms of message’ regarding approach strategy, forms of appeal as well as the use of syntax, lexis, and layout.

Based in this research, the conclusion was that there was a need for improvement in terms of handling UWL as initial indicator of malnutrition in general practice, as the patients wish to receive more information about nutrition before and during their cancer course. In addition, the recommendations can be used, when a nutritional intervention is developed and implemented in general practice, where the GPNs can give the nutritional guidance to patient with UWL after receiving training in nutrition.

6.4 Manuscript IV: Submitted

The aim was to investigate the feasibility of a complex early nutritional intervention in ten general practices targeted patients with UWL and referred to hospital due to suspected malignant disease. Furthermore, the aim was also to explore the impact of the intervention on the participants' health.

The early nutritional intervention implemented in general practice was less feasible concerning recruitment of general practices and patients. It took ten months to recruit ten general practices and the recruitment rate was 27.8%. During the nine months intervention 27 eligible participants were recruited by GPs, where the recruitment rate was unknown. In addition, during the intervention the included general practice received minimum one monthly contact from the PhD student or the main supervisor. During the intervention, all included general practices were offered a follow-up meeting. Only four accepted the offer related to the follow-up meetings.

The intervention was feasible concerning retention with a retention rate at 95.8% and in some degree feasible concerning outcomes, as only few data were missing. The reason for missing data were that some participants had telephone follow-ups due to lack of mental capacity, and therefore only self-reported weight was included.

Among the 27 eligible included participants, three participants were excluded before M0. Among the 24 participants, five had a cancer diagnosis. Overall, the intervention had a positive impact on the participants' health, as dietary intake, MM and PBF increased from M0 to M3 among two-thirds of the participants. The weight, lower strength and power, HRQoL and EQ-VAS increased among half of the participants from M0 to M3.

As described in the data collection section: Materials and measurements, data about calf circumference and information about cancer treatment as well as information about hospitalization, if the participants had any were collected. Due to lack of participants as well as participants with a cancer diagnosis, the information about hospitalization and cancer treatment make no sense to report. The data about calf circumference are not reported, as the results are not valid when comparing calf circumference and FFM index, according to the BIA measurements [2,135].

In conclusion, the early nutritional intervention implemented in general practice was likely feasible based on the recruitment of general practice and participants, even though the intervention was feasible concerning retention, and in some degree feasible concerning outcomes. The nutritional intervention had a positive impact on the participants' health. Early nutritional intervention can be implemented in general practice, but the methods concerning recruitment of both general practices and participants causes concern.

7.0 Discussion

In this section, the results and findings from the four studies will be discussed with other literature, and thereafter the methods used in the four studies will be discussed.

7.1 Discussion of the results and findings

In this thesis, the overall aim was to evaluate nutritional risk in the general practice setting. Nutritional risk was a problem in general practices and is to a low degree managed by the health professionals in general practice. Furthermore, the aim was to test the feasibility of a complex early nutritional intervention towards patients with UWL and referred to investigation at the hospital due to suspected malignant disease. The intervention was less feasible related to the recruitment of general practice and patients, but feasible concerning retention and in some degree feasible concerning outcomes. Furthermore, the intervention had a positive impact on the participants health, since the participants' dietary intake, MM and PBF was improved among two-thirds of the participants, and the weight, lower strength and power, HRQoL and EQ-VAS were increased among half of the participants. Based on the results, it is relevant with early nutritional interventions in general practice, but some improvements are required.

In this thesis, the MRC framework and pragmatism were used throughout the study, and they complemented each other. The MRC framework was used during the development and evaluation of the early nutritional intervention, while pragmatism was used in the selection of methods. By using pragmatism, the methods were chosen with the aim to give the best solution of the problem, which was identified continuously during the development phase. Another framework and scientific theoretical orientation could have been used, which could have affected the studies, the chosen methods as well as the results and findings.

7.1.1 The prevalence of nutritional risk

In study I, 14.2% were at nutritional risk based on an UWL with a median weight loss at 4 kg. The prevalence is slightly lower compared to the prevalence of nutritional risk in two other Danish studies [60,61]. However, the patients included in the two other Danish studies were older, as they included patients were above 65 and 70 years of age respectively [60,61]. This can explain the slightly higher prevalence, as the older patients in study I had higher risk of having an UWL and therefore being at nutritional risk [82]. However, in the study I patients between 18-39 years of age had also higher risk of experience UWL and being in nutritional risk [82]. When comparing the

prevalence of nutritional risk with international studies, the prevalence ranges from 2.2% to 83.0% [51–54,57–59]. The different prevalence of nutritional risk can be explained by using different screening tools, the patients' age as well as other diseases [23,55,58]. In study I, patients with low BMI and chronic pain had higher risk of UWL and therefore being at nutritional risk [82]. This are supported by other studies [57,59], however other studies found that patients at nutritional risk had poor family function, feeling loneliness, having limitations regarding mobility as well as poor self-rated health [59,144]. A study from Czechia found that higher BMI among the older patients the higher MNA score and therefore better nutritional status [55]. Most of the aforementioned studies investigated nutritional risk among older adults above 65 years of age, and none had found that younger had higher risk of nutritional risk or malnutrition like in the study I.

In study I, a UWL at minimum one kg within the last two months were chosen [82]. Based on the Danish Health Authority, an UWL at minimum one kg should be considered as nutritional risk among patients and should be investigated further [87,88]. However, in the new recommendations an UWL at 2-3 kg within the last three months or two kg within the last two months can be more relevant [3]. It can be discussed whether the one kg in study I was too low, as it can lead to too many false positives, because there may be some who were included, whose weight fluctuates from day to day by ± 1 kg. In the GLIM criteria, a weight loss at $>5\%$ within past six months or $>10\%$ beyond six months are used as a phenotypic criterion related to diagnosing malnutrition [2]. If another weight loss criterion was used in study I, it may also have had an impact on the patient groups with higher and lower risk of experiences UWL. This could have an impact on the chosen target group in study IV, as there could be another patient group, which had higher risk of experienced UWL. However, the patient group that visit general practice due to suspicion of serious illness had an unadjusted OR at 8.72 and adjusted OR at 10.17 [82], so this may not change the fact, that this group will have higher risk of experience UWL. In addition, a study concluded that patients with an UWL registered at their GPs had increased risk of some types of cancer within the following three months. The study also found that there was an association between UWL and cancer at late-stage, however some associations between UWL and cancer at stage II and III were also found [145]. This indicate that the change of weight loss criterion may not have had an impact on the targeted group in study IV, since an early UWL is associated with cancer.

Furthermore, some of the validated screening tool use weight loss as one of the elements. MUST, MNA and NRS-2002 use a $\geq 5\%$ weight loss within the last three to six months, a three kg weight loss within the last month and $>5\%$ weight loss within the last three months, respectively [23]. However, it can be argued that any UWL should be taken seriously, as it has been shown that any weight loss has a negative impact on survival among cancer patients [69]. Therefore, it can be necessary to take any weight loss seriously and preferably early if the patients ended with a cancer diagnoses. Another Danish study have also used a minimum one kg UWL like in the study I [61], which support the use of an one kg UWL. However, it can be interesting

to investigate the use of other limit values and compare, if these can have an impact on the patient groups targeted any nutritional interventions in general practice in the further.

