Nutritional status and oral health in patients at St. Olavs hospital, Trondheim University Hospital

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Thomas Kvitvang Reinan

Abstract

Background: It is estimated that every third hospitalized patient is malnourished or at nutritional risk. This can lead to increased risk of complications, longer hospital stays, higher mortality and increased healthcare costs. Oral health includes several factors that can affect food intake, such as reduced chewing ability, swallowing problems, oral mucosal sores, decayed teeth, poorly functioning dentures or dry mouth. Dry mouth is a common side effect of medications and can manifest as xerostomia (subjective feeling of dry mouth) and/or hyposalivation (salivary flow rate below normal). Dry mouth is known to increase with age and can adversely affect other oral health factors. There is currently a lack of knowledge and priority with regard to oral health-related problems in the hospital setting, and as such the relationship between poor oral health and malnutrition may be neglected.

Objectives: The first objective of this thesis is to investigate the prevalence of malnutrition, hyposalivation and other oral health problems among inpatients at St. Olavs hospital. The second objective is to contribute with knowledge within the field of malnutrition and oral health by investigating whether 1) hyposalivation is associated with malnutrition; 2) other oral health factors than hyposalivation are associated with malnutrition; 3) medication intake is associated with hyposalivation; 4) the inpatients categorized as malnourished in the present study also were screened to be at nutritional risk by the nutritional screening tool used at the hospital.

Materials and methods: A cross-sectional study was conducted from October 2018 to March 2019 on 118 inpatients (median age 68 years, 56% men) from 15 somatic and 3 psychiatric wards at St. Olavs hospital. Nutritional status was assessed with the Patient-Generated Subjective Global Assessment (PG-SGA), complemented with the mid-arm muscle circumference. Salivary flow rate was measured by collecting unstimulated whole saliva for 5 minutes, with hyposalivation defined as flow rate $\leq$0.1 ml/min. Oral health was assessed with the Revised Oral Assessment Guide-Jönköping (ROAG-J) and with a self-administered questionnaire. Number and types of orally administered medications and nutritional screening data, Nutrition Risk Screening 2002 (NRS 2002), were obtained from medical journals. Logistic regression was performed to calculate odds ratios (ORs) of malnutrition and hyposalivation.

Results: Of the study patients, 57% were categorized as malnourished (PG-SGA B or C), 19% had hyposalivation, 93% were assessed to have at least one oral health problem and 36% reported being bothered by dry mouth. The most frequent oral health problems were found regarding lips, teeth and the tongue. In adjusted models, increased risk of malnutrition was found in patients who had problems related to oral mucosa (OR 4.67, 95% CI 1.92-11.36), lips (OR 4.22, 95% CI 1.78-9.94) and teeth (OR 3.62, 95% CI 1.51-8.72). Hyposalivation was associated with risk of malnutrition in the unadjusted model (p=0.04), but the association disappeared when adjusting for age and gender (OR 2.26, 95% CI 0.74-6.87). Intake of orally administered medications per day was higher in patients with hyposalivation (median number 8) compared with patients without hyposalivation (median number 4) (p=0.004). Of the 118 study patients, 21 had not been screened at the hospital by the NRS 2002. Of the 97 screened patients, 11 were found to be at nutritional risk. Among the study patients categorized as malnourished by the PG-SGA (57%, n=67), nine had not been screened at the hospital by the NRS 2002. Of the 58 malnourished patients that had been screened, 11 (19%) were found to be at nutritional risk.

Conclusion: The prevalence of malnutrition and oral health problems among the study patients were high, and several associations between poor oral health and malnutrition was found. Increased medication use was associated with hyposalivation. The quality of the nutritional screening practice at the hospital was poor, with the majority of malnourished patients screened to not to be at nutritional risk. Because of the high proportion of malnourished patients in the hospital, this suggests that an improvement in nutritional routines is needed. More attention should also be directed towards oral health in the hospital setting, particularly in the elderly and in patients using many medications. Furthermore, assessment of oral health status should be included as a natural part of patient care. There is a need for more research investigating the prevalence of oral health problems in hospitals, and the relationship between nutritional status and oral health should be explored further in future studies.