7.1.2 Health professionals' perspective on malnutrition and nutritional risk

In study II, the health professionals expressed that patients with UWL are rarely seen in general practice, and they did not use systematic detection of UWL as an indicator of malnutrition [83]. Other studies have found almost the same, as health professionals find it difficult to identify malnutrition at the first meeting with the patient and that malnutrition is second concern among GPs [63,64,99]. This may be due the fact that overweight and obesity has become a much common problem in general practice including Denmark [16,63].

Based on the findings from study II, UWL is something the health professionals did not have focus on except if it is in front of the health professionals' eyes. This could be if a patient had a major and directly visible weight loss, thin patients or if the patients have other symptoms [83]. This is also found in a study from England, however the study also found that timely identification among patients at low risk need some improvements [99]. Other studies have found that self-reported or documented UWL, cognitive problems, self-reported exhaustion, self-neglect or recurrent falls were factors that could cause suspicion among the GPs concerning malnutrition [99,146]. A solution to increase the awareness of UWL as an initial indicator of malnutrition could be, if the patients measured their weight in the waiting room before a consultation with GPs and GPNs, so the health professionals can follow the development of the weight [99].

In study II and III, the health professionals highlighted the need for more education and they need to improve their skills in providing nutritional guidance [83,84]. Other studies have found that health professionals in general practice need training and knowledge about nutrition and screening tools [63,64,99,147–151]. This can be explained due to the inadequate nutrition education during medical and nursing school. This has been found in different studies, and the medical students have also expressed that they think nutrition is important, but the education in nutrition is not sufficient [152–154]. If it is not possible to have more nutrition education during the GPs medical school, then an opportunity is to have post-graduate education concerning nutrition for the GPs. A study from Ireland investigated the implementation of a nutrition education programme to GPs as well as a referral pathway to the community dietetics service. The intervention resulted in more patients screened for nutritional risk, ONS prescriptions were more targeted patients, and a good proportion of the patients were referred to the dietetics service [155]. The education of the GPs in the study from Ireland reminds of the teaching day provided in study IV, however this was only

aimed at GPNs. Based on the study from Ireland, it indicates that more education to GPs and referral opportunities can improve the detection of patients at nutritional risk as well as increase the knowledge about opportunities to manage the problem.

Concerning the lack of knowledge about nutritional risk among health professionals in general practice, a study from England found that if a GP identified a patient with weight loss, the patient was referred to a dietitian, as the GP did not know what else to do due to lack of knowledge [99]. In Denmark, not all general practice and municipalities have the opportunity to refer the patients to a dietitian, which was also something the health professionals expressed in study II [83]. This indicates that the health professionals need more information and education in giving nutritional guidance in general practice, since only few general practices can use a dietitian. Another option is to have a dietitian in general practice, and then the GPs and GPNs can refer the patients to the dietitian. This has been investigated in a study implemented in UK, and the study showed that a dietitian in general practice improved the patients' strength, nutrition status and frailty [156].

In study II and III, the health professionals expressed the need to consider the patients' socioeconomic status and provide individualized nutritional guidance and interventions [83,84]. This is also recommended in the ESPEN guidelines and from the Danish Health Authority [1]. Furthermore, the health professionals also expressed that some patients enjoy an easy weight loss [83,84], however the patients in study III express that they did not like losing the control related to the weight loss [84]. Other studies have found that patients can have some attitudes to nutrition and can have been misled by health eating messages from the environment [99,148,149]. Some older adults can also be unaware about the consequences of UWL and think that a decrease in nutritional status (both weight loss and lack of appetite) is a normal part of being old or did not recognize it as a problem [157–159]. However, older patients express, that they would value advice from their GPs or GPNs, a dietitian or some other professionals that were trained [159]. The findings about the patients' thoughts about nutrition and UWL can make it difficult to change the patients' mindset from health eating to eat what you want also unhealthy food.

The financial perspective has been found as a barrier for handling patients with UWL as an initial indicator of malnutrition in study II and III as well as in other studies [83,84,99,148]. This highlights the need for organizational changes in primary care if general practice should be motivated to screen and treat citizens and patients with UWL and therefore being in nutritional risk.

In study II, the GPs' and GPNs' time was highlighted as an issue related to implementation of nutritional intervention in general practice [83]. This is supported by a study from Germany, as they found that almost two-thirds of the GPs could see themselves as the primary person to talk about nutrition and physical activity among cancer patients, but they did not have time to perform these talks [151]. Other studies have also found that short appointment times as well as an overwhelming workload were challenges

related to address and manage malnutrition in general practice [64,99,148–150,157]. This indicates that the time in general practice is a structural problem, which should be considered in further studies.

The patients in study III express that they had been worried about the UWL and they would like to have received information about the negative consequences associated with UWL [84]. Two studies from Germany investigated the timing for providing nutritional information among cancer patients. The first study found that 40% of the GPs indicated, that information about nutrition and physical activity could happen at diagnosis time, however almost 80% indicated that the best time was during rehabilitation among cancer patients [151]. The second study found that most of the patients with cancer indicated that they had received information about nutrition and physical activity in an outpatient oncology clinic or in a rehabilitation clinic. Most of the patients had received the information about nutrition and physical activity after initial treatment. They also concluded that the patients could have received information about the importance of nutrition and physical activity earlier on in the treatment [160]. An early intervention can be relevant to investigate, as it can be difficult to improve dietary intake and physical activity after adaptation to less efforts [17,18]. Other studies have also found that the negative consequences are proportional with weight loss [69,70]. Therefore, the development and investigating the feasibility of an early intervention concerning nutrition and physical activity may be more relevant compared to starting with guidance in the rehabilitation setting.

7.1.3 Feasibility of nutritional intervention in general practice

This early nutritional intervention was less feasible concerning recruitment of general practice. It took ten months to recruit the ten included general practices. Some of the explanations for not participating in the study was lack of resources, lack of interest and about 60% did not respond at all. A study concerning oral nutritional supplements in a community setting had a higher recruitment rate (59%). However, some of the reasons to not participate were: were too busy, concerns about the time that demand on the other health professionals in the practice as well as did not find nutritional support as being an important issue among their patients [161]. A study about barriers for not participating in community-based studies found, that lack of time, lack of resources like staff, if the GPs had been part of previous research that was found irrelevant as well as fear of evaluation were some of the barriers [162]. This may indicate that general practice can be a difficult place to implement nutritional interventions.

A Danish study has investigated Solberg's framework concerning recruitment of medical groups for research, which includes seven R-factors [163,164]. The seven R's are: relationships, reputation, requirements, rewards, reciprocity, resolution, and respect [164]. The Danish study investigated the feasibility of the framework in relation to the recruitment of general practices for a study which aims to investigate the implementation of low back guidelines. The study concluded that the framework was

feasible to use during their recruitment process [163]. The seven R-factors in Solberg's framework could have been used more systematic already in the development phase of the intervention in this thesis, so we could have been more aware of the requirements of the participating general practices as well as the rewards in the invitations. This could have had a positive impact, so the recruitment process of the general practices had been easier in study IV. Other studies have investigated other factors that can help concerning recruitment of general practices, which can be to identify key decision markers, identify how the individual practices work, use an individual approach to each GPs, streamline the research process so it makes minimal disruption in the practice, incentives, obtain contact information and perform relevant research [162,165–168]. However, it can be discussed how viable a very individual approach is in the Danish healthcare system. If all need to do it individually and use a lot of time adapting new interventions to the individual practice, what should the nationally and internationally recommendations be used for, if all practices still do it differently. However, some individual approaches can be used, but a very individual approach can be difficult. Even though some of the aforementioned factors were included in study IV like incentives to participate as well as identifying key decision markers, some of the other factors could have been considered. A study found that participation rates to community-based health services research were between 2.5-91.0%, and personal contact as well as friendship network were useful during the recruitment of physicians. Furthermore, the study found that modest incentives did not influence the rate of participation [169]. In study IV, snowball sampling was used, as some of the supervisors knew GPs in the included general practices, but some of the practices that were contacted refused despite of the relation between the supervisor and the GPs. Concerning incentives, each general practices received financial compensation for participate in study IV as well as per included patient. The financial compensation was neither too high nor modest. In addition, a study found that sending mails to the individual GPs was the method with the lowest response rate and the method was also cumbersome [166]. This can explain the poor recruitment rate, as most of the practices were contacted through mail, although both common mail and safe mail was used, and phone calls were made to the clinics to inform about the e-mails, when no response came. However, it was the only way to contact them directly, but all practices had received newsletters about the study from NordKap.

This early nutritional intervention was less feasible concerning recruitment of patients. The group of patients included in study IV were chosen based on the results from study I, as patients who suspected a serious illness had significantly higher risk of having experienced UWL and therefore being at nutritional risk [82]. Since the GPs had difficulty recruiting patients, it may indicate that the target group should have been different or perhaps other patient groups should have been included as well. A possibility could be patients with chronic pain and mental discomfort, who also had higher odds for experiencing UWL in study I [82]. This can also be supported by the recommendations from Danish Health Authority, as all patients with UWL at one kg or more should obtain increased focus on detecting the reason that cause UWL [3]. A

study from Australia investigated the implementation of MNA-SF in general practice among ≥ 75 years old patients. Most of the health professionals found MNA-SF useful and they had easier to make decisions regarding the patients' nutritional status and further treatment. However some health professionals expressed, that it could help if MNA-SF was implemented in their health assessment software [52]. Related to study IV, this may have had an impact on the recruitment of patients, if the inclusion and exclusion criteria were incorporated in the general practices' software. However, this would be more elaborate to do related to time and financial. Therefore, further studies can investigate an early nutritional intervention towards another and larger group of patients in general practice, if general practices are willing to participate.

Concerning the not sufficient recruitment of patients, another explanation can also be the patients. The patients could decline to participate in the intervention and therefore also to receive nutritional guidance when they were referred to the hospital due to suspected malignant disease. This can both be explained by the patients' health literacy but also the patient-centered communication from the GPs, which were some of the concepts used in study III [84]. If the GPs did not inform the patients with the necessary information, then the patients will not have the opportunity to take the right decisions related to their lives and health. However, the intervention can also be too much for the patients as they may not understand the information from the GPs due to their health literacy. However, the term health literacy and patient-centered communication were some of the concepts considered during the development of recommendations in study III as well as in the development of the nutritional intervention [84]. A study found that their eHealth intervention implemented in general practice was difficult and suited patients with high socio-economic status as well as the proportion of patients participating had a healthy lifestyle [170]. This problem should not have been in study IV, as the nutritional guidance should be possible to individualize, so the patients' health literacy was considered. A study found that many of the included patients with cardiovascular disease did not understand the purpose as well as benefits and harms related to the medication even though they were informed [171]. This can be related to the patients that decline to participant in study IV, as even though the patients were informed about the intervention, they may not understand the purpose or thus the advantage of being involved in the study. Many things can affect whether a patient sign the written consent form in study IV, however the patients had the opportunity to take the consent form home and read it again before they possibly signed it. The forementioned study also found, that the patients valued more patient-centered communication than active involvement related to the medication [171]. In study IV, attempts were made to facilitate patient-centered communication between the health professionals and patients during the introduction and nutritional guidance based on the findings from study III [84]. However, it was not possible not to involve the patients completely in study IV due to the consent form. This is a different scenario compared to the situation when the health professionals order medication to patients. Further studies can have more focus on the communication between the patients/participants and the health professionals, as this may have an impact as well.

The early nutritional intervention was feasible concerning retention, as the retention rate was 95.8%. The high retention rate can indicate that the intervention was adapted to the participants' empowerment and health literacy, as the GPNs have adapted the amount of information and material to the individual participant in the patient-centered communication. This may indicate that the health professionals have used some of the elements in the communication strategy from study III [84]. Therefore, the participants' motivation increased regard to prevent further weight loss, and they stayed in the intervention. This was however not investigated in study IV.

The intervention in study IV was in some degree feasible concerning outcomes due to the little amount of missing data. Few of the participants found it difficult to complete all questions in the EQ-5D-5L questionnaire, and few of the participants could not perform the 30s-CST, as they recently had a surgery. Another questionnaire to assess the participants' HRQoL could be considered in further studies. It can be EORTC core quality of life questionnaire 30-item (EORTC QLQ-C30), which is targeted cancer patients [172], or WHO Quality of life (WHOQOL) as well as 12-item short-form health survey (SF-12), which are both generic questionnaires [173–175]. However, the problem with EQ-5D-5L was that the participants with a cancer diagnosis found it difficult to assess their health, since they just had got the cancer diagnosis. The participants with cancer were sad and did not know whether they need further investigations at the hospital or what kind of treatment they should have. This will probably be the same problem with the other questionnaires (EORTC-QLQ-C30, WHOQOL, SF-12).

In the study IV, other tests could have been performed to measure the participants strength like for instance hand grip strength or time up-and-go. A study had used the hand grip strength test in general practice among patients from 18 to 74 years of age with the aim to assess muscle strength. In the study, they found that hand grip strength test was easy to use in general practice [56]. Therefore, hand grip strength could have been used in study IV, when the participants could not perform the other physical tests. Time up-and-go could also have been used, which is also recommended by the Danish Health Authority, however it is normally used among elderly related to their mobility [3]. So different test could have been used in study IV, however the choice of test depends on the aim of the study. In study IV, the early intervention included both nutritional guidance as well as information about the importance of staying physically active. Furthermore, the aim with the intervention was to have an intervention with measurements that were the same among all participants, but ideally the measurement method should be chosen based on what suited the individual participant.