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Abbreviations

BMI	Body mass index
CI	Confidence interval
DRM	Disease-related malnutrition
ESPEN	European Society for Clinical Nutrition and Metabolism
FFMI	Fat free mass index
HUNT4	The Nord-Trøndelag Health Study (2017-2019)
ICD	International classification of diseases and related health problems
IQR	Interquartile range (25^{th}–75^{th} -percentiles)
MAMC	Mid-Arm Muscle Circumference
MNA	Mini Nutritional Assessment
MUAC	Mid-Upper Arm Circumference
NRS 2002	Nutrition Risk Screening 2002
OR	Odds ratio
PG-SGA	Patient-Generated Subjective Global Assessment
ROAG	Revised Oral Assessment Guide
ROAG-J	Revised Oral Assessment Guide-Jönköping
SD	Standard deviation
SGA	Subjective Global Assessment
TkMidt	Center for Oral Health Services and Research, Mid-Norway
WHO	World Health Organization

1 Background

1.1 Malnutrition

1.1.1 Defining and diagnosing malnutrition

In its simplest form, malnutrition can be defined as any nutrition imbalance (1). There is however currently no universal agreement on its definition, but in a recent guideline from the European Society for Clinical Nutrition and Metabolism (ESPEN) malnutrition is defined as "a state resulting from lack of uptake or intake of nutrition leading to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function" (2). Others refer to malnutrition as an umbrella term, encompassing not only deficiencies but also excesses or imbalances in intake of nutrients (3). Both undernutrition and overnutrition are therefore often classified as subtypes of malnutrition. For the purpose of this thesis, the term malnutrition will be synonymous with undernutrition.

Diagnosing malnutrition is a two-step process (2). First, a patient must be screened by a validated screening tool and identified to be "at nutritional risk". Further assessment of those who are at risk is then performed, however the diagnosis is dependent on which criteria is used as no standardized method for identification has reached global consensus. ESPEN published a consensus statement in 2015, suggesting that malnutrition is diagnosed based on either body mass index (BMI) <18.5 kg/m^2 (alternative 1) or specific cut-off points for weight loss in combination with reduced BMI or fat-free mass index (alternative 2) (4). Recently, as a result of a collaborative effort between several of the major global clinical nutrition societies the "GLIM criteria for the diagnosis of malnutrition" was published (5). The consensus report aims to standardize the clinical practice of malnutrition diagnosis on a global scale, and proposes diagnosing malnutrition based on the presence of least one phenotypic criterion (weight loss/BMI/muscle mass) and one etiologic criterion (food intake/inflammation). For the time being, the diagnosis of malnutrition in Norway is based on the diagnostic codes in ICD-10 (The International classification of diseases and related health problems) and the national guidelines (6,7). The guidelines recommend that hospital patients are screened for nutritional risk upon admittance and then weekly with one of the following tools: Nutritional Risk Screening 2002 (NRS 2002), Malnutrition Universal

Screening Tool (MUST) or Mini Nutritional Assessment (MNA). A patient found to be at nutritional risk will then receive a diagnosis of either moderate malnutrition or severe malnutrition if the person fulfils one of the criteria listed in Table 1.

Table 1. National diagnostic criteria[a] of malnutrition. Adopted from (6).

	E44.00 Moderate malnutrition	E43.00 Severe malnutrition
1	Weight loss > 10% last 3-6 months or >5% last 2 months	Weight loss > 15% last 3-6 months or >5% last month
2	BMI[b] < 18.5 kg/m^2 (>70 years: BMI < 20)	BMI < 16 kg/m^2 (>70 years: BMI < 18.5)
3	BMI < 20.5 kg/m^2 (>70 years: BMI < 22) and weight loss > 5% last 6 months	BMI < 18.5 kg/m^2 (>70 years: BMI < 20) and weight loss > 5% last 3 months
4	Food intake < 50% last week and acute/chronic inflammatory conditions	PG-SGA[c] Category C
5	PG-SGA Category B	

[a] Malnutrition is diagnosed when one of the five criteria is fulfilled.
[b] Body mass index.
[c] Patient-Generated Subjective Global Assessment.