7.2 Methodological considerations

Related to the quantitative methods, the terms internal validity, external validity and reliability are discussed, while the terms credibility, transferability and dependability are discussed related to the qualitative methods.

Internal validity concerns whether the used methods and materials examine what was intended [176]. External validity concerns whether the results can be generalized to other contexts [176]. Reliability concern whether the results can be reproduced [176]. To assess the quality of the qualitative methods, different terms can be used [81,177,178]. However, credibility, transferability and dependability were chosen in this study [179–181]. Credibility concerns the truth value, which means to evaluate whether the data fits to the informants' views. Transferability concerns applicability, which means whether the findings can be transferable to another/other setting(s). Dependability concerns consistency, which means, to evaluate whether the process is logical, clearly documented related to the used methods as well as the decisions made during the research process by the researchers [179–181].

7.2.1 Study I

Internal validity

The used questionnaire was qualified among the health professionals in the general practice setting. This may affect the internal validity, as the patients could possibly have had different understandings of the questions in relation to what the aim was. This was sought avoided by the researchers being present and presenting the questionnaire and aim to the participants, instead of letting the secretaries in the practices hand out the questionnaires to their patients. Furthermore, the researchers could also help the patients fill out the questionnaire or answer possible questions. With regard to the questionnaire, it was developed and inspired by literature and another questionnaire used in the outpatient settings [39–41]. This have a positive impact in the internal validity, as the other questionnaire had been used and tested among patients. The UWL was measured as an UWL of at least one kg within the last two months, according to the recommendations [87,88], while intended weight loss was without a time interval, which can affect the internal validity, but this will not affect the prevalence of UWL in the study. Furthermore, there are no recommendations for the assessment time for voluntary weight loss. In addition, some patients got help from the investigators/PhD student, which can affect the patients' answers. Some patients may not be completely honest about why they visit general practice as well as their weight if they had their weight measured on the same day at home and thus not be weighed in general practice. The same considerations could be applied regarding measurements of height, where the participants could give a biased information if they did not like to be measured in general practice. The data collected in the study are all self-reported data, and

therefore it is not possible to examine whether the answers were true, as it was not possible or attempted to get access to the patients' medical journals. The answers can thus be affected by recall bias, which may have had a negative impact on the internal validity.

Only few missing data were observed, which indicate that the questionnaire was developed in a way, so it did not cause confusion among patients, which increase the internal validity. Data were not collected among the patients who chose not to participate in the study. Therefore, it was not possible to perform a dropout analysis among these patients, which may have affected the internal validity due to selection bias.

This study was a cross-sectional study, which means that it is not possible to investigate causality but only associations [85]. Therefore, it is not possible to investigate, whether the UWL can be caused by another exposure than the reason/reasons for visiting the general practice. It is only possible to investigate the associations like some patient groups had higher risk of experience UWL compared to other patient groups.

External validity

It was possible to collect data from 1087 patients from five general practices, which have a positive impact on the external validity. Furthermore, the five general practices had different internal organizations and were in both city and country, and therefore the generalizability to other settings was strengthened. The data collection was performed for four days in each general practice, which increase the representativity og generalizability to the general Danish population. However, some patients were excluded as they were not willing to disclose the weight. It was the subjective impression of the researchers that those who did not want to participate were primarily female overweight patients. This can have an impact on the external validity and therefore the generalizability. However, this was not measured.

Reliability

The data were collected by two investigators and the PhD student, which all had experience with collecting data among inpatients, outpatients, and citizens in the community, which increased the reliability in the study.

7.2.2 Study II and study III

Credibility

During the interviews, some of the GPNs spoke hypothetically during the interviews, since they found they never had experienced patients with UWL as indicator of malnutrition, which can affect the credibility negatively. However, the health professionals had participated in study I, so the results from the study were included and discussed during the interviews, which helped the health professionals to think of possible cases, interventions and improvements related to implement an intervention in general practice targeted patients at nutritional risk. This has a positive impact on the credibility, as the highlighted suggestions were some they could see be implemented in their general practices.

Before the interviews were performed in study II and III, the interview guides were tested and validated. This increases the credibility of the data collected in the studies, as the health professionals and patients understood the questions. During the interviews in study II and III, follow-up questions were included, which also increases the credibility of the data. In study II, the PhD student performed the transcription, condensation, coding, and themes of the interviews. Thereafter, the codes, themes and the interpretation of the findings were discussed with all the co-authors. In study III, the interpretive thematic analysis was performed by the first two authors, and the interpretations were discussed with all the co-authors thereafter. To increase the credibility in both study II and III, the analyses should be performed by all the authors, but this was not possible due to lack of time. In study III, a secondary analysis was performed based in the health professionals' interviews. This can lead to a risk of insufficient data since the original aim was something different compared to the aim in study III. This may have a negative impact in the credibility of the findings.

The findings in study II were presented to the health professionals with the aim to increase the credibility, so the findings were true to their own impression, however none of the health professionals had anything to add.

In study II and III, no goals were set related to the number of informants. During the last interviews with the GPs and GPNs as well as the patients, no new topics occurred, so data saturation was achieved. However, to increase the credibility study aim, sample specificity, established theory, quality of dialogue and analysis strategy could have been used to assess and increase the information power and thereby how many informants should have been included in study II and III [182].

The aim in study II was neither narrow nor broad, and therefore the number of included informants was found appropriate. The sample in study II was specific, as the aim was to investigate GPs' and GPNs' perspective about malnutrition, however, the health professionals had different years of experiences in general practice. In study II, no theory was established during the analysis, which means that a larger sample would have been needed compared to if a theory had been established. However, the findings

were discussed with other literature in the discussion, which may compensate for the lack of theory. Minimum two interviewers/moderators participated in study II with the aim to be sure that all the questions were asked before the interviews were ended, which had a positive impact on the quality of the dialogue. Therefore, the sample size can be smaller if the dialogue were strong [182]. Furthermore, the interviewers/moderators were experienced with performing interviews with different groups of informants, which also makes the quality of the dialogue stronger. The analysis strategy in study II was case analysis and not cross-case analysis. A case analysis requires a smaller sample [182], and in that respect the sample size was fine. Overall, the information power was good in study II with the health professionals based on the above discussion.

In relation to study III, the aim was broad. Concerning patients' interviews, more patients should probably have been included, as the aim was all patients with an early UWL, which makes the aim broad. The patients in study III were specific, but the aim was targeting a more limited specificity. Therefore, the sample should probably have been larger. It remains unknown whether adding further participants would have added to the data, however maybe adding participants at other stages of disease and by recruitment in other settings may have added to the data. In study III, theories were established in the analysis of the data, which compensates for the fact that the sample was small. Minimum two interviewers participated in the interviews with the patients, which had a positive impact on the quality of the dialogue. The analysis strategy in study III was case analysis and not cross-case analysis. The aim was broad in study III, and therefore there was a need for a larger sample, however all the patients had a cancer diagnosis, and therefore the information power was fine related to cancer patients' experiences with early UWL in general practice. However, the information power was poor related to patients in general with an early UWL in general practice, but in study III the health professionals' interviews were also included. This improved the information power.

Transferability

To increase the transferability, demographic information related to the health professionals and patients are presented in the two studies [83,84]. The health professionals in study II had different years of experience in general practice, and different organizational structures in general practices were represented. This increases the transferability to other health professionals in other general practices. The included patients in study III had all a cancer diagnosis, which affects the transferability to other patient group. However, by including both patients and health professionals the finding may be transferable to use in general practice, as most of the recommendations were general and not cancer specific.

Dependability

The process in study II and III are well documented related to the data collection and analysis in the method sections. Furthermore, in study II a table illustrated the theme, main categories and subcategories identified during the analysis, which increases the dependability. In study III, the findings from the analysis were also illustrated in a figure with the elements in the communication strategy, which affects the dependability positively.

7.2.3 Study IV***Internal validity***

The data collected in the study were self-reported data as well as physical measurements. Self-reported data might have a negative impact on the internal validity, as it is not possible to examine whether the participants gave the right information related to EQ-5D-5L as well as information about cancer diagnosis and co-morbidities. It was not possible or intended to access the participants' medical journals, as the aim was to test the feasibility of a nutritional intervention rather than diagnosis or disease severity. While all the self-reported data may be affected by recall bias, the EQ-5D-5L is a thoroughly validated instrument with good Cronbach's alpha properties in a vulnerable but different population [183]. Concerning the BIA measurements, the participants were asked to fast two hours before the measurement as well as perform no physical activity eight hours before. The laboratory guideline from our center, fasting is recommended for four hours, regardless of whether the BIA is used for research or clinical work. For this study fasting was reduced to two hours, aiming at increasing the chance that participants were able to be compliant to the procedure. It was not possible to examine, whether the participants were complied with this, which may affect the internal validity. However, a recent study found that having breakfast rather than full fasting had no influence on the BIA results and recommended to remove the fasting procedures from the guidance [184]. The internal validity was strengthened, as only the PhD student and one of the co-authors performed the follow ups, and both were introduced to the measurements and questionnaires before the follow-ups. This was done to minimize errors, as measurements performed in the same way increase internal validity.

It was not possible to perform any dropout analysis, as only one participant dropped out during the intervention. However, three participants were excluded before the first measurement. These could have been included in a possible dropout analysis, but there was no information on these patients that could be used.

This study was a feasibility study with a cohort study design, but it was not possible to conclude, if the participants would have improved their dietary intake anyway

regardless of the early nutritional intervention, as there was no control group to compare with. However, this was the secondary aim of this study, as the primary aim was to investigate the feasibility of the intervention, as this is one of the phases in the MRC framework, and therefore a control group was not relevant.

External validity

The external validity was strengthened, as the included participants were distributed between city and country. Unfortunately, not all included general practices recruited patients, which may indicate, that this kind of intervention cannot be implemented and therefore generalized to all general practices. During the nine months intervention, only 27 patients were recruited from eight general practices. This affect the study's external validity, as it is not possible to generalize the results to the Danish population with an early UWL and referred to investigation at the hospital due to suspected malignant disease. However, most of the participants ended with no cancer diagnosis and still had improvement of dietary intake among others. This may indicate that this intervention can have a positive impact among other patient groups in general practice with UWL and other symptoms of disease.

Reliability

Data were collected by the PhD student and the main supervisor. Both had previous experience with collecting data among patients, which may have had an impact on the low dropout as well as missing data during the intervention. This strengthened the reliability of the study. However, even though the general practice had given procedures, support material and training for recruitment and guidance, it is not possible to know how the recruitment and guidance sessions were performed in the ten very different practices. Although different handling of these procedures may impair reliability, this is the realistic picture of the circumstances of an intervention in real practice that the feasibility study intended to investigate.

8.0 Conclusion

The overall aim of the thesis was to evaluate nutritional risk in the general practice setting as well as to test the feasibility of a relevant complex early intervention towards nutritional risk in a group of relevant patients.

Study I showed that the prevalence of nutritional risk measured by UWL and RFI was a common problem among adult patients in five general practices in North Jutland. Patients visiting general practice due to chronic pain, mental discomfort and suspicion of serious illness had higher odds of experienced UWL as well as RFI. In addition, UWL can be used as a relevant and feasible initial indicator for further assessment in general practice.

Study II showed that UWL as indicator of malnutrition were to a low degree managed in general practice, as the health professionals found they rarely see patients with UWL, and they did not have any tradition for detecting malnutrition. An early nutritional intervention may be relevant to implement in general practice, where GPs and GPNs found that GPNs could perform the nutritional guidance to the patients. However, possible facilitators and barriers must be considered before the development and implementation of an early nutritional intervention in general practice.

In study III the patients indicated that they did not receive any nutritional guidance concerning their initial UWL, when they had visited general practice. Most patients would have liked to receive nutritional guidance as well as information about negative consequences regarding UWL. Based on the interviews with the patients and the health professionals, recommendations were established related to a communication strategy. The recommendations can be used in the development of an intervention. The recommendations were: Strategy and preparation of health professionals (e.g., education), means of communication (e.g., individual guidance) and forms of message (e.g., approach strategy).

Study IV showed that an early nutritional intervention was less feasible concerning recruitment of general practice (recruitment rate: 27.8%) and patients (recruitment rate: unknown), however feasible concerning retention (retention rate: 95.8%) and in some degree feasible concerning outcomes (few missing data). Furthermore, the intervention had a positive impact on the participants' health concerning an increase in energy and protein intake as well as MM and PBF among two-thirds of the participants from M0 to M3 after inclusion.

9.0 Perspectives and implications for future research and practice

Based on the results from study I, nutritional risk measured by UWL is a problem in general practice, however UWL is only to a low degree handled in general practice. Therefore, further interventions are needed with the aim to detect patients at nutritional risk by using UWL more systematic as well as to handle nutritional risk. The early nutritional intervention in study IV was aimed to handle patients at nutritional risk and suspected a malignant disease. Based on the findings from study II and III, the health professionals found the early nutritional intervention relevant or possible to implement in general practice, if the highlighted suggestions, facilitators, and barriers were taken into consideration. Almost all suggestions (written material like overview with pictures and folders, introducing an app, individual approach, and follow-ups) were included in the development of the intervention. Furthermore, manageable facilitators and barriers were taken into consideration in the development of the intervention. Therefore, the expectation was that the early nutritional intervention in general practice would be feasible and have a positive impact on the included participants' health. However, the reality was different, as the intervention was less feasible concerning the recruitment of general practices or patients. Therefore, a qualitative study is necessary to investigate the health professionals' perception and experiences with recruiting patients and performing the nutritional guidance in study IV. Based on the interviews, a process evaluation can be performed with the aim of investigating the relationship between implementation, mechanisms and context related to the early nutritional intervention [185]. The process evaluation should help to identify whether the problems with the recruitment were due to internal activities in the study, structural factors in general practice or other things. The findings from the process evaluation can be included in implementation of further nutritional interventions in general practice targeted other patient groups with an UWL and not only patients with suspected malignant disease. Perhaps just as important, the findings can be used in the actual implementation of the recommendations from the Danish Health Authority related to the detection of patients at nutritional risk and management of nutritional risk in general practice [3]. The recommendations from the Danish Health Authority are meant to ensure good nutritional status among citizens/patients, which is prerequisite for good outcomes related to the patients' treatment both at the hospital and in general practice. In the "Vision for general practice in 2030", general practice is going to have a far greater role in relation to the disease treatment in the Danish society [186]. However, nutritional risk or nutrition is not expressed in the "Vision for general practice in 2030". Since nutritional risk and nutrition are not expressed in the vision for general practice, it may be difficult to implement in general practice, which also can explain some of the challenges in study IV.