1.1.2 Etiology and prevalence

The causes for malnutrition are various, but can be divided into disease-related malnutrition (DRM) and malnutrition without disease (non-DRM) (2). In poor developing countries, hunger-related malnutrition is the main cause non-DRM. Two other examples of non-DRM in both affluent and poor developing countries are socioeconomic and psychologic malnutrition, as difficult situations such as social inequities, psychological distress or poor self-care can lead to a reduced energy intake. However, in developed countries the main cause of malnutrition is disease-related. Based on etiologic mechanisms, DRM can be classified according to inflammation; DRM without inflammation (e.g. anorexia nervosa or upper digestive obstruction resulting in dysphagia), chronic DRM with inflammation (e.g. inflammatory bowel disease or cancer resulting in loss of muscle mass with or without fat loss), and acute disease- or injury-related malnutrition (e.g. major infections or burns resulting in a proinflammatory state and increased metabolic demand). A low food intake can occur in all three classifications of DRM, as disease in combination with the medical treatment usually result in a reduced appetite (8). Other medication-related side effects (e.g. diarrhea and nausea) can also interfere with the ingestion of food, and the hospital setting can further aggravate the situation due to obligatory fasting before medical tests or adverse

hospital routines with regard to meal palatability, timing and frequency (9). Lastly, advanced aging is known to contribute to any form of malnutrition (2).

The prevalence of hospital malnutrition is high, although the proportion depends on the patient populations and the criteria used in the diagnosis. A weighted mean of 17 US and European studies showed that 31.4% of hospital patients were malnourished or at nutritional risk (9). A recent systematic review examining 66 Latin American studies found a consistent prevalence of 40-60% on admission and an even higher prevalence among older adults, in addition to an increasing prevalence during hospitalization in the general population and especially in surgical and critically ill patients (10). In Norway, it is estimated that every third patient is malnourished or at nutritional risk (11,12). Among the hospitalized elderly the prevalence is even higher ranging from 40-60% in patients $\geq$70 years (12–14).

1.1.3 Consequences and solutions

The prognostic impact of malnutrition is serious, with numerous consequences demonstrated in several studies (15). Some of the clinical implications are impaired immune function and wound healing, increased convalescence, decreased functional status, longer hospital stays, greater complication rates and increased mortality (10). The economic impact is also vast, with one study demonstrating a mean daily cost of care being 61% higher in malnourished patients compared with well-nourished patients (16). Henriksen et al. found that only 41% of malnourished patients were receiving nutritional treatment, and an estimated potential cost saving of 250 million euros per year was calculated based on a reduction of hospital stay by one day for each patient receiving nutritional treatment (11). During the last years several national and international reports, programs and guidelines have been published discussing how the challenges with regard to malnutrition can be solved (17–23). Proper nutritional assessment of the patient is the first step, and interprofessional collaboration has been recommended when identifying and treating the cause(s) for the reduced food intake or poor nutritional status (24). The recent medical, social and economic advances have resulted in an aging population where the elderly are living longer, often with non-curable diseases or chronic diseases (25). As a result, improved nutritional care in the coming years will be of great importance, with an emphasis on proper nutritional screening of patients and identification of the underlying cause(s) in order to prevent and treat malnutrition.

1.2 Oral health

1.2.1 Oral health and systemic health

Unhealthy diets have been associated with oral diseases, and there is a close relationship between nutritional and oral health (26). Oral health is defined by WHO as "a state of being free from chronic mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit an individual's capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing" (27). It follows that oral health is not only related to the diet, but linked to the general health of a person and integral to a person's quality of life (28). This is particularly evident in the geriatric population, where epidemiologic data indicate a reduced state of well-being related to increased caries prevalence, moderate periodontal disease and tooth loss (29). Complex interactions between systemic diseases and changes in the oral status have been explored, among them association between periodontal disease and diabetes mellitus and cardiovascular disease (30). Periodontal disease is a chronic multifactorial and inflammatory disease, associated with the colonization of the oral cavity by specific bacterial taxa. The oral microbiome is incredibly complex and contains approximately 700 predominant bacterial species in total, with about 200 species living in the oral cavity of the average adult (31). Owing to technological advances oral bacteria may also serve as biomarkers for systemic diseases. While development of periodontal disease can go unnoticed over a longer period of time, other oral health-related problems can have more immediate symptoms such as poorly fitted dentures or the pain from wounds or an abscessed tooth and the following problems with food intake. In the elderly, one of the most frequently reported oral health problems with a substantial impact on their daily life is dry mouth (29,32).