10.0 References

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11.0 Appendix

Appendix 1: Questionnaire used in study I

Appendix 2: Interview guide used to health professionals

Appendix 3: Interview guide used to patients

Appendix 4: Written material to general practitioners and general practice nurses

Appendix 5: Questionnaires used in study IV

Appendix 6: Papers I

Appendix 7: Papers II

Appendix 8: Papers III

Appendix 9: Manuscript IV

Appendix 1: Questionnaire used in study I

Til patienter hos praktiserende læge

Almen praksis: _____

Kære Patient

I dette projekt undersøger vi forekomsten af ikke planlagt vægttab blandt patienter som henvender sig hos praktiserende læge. Undersøgelsen laves af forskere ved Aalborg Universitetshospital i samarbejde med din og 4 andre lægepraksis i Nordjylland. Formålet er at få viden om hvorvidt der brug for en øget indsats omkring uplanlagt vægttab hos praktiserende læge.

Vi håber at du, uanset din vægt og om du har vægttab eller ej, vil hjælpe med at svare på spørgsmålene, og få målt din vægt og højde idag. Dine svar vil ikke kunne spores tilbage til dig.

1. Baggrundsspørgsmål:

Køn Mand Kvinde Andet

Alder _____år. Vægt i dag: _____kg. Højde: _____cm.

2. Dit besøg i lægehuset i dag er til (sæt evt. flere kryds):

Lægen Sygeplejersken Blodprøver

3. Årsag til dit besøg i lægehuset idag (sæt evt. flere kryds):

| | | | |
|---|--------------------------|--------------------------------|--------------------------|
| Nyopstået sygdom | <input type="checkbox"/> | Træthed | <input type="checkbox"/> |
| Nytilkommet skade | <input type="checkbox"/> | Mistanke om alvorlig sygdom | <input type="checkbox"/> |
| Opfølgning på kronisk fysisk sygdom (f.eks årskontrol) | <input type="checkbox"/> | Hudproblemer og sår | <input type="checkbox"/> |
| Smerter | <input type="checkbox"/> | Graviditetsundersøgelse | <input type="checkbox"/> |
| - Hvis ja til smerter, er de: Kroniske <input type="checkbox"/> Nyopståede <input type="checkbox"/> | | Sundhedstjek | <input type="checkbox"/> |
| Besøg for receptfornyelse | <input type="checkbox"/> | Lægeerklæring (f.eks kørekort) | <input type="checkbox"/> |
| Virus/Influenzasymptomer | <input type="checkbox"/> | Vaccination | <input type="checkbox"/> |
| Psykisk ubehag (Angst/depression el. også kontrol) | <input type="checkbox"/> | Andet (udfyld): | <input type="checkbox"/> |

4. Spørgsmål om vægttab og ernæring:

Har du haft et uplanlagt vægttab indenfor de seneste 2 måneder:

Ja Nej - Hvis ja, hvor mange kilo har du tabt dig: _____kg.

Har du spist mindre end du plejer indenfor den seneste uge?

Ja Nej

Du har tabt dig, men det er med vilje (slankekur) (sæt kryds hvis ja)

- Hvis ja, hvor mange kilo har du tabt dig: _____kg.

5. Hvis ja til spørgsmål 4 (uplanlagt vægttab eller spist mindre), bedes du sætte kryds ved de af nedenstående faktorer, som er relevant for dig, og som kan have medvirket til at du har spist mindre (sæt evt. flere kryds):

Kvalme Smerter Bekymringer Tygge/synkebesvær Nedsat appetit
Forstoppelse Manglet hjælp til madlavning eller indkøb Manglet lyst, fordi jeg skal spise alene

Mange tak for hjælpen

Appendix 2: Interview guide used to health professionals

Interviewguide til læger/sygeplejersker:

Briefing:

Hvem er vi?

- Mette: forskningsleder for Klinisk Ernæring og projektansvarlig.
- Sabina: projektmedarbejder på projektet.

Som du (I) nok ved er vi i gang med en undersøgelse af sygdomsrelateret underernæring målt ved uplanlagt vægttab i almen praksis. Indtil videre har vi samlet data ind med vores vægt og spørgeskema i fem klinikker herunder jeres.

Udover de kvalitative data skal vi interviewe sundhedsfaglige, altså jer, og senere patienter som har haft et uplanlagt vægttab. Dem finder vi på hospitalet.

Formål med interviewet: at undersøge mulighederne for at indføre en tidlig indsats mod uplanlagt vægttab i AP, herunder

- At afklare hvilke ressourcer, der er nødvendige for, at I almen praksis kan optimere handlekapaiciteten hos patienter med risiko for sygdomsrelateret underernæring, som skal henvises til videre udredning/behandling.
- Vi ønsker at få jeres viden og holdninger, og interviewet skal på ingen måde betragtes som en undersøgelse af den kvalitet der leveres på området i hverken jeres eller de øvrige praksis.

Praktisk:

- Interviewet optages, men bliver kun brugt af os. Det transskriberede materiale bliver ikke vedlagt nogen steder, og lydfilerne slettes efter brug.
- Varighed: Interviewet vil vare ca. 20-30 min.
- Underskriv samtykkeerklæring.

| | |
|---------------------------|--|
| Baggrundsspørgsmål | <p>Hvor mange dage om ugen er I hver især i klinikken?</p> <p>Hvor mange års erfaring har I i almen praksis?</p> |
| Rolle | <p>Hvilken rolle har I som almen praksis i forbindelse med sygdomsrelateret underernæring?</p> |

NUTRITIONAL RISK IN GENERAL PRACTICE

| | |
|--|--|
| | Hvilke patientgrupper tænker du I som almen praksis har en rolle overfor, når det gælder vejledning i ernæringstilstand? |
| Kompetencer indenfor ernæring | <p>Hvordan vil du selv vurdere dine kompetencer indenfor ernæring i forhold til den opgave?</p> <p>Tænker I, at der er andre fagprofessionelle/faggrupper end jer selv f.eks. konsultationssygeplejersken/lægen, der skal være mere fokus på i forbindelse med uplanlagt vægttab?</p> |
| Håndtering af ernæring | <p>Hvilke indikatorer trigger for dig, en samtale med patienten om underernæring/ uplanlagt vægttab?</p> <ul style="list-style-type: none"> - Italesætter du selv ernæring overfor patienten? - Italesætter patienten det selv? <p>Hvad gør du, hvis du kan se, at en patient har tabt sig?</p> <p>Hvilke muligheder har du for at hjælpe en patient med ernæring?</p> <ul style="list-style-type: none"> - Henviser? Har I henvisningsmuligheder lige nu? Hvilke bruger I? - Taler med patienten om det? <p>Oplever du, at der er barrierer mod at snakke med patienten om uplanlagt vægttab f.eks. mange samtidige informationer, manglende tid, andre...?</p> <ul style="list-style-type: none"> - Hos patienten selv? - Organisatorisk? <p>Er der nogle patientgrupper, som særlig ikke vil tale om patienternes vægt?</p> |
| Løsninger/muligheder/ redskaber | <p><i>Hvordan tænker du håndtering af sygdomsrelateret underernæring/ uplanlagt vægttab kan være en defineret honoreret ydelse i almen praksis?</i></p> <p>For hvilke patientgrupper finder du det ville være relevant?</p> <p>Monitorering af vægt:</p> <ul style="list-style-type: none"> - Kan man overveje at have en sygeplejerske til at veje patienterne hver gang, og det så bliver registreret i deres journal, og på den måde kan man følge med i deres vægt og opspore det noget før? |

NUTRITIONAL RISK IN GENERAL PRACTICE

| | |
|--|---|
| | <ul style="list-style-type: none"> - Kan man have en vægt stående udenfor, så patienterne selv kan veje sig, inden de kommer ind? Det kunne så stå på skærmen, at de skal huske det? <p>Vejledning af patienter/Kliniske guidelines:</p> <ul style="list-style-type: none"> - Har I kendskab til kliniske guidelines indenfor jeres område? Har I noget at bruge? - Fordele og ulemper ved kliniske guidelines til håndtering af uplanlagt vægttab? <p>Skriftligt materiale til udlevering til patienter (dem selv):</p> <ul style="list-style-type: none"> - Har I skriftligt materiale, som I kan udlevere til patienterne i forbindelse med ernæring og uplanlagt vægttab? - Fordele og ulemper ved skriftligt materiale til udlevering til patienter til håndtering af uplanlagt vægttab? <p>Henvisningsmuligheder (dem selv):</p> <ul style="list-style-type: none"> - Hvilke henvisningsmuligheder kunne du forestille dig, at I skulle bruge? - Skal det være mere tydeligt, hvem I kan henvise til? <p>Samarbejde med andre sektorer:</p> <ul style="list-style-type: none"> - Har I et samarbejde med andre sektorer i forbindelse med uplanlagt vægttab? Hvis ja, hvilket samarbejde har I? - Skal det være mere tydeligt, hvem I kan henvise til? |
| <p>Implementering af ernæringstiltag i AP</p> | <p>Barrierer:</p> <ul style="list-style-type: none"> - Hvilke barrierer vil der være ved at implementere et ernæringstiltag i jeres praksis? <p>Facilitatorer:</p> <ul style="list-style-type: none"> - Hvilke faktorer tænker I, der kan være med til at fremme implementeringen af ernæringstiltaget i jeres praksis? |
| <p>Afsluttende kommentarer/debriefing</p> | <p>Vi er ved at være færdige med interviewet.</p> <ul style="list-style-type: none"> - Har I nogen afsluttende bemærkninger? Har I mere at tilføje? - Evt. Gentage nogle af hovedpunkterne |

Appendix 3: Interview guide used to patients

Interviewguide til patienterne:

Briefing:

Hvem er vi?

- Mette: forskningsleder for Klinisk Ernæring og projektansvarlig.
- Sabina: projektmedarbejder på projektet.

Formål med interviewet: at undersøge mulighederne for at indføre en tidlig indsats mod uplanlagt vægttab i AP, herunder

- At afklare hvordan patienter, som henvises til sygehuset for udredning for alvorlig sygdom, ser de kunne modtage initial vejledning om ernæring i AP allerede på henvisningstidspunktet.

Praktisk:

- Interviewet optages, men bliver kun brugt af os. Det transskriberede materiale bliver ikke vedlagt nogen steder, og lydfilerne slettes efter brug.
- Varighed: Interviewet vil maksimalt tage 45 minutter.
- Underskriv samtykkeerklæring.

| | |
|------------------------------|---|
| Åbningsspørgsmål | Du har oplevet et stort vægttab i forbindelse med din sygdom. Kan du fortælle lidt mere om det? |
| Opsporing af vægttab | Hvornår startede vægttabet i forløbet? Og hvor meget har du tabt dig? Har du snakket med nogen om vægttabet? - Hvis ja; Snakkede I om, hvad I kunne gøre ved vægttabet? |
| Konsekvens af vægttab | Hvordan har vægttabet påvirket din forløb ud fra dit synspunkt? Har du oplevet nogle konsekvenser ved vægttabet ift. din sygdom? Kunne det have gjort nogen forskel på din nuværende tilstand, hvis du havde undgået vægttabet? |
| Forløbet | Hvordan har din oplevelse været i forbindelse med din ernæringstilstand og -behandling? - Information |

NUTRITIONAL RISK IN GENERAL PRACTICE

| | |
|---|--|
| | <ul style="list-style-type: none"> - Kommunikation - Beslutningsstøtte - Samarbejde med sundhedsprofessionelle |
| Praktiserende læger | <p>Tænder du, at der var nogen i almen praksis, som kunne inddrages i forbindelse med tidlig opsporing af uplanlagt vægttab?</p> <ul style="list-style-type: none"> - Hvis ja: Hvordan kunne disse læger inddrages? <p>Tænder du, at man kunne håndtere vægttabet allerede fra første besøg i almen praksis ved mistanke om alvorlig sygdom?</p> |
| Forebyggelse af vægttab | <p>Havde du kompetencerne til at håndtere vægttabet i starten af forløbet?</p> <p>Hvad tænker du kunne hjælpe dig med at undgå vægttab?</p> <ul style="list-style-type: none"> - Tidlig samtale om det? - Informationer omkring risikoen ved vægttab? - Pjecer omkring mad under sygdom? - Diætist? - Vejledning fra læger i almen praksis eller sygehuset? |
| Afsluttende kommentarer/debriefing | <p>Vi er ved at være færdige med interviewet.</p> <ul style="list-style-type: none"> - Har d nogen afsluttende bemærkninger? Har du mere at tilføje? - Evt. Gentage nogle af hovedpunkterne |

Appendix 4: Written material to general practitioners and general practice nurses

Appendix 4.1: Inspiration material to general practitioners



Stærkere fra Start

Projekt for patienter med uplanlagt vægttab, der henvises til kræftpakkeforløb

Forslag til, hvad du som læge kan sige til patienten:

Nu ved vi jo ikke, hvilket forløb du står overfor at skulle igennem. Men vi ved, at der er noget galt, fordi du har de symptomer, du har, og fordi du har tabt dig.