1.2.2 Dry mouth: hyposalivation and xerostomia

Saliva is produced by three pairs of major salivary glands (parotid, submandibular, sublingual) and numerous minor salivary glands. Secretion is regulated through interactions between the sympathetic and parasympathetic nervous system (33). Saliva consists of water, electrolytes and a complex mixture of organic molecules, e.g. enzymes, mucins and antimicrobial proteins. Saliva has several critical functions, as it protects the oral mucosa and teeth against mechanical, chemical and infectious damage, promotes the digestion of

food, remineralizes teeth, and it lubricates the mouth, making it easier to speak, chew and swallow. In addition to its protective and alimentary effect on the oral cavity, it can be regarded as an indicator of oral and systemic irregularities and diseases (34).

The importance and clinical significance of dry mouth is considered to be severely under-appreciated, underdiagnosed and undermanaged (35). Hyposalivation refers to a reduction in salivary flow rate and diagnosis is based on objective measures of saliva (36). Xerostomia is the subjective perception and complaint of dry mouth, and normally occurs when the salivary output for an individual is reduced by more than 50% (37). Hence, dry mouth diagnosis consists of two components, where one is objective and the other is subjective.

A patient may complain of xerostomia without being diagnosed with hyposalivation when salivary flow rate is measured, but at the same time not everyone with hyposalivation will experience xerostomia (33). To identify xerostomia and hyposalivation, single-item (known as "global" item) approaches and several questionnaires (multi-item approaches) have been developed in order assess the severity of dry mouth and predict hyposalivation (38–41). One common method used to diagnose hyposalivation is sialometry, a non-invasive process where salivary flow is measured by collecting saliva from the patient according to a standardized procedure (42). Collection of saliva can be performed either unstimulated or stimulated. For unstimulated saliva, the patient accumulates saliva in the mouth for 5-15 minutes, and either allow it to passively drain into a funnel (draining method) or spit into a collecting vessel 1-2 times per minute (spitting method) (34). For stimulated saliva, the patient can chew paraffin wax (masticatory method) or have citric acid dropped onto the tongue (gustatory method) while actively spitting into the collecting vessel for 5 minutes. Although there is high individual variability in saliva production, a common classification of unstimulated and stimulated salivary flow rate is presented in Table 2.

Table 2. Classification of unstimulated and stimulated[a] salivary flow rate in adults. Adopted from (33,42).

	Normal salivation (ml/min)	Low salivation (ml/min)	Hyposalivation[b] (ml/min)
Unstimulated	> 0.25	0.1 - 0.25	$\leq$ 0.1
Stimulated	> 1.0	0.7 - 1.0	$\leq$ 0.7

[a] By chewing paraffin wax.

[b] Hyposalivation defined by these threshold values is a criterion that automatically qualifies for coverage of dental care expenses in Norway (43).

The causes and consequences of dry mouth are many. The most common iatrogenic causes are medication use and radiotherapy (44). Several diseases can also cause salivary hypofunction, by affecting salivary glands (Sjögren's syndrome, cystic fibrosis), neural control of salivary secretions (e.g. Alzheimer's disease, dysautonomia) or by causing dehydration (diabetes mellitus). Because women have a lower salivary gland capacity than men, they are more vulnerable to factors causing salivary hypofunction (45). Although aging is linked to dry mouth it is unclear whether age is a direct cause or whether it is the age-related increase in medication use and certain medical conditions that drive the salivary flow changes (42), but age appears to play a role in the secretion of unstimulated saliva (34). The prevalence of hyposalivation is difficult to estimate due to variation in measurement methods and the cut-off values used for each method (46). Among older adults, the prevalence has been shown to range from 5% to 47% (47). The range of reported xerostomia estimates is wide too, but the prevalence is estimated to be around 20% in the general population and 40% in older adults (33,46). Symptoms of dry mouth, i.e. xerostomia and/or hyposalivation, include rapid development of caries, oral mucosal sores, fungal infections, difficulty speaking and swallowing, bleeding gums, cracked lips, dry tongue, altered taste, reduced masticatory function, sleep disturbances, decline in quality of life, denture discomfort, and more (37). In addition to affecting the whole oral cavity and its constituents, dry mouth in the form of hyposalivation has also been associated with increased mortality in elderly (48). As none of the current treatment strategies for dry mouth (e.g. proper hydration, chewing gum, oral lubricants) are entirely satisfactory, addressing the underlying cause(s) is important (35). In some cases, the symptoms can be decreased by medication changes or by reducing dosage of medications that can cause dry mouth (36,49).

1.2.3 Medications' impact on oral health

Medication use can adversely affect all oral tissues and is considered the most important risk factor for dry mouth (44,50). Many commonly prescribed medications are xerogenic, i.e. can reduce salivary flow or reduce the threshold for perception of dry mouth, and more than 500 medications have been associated with salivary hypofunction. The mechanisms are complex, as the presence of xerostomia or hyposalivation is not only dependent on how xerogenic each medication is, but also on the overall number of medications the patient is using (51,52). Furthermore, the medication doses, their form, time of ingestion, length of time on each medication and possible interactions between different medications are all factors

affecting the salivary output (34). Polypharmacy, most commonly defined as five or more medications daily (53), is therefore an area for concern with regards to the development of dry mouth. Polypharmacy may also increase the risk of adverse drug reactions (54) and may be associated with poor nutritional status and malnutrition (55).

1.3 The relationship between nutritional and oral status

1.3.1 Results from earlier studies

The ingestion and digestion of food starts in the oral cavity. Poor oral health may therefore adversely affect food intake in multiple ways, and several studies in hospitalized or institutionalized elderly people (mean age $\geq$65 years) have shown that oral health-related problems are associated with poor nutritional status or difficulties eating food.

In a group of geriatric rehabilitation patients, problems with regard to the lips, tongue, saliva and swallow function were associated with malnutrition (56). In another group of elderly rehabilitation patients, low saliva production and tongue alterations were associated with being malnourished (57). In a third group of patients undergoing rehabilitation, the best predictor in univariate analyses for weight loss greater than 10% the last year was the total number of general oral problems, including but not limited to poor oral hygiene, xerostomia, inability to chew, pain in the mouth and lesions (58). In a final group of rehabilitation patients, those without any oral problems had lower risk of malnutrition compared with those with at least one problem (59)

Elders from private geriatric centers reporting at least one problem in a questionnaire measuring oral health-related quality of life (OHRQoL) had a higher risk of malnutrition compared to those with no problems (60). Another study found a significantly worse OHRQoL in oral cancer patients with malnutrition or risk of malnutrition (61). Both xerostomia and hyposalivation were associated with low BMI in hospitalized elderly patients (62), and in another group low number of own teeth was associated with a low body cell mass (consisting of mainly muscle tissue) (63). In a group of institutionalized older adults, the two strongest factors associated with malnutrition were dentures with defective bases or not wearing dentures at all, and adults with compromised oral health (poor periodontal state, poor denture quality, caries prevalence or oral mucosal lesions) had a

lower BMI and serum albumin concentration (64). Nursing home residents reporting denture or chewing problems were 1.6 and 1.3 times more likely to be malnourished, respectively, compared with those without problems (65). Reduced chewing ability and number of teeth was also found in malnourished adults living at home (66). Lastly, in community-based elderly the intake of several micronutrients was lower in those with hyposalivation (67).

1.3.2 More research is needed

In light of the high prevalence of hospital malnutrition and the known adverse associations between nutritional and oral status, there is a lack of knowledge and priority with regard to oral health-related problems in the hospital setting (68,69). Proper nutritional assessment includes identifying the underlying causes in patients at nutritional risk. Although malnutrition is often caused by disease (DRM), socioeconomic or psychologic malnutrition should not be neglected since difficult life situations can lead to a lack of oral care and poor oral status. At the same time, disease itself can influence oral health (e.g. diabetes mellitus affecting salivary flow) and can cause polypharmacy, which may result in even further reduced oral health.

In Norway, there is a lack of data on dental health among adults over 20 years (70). Data on the prevalence of dry mouth is also lacking, but one study conducted in 1996-1998 (71) and one study from 2004 (70) showed that around 35% and 30% of nursing home residents had dry mouth, respectively. Very little is known, however, about oral health and its effect on nutritional status in hospitals. Previous studies have shown that the prevalence of malnutrition or risk of malnutrition at St. Olavs hospital in Trondheim was 21% (72) and 65% (73) in cancer patients. In St. Olavs hospital's nutritional strategy for 2010-2020, it is stated that under 1% of patients at the hospital were assigned diagnosis codes for malnutrition in 2006-2009, indicating that many patients are underdiagnosed (74). Two objectives in the strategy is to implement a research and development program and to study the prevalence of malnutrition. In the Ministry of Health and Care Services' action plan "Sammen om kunnskapsløft for oral helse (2017 -2027)", an increased number of multidisciplinary projects looking at oral health in the context of other health and disease conditions is recommended (75). This, together with the objectives in St. Olavs hospital's nutritional strategy, forms the background for this thesis and the study "Nutritional status and oral health in patients at St. Olavs hospital, Trondheim University Hospital".

2 Objectives

The first objective of this thesis is to investigate the prevalence of malnutrition, hyposalivation and other oral health problems among inpatients participating in the study at St. Olavs hospital. The second objective is to contribute with knowledge within the field of malnutrition and oral health by answering the following research questions:

1) Is hyposalivation associated with malnutrition?
2) Are oral health factors other than hyposalivation associated with malnutrition?
3) Is medication intake associated with hyposalivation?
4) Were the inpatients categorized as malnourished in the present study also screened to be at nutritional risk by the nutritional screening tool used at St. Olavs hospital?

3 Materials and methods

3.1 Study design

The project was designed as a cross-sectional study with informed consent, led by the Nutrition Committee at St. Olavs hospital in collaboration with Center for Oral Health Services and Research, Mid-Norway (TkMidt) and the Norwegian University of Science and Technology (NTNU). Patients were recruited between October 2018 - December 2018 and between February 2019 - March 2019. The study was conducted at one ward per week, from Tuesday to Thursday or Friday.

Eligible patients were men and women aged 18 years and older, hospitalized before the end of Tuesdays and available at the ward 1-3 days after consenting to the study. Exclusion criteria were situations where patients or guardians/relatives would feel discomfort when asked to participate, e.g. terminally ill patients, instability or unresolved medical conditions. Further exclusion criteria were contact, droplet or airborne isolation, and having an unhealthy relationship with food or fear of dentistry. Nurses at the wards were asked if any of the patients met these criteria before recruitment started. All eligible patients received verbal and written information about the study from the master student in clinical nutrition. After signing the consent form (Appendix 1), patients still had the opportunity to withdraw at any point during the study. The study was approved by the Regional Committees for Medical and Health Research Ethics (REC Protocol Approval 2018/621) (Appendix 2, 3, 4).

3.1.1 Data collection

Data in the form of two self-administered questionnaires (available in Norwegian and English), clinical data (saliva test, oral health assessment, forehead temperature measurement) and anthropometric measurements (height, weight, triceps skinfold thickness, mid-upper arm circumference) were collected at the ward. Data on nutritional screening, diagnoses and medication use were collected from the medical records. The master student and four study nurses from the Department of Research and Development (Forskningsposten) at the hospital were responsible for gathering data at each ward. Data from medical records were collected by the master student. WebCRF, an electronic solution for data collection made by Section for Applied Clinical Research, Faculty of Medicine and

Health Sciences at NTNU, was used by the master student to plot collected data into a database (76). An overview of the study design and methods used is presented in Figure 1 and expanded upon in the following sections.

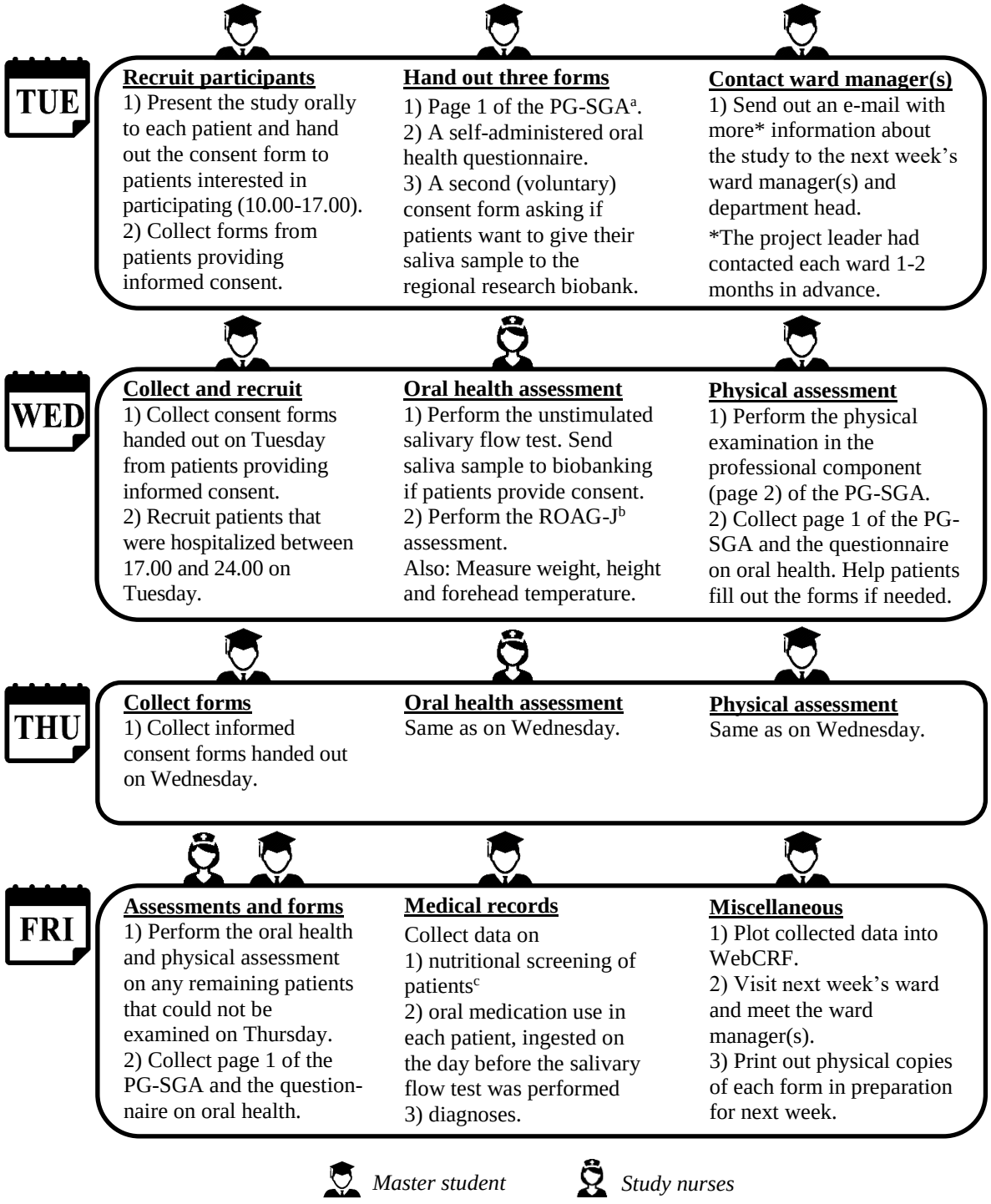

Figure 1. Overview of the study design. The study was conducted at one ward per week, and ward managers were contacted by e-mail one week in advance in order for them to prepare and inform the nurses at the ward.
[a] Patient-Generated Subjective Global Assessment.
[b] Revised Oral Assessment Guide-Jönköping.
[c] Performed by nurses at the hospital with the screening instrument Nutrition Risk Screening 2002 (NRS-2002).

3.2 Subjects and recruitment

Subjects were recruited from 18 wards, of which 15 were somatic and 3 were psychiatric. In total, 118 patients were included in the study. Except for four participants, all who produced more than 0 ml saliva signed a second consent document agreeing to give biological material (i.e. their saliva