Vi ved, at det er rigtig vigtigt at holde på muskelmassen, når man er syg og måske skal i behandling. Muskelmassen betyder rigtig meget for, hvor godt man tåler behandlingen, og for hvor let immunforsvaret påvirkes. Derfor er det vigtigt at spise hensigtsmæssigt og undgå vægttab samt at holde sig aktiv.

Men vi ved også, at det kan være svært at spise, når man ingen appetit har (og den enkelte symptomer). Desuden ved man, at det er rigtig svært at indhente muskelmasse, der allerede er tabt under sygdom.

Vi er med i et projekt, der hedder “*Stærkere fra Start*”, hvor man vil prøve at give tidlig vejledning til patienter, der har oplevet et uplanlagt vægttab og henvises til udredning i kræftpakkeforløb, netop for at undgå vægt- og muskeltab ved en tidlig indsats.

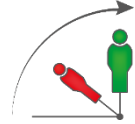
Det starter med, at du får vejledning af sygeplejersken her hos os og får noget materiale, der kan hjælpe med at spise hensigtsmæssigt og proteinrigt samt motivere dig til at holde dig aktiv.

Hvis du er interesseret i at høre mere om projektet og måske være med, skal du henvende dig hos sekretæren og få den først ledige tid hos (sygeplejersken navn), og huske at tage din smartphone eller tablet med på dagen.

Sygeplejerskens navn er: _____

Appendix 4.2: Reminder material to general practitioners' office

Forskningsprojektet “Stærkere fra Start”



Målgruppe:

- Alle patienter over 18 år med et uplanlagt vægttab, OG som henvises i kræftpakkeforløb.

Interventionen består af:

- Ernæringsintervention, som gives af en sygeplejerske fra jeres praksis.
- Patienten anvender materiale; app, skriftligt materiale om ernæring og fysisk aktivitet i hele behandlingsforløbet.
- Patienterne monitoreres efter 0, 1, 3, 6 og 12 mdr. og modtager støtte ved Ph.d. stud. Sabina.
- Patienter, der viser sig ikke at have kræft følges 1 mdr.

Hvad får patienterne ud af det?

- Minimere risikoen for yderligere vægttab samt muskeltab.
- Reducerer forventeligt risikoen for komplikationer i forbindelse med kræftbehandlingen fx genindlæggelser og pauser i behandlingen.
- Øger sin viden om, hvad der er godt at spise under sygdom og behandling samt får materiale, der kan støtte kostindtag og fysisk aktivitet.

De ansvarlige, for projektet her i praksis, er: _____

Appendix 4.3: Inspiration material to general practice nurses



Projekt for patienter med uplanlagt vægttab, der henvises til kræftpakkeforløb

Stærkere fra Start

Forslag til, hvad du som sygeplejerske kan sige til patienten:

Uplanlagt vægttab er desværre en almindelig komplikation der kan skyldes, at en sygdom kan øge kroppens forbrænding. Derfor taber du dig, selvom du måske synes, du spiser, som du plejer. Din krop har brug for mere energi og især protein end normalt.

Når du taber dig, risikerer du bl.a. at miste muskelmasse, og immunforsvaret nedsættes. Efter-som vi ikke ved, hvad du skal igennem på nuværende tidspunkt, er det vigtigt, at du har et så godt helbred og immunforsvar som muligt. Det kan hjælpe dig med at komme bedst muligt igennem en eventuel behandling og til at mindske risikoen for infektioner, komplikationer og ubehag af behandlingen.

Det betyder derfor, at det er vigtigt, at du får en god kost og i videst muligt omfang holder din vægt under sygdomsforløbet. Uanset hvad du vejer, når du starter et behandlingsforløb, er det altså vigtigt, at du undgår at tabe dig, og du holder dig fysisk aktiv.

Vi ved, at det er rigtig vigtigt at holde på muskelmassen, når man måske skal i behandling. Muskelmassen betyder rigtig meget for, hvor godt man tåler en eventuel behandling, og for hvor let immunforsvaret påvirkes. Motion kan også gøre dig i bedre humør, give dig mere energi samt give dig en bedre søvn.

Hvad kan du selv gøre for at holde vægten?

- Det er stadig vigtigt, at du spiser sundt, men dine behov er højere, og du har derfor brug for flere kalorier og især mere protein.
- Hvis du ikke kan spise så meget ad gangen, må du spise oftere. Det kan sagtens være nødvendigt at spise 6-8 gange dagligt.
- Spis mellemmåltider og hovedmåltider med protein.
- Drik ting med kalorier i - ikke kun vand. Mælkeprodukter er en god kilde til protein. De kan fint bruges som mellemmåltid.
- Forsøg at have maksimum 11 timers pause mellem måltider med protein – spis et sent mellemmåltid, f.eks. en ernæringsdrik, et glas mælk, en proteinbar eller lignende inden sengetid og indtag protein igen i dit første måltid om morgenen.
- Forsøg at spise på faste tidspunkter hver dag - også hvis ikke du mærker sult.
- Hvis du har svært ved at få plads til så meget mad, må du skære ned på grøntsagerne. Husk at tage en vitaminpille hvis du ikke spiser så meget grønt.
- Slik med meget sukker hjælper ikke. Det er bedre at få gode næringsstoffer med protein og sundere fedt.

NUTRITIONAL RISK IN GENERAL PRACTICE

Ikke kommet i gang med behandling, men den er planlagt? Ja Nej

Hvis ja, Hvilken type behandling er planlagt: Stråling

Immunterapi Operation

Kemoterapi (venøs) Kemoterapi (piller) Andet: _____

Ny aftale: _____



Spørgeskema til monitorering ved måned 1

Patient nr.: _____

Indlæggelse siden sidste opfølgning? Ja Nej

Type af indlæggelse:

Akut Antal: _____ Antal dage pr. indlæggelse: _____
 Planlagt Antal: _____ Antal dage pr. indlæggelse: _____
 Begge dele Antal akut: _____
 Antal planlagt: _____
 Antal dage pr. indlæggelse: ____ Antal dage pr. indlæggelse: ____

Sygdom:

Hvor langt er patienten?

Kræftdiagnose Hvilken: _____
 Anden sygdom Hvilken: _____
 Ikke kommet så langt endnu

Hvis patienten har fået en kræftdiagnose: Kræftbehandling

Kommet i gang med behandling? Ja Nej
 Hvis ja, hvilken type behandling: Stråling Immunterapi Operation
 Kemoterapi (venøs) Kemoterapi (piller) Andet: _____
 Ingen ny behandling siden svar ved opfølgning mdr. 0

Ikke kommet i gang med behandling, men den er planlagt? Ja Nej
 Hvis ja, hvilken type behandling er planlagt: Stråling Immunterapi
 Operation
 Kemoterapi (venøs) Kemoterapi (piller) Andet: _____

NUTRITIONAL RISK IN GENERAL PRACTICE

Pause i behandlingen (hvis startet)? Ja Nej

Længde af pausen: _____

Færdig med behandlingen? Ja Nej

Opfølgning:

Skal patienten følges op på ved 3 mdr.? Ja Nej

Hvis ja til opfølgning: Ny aftale _____

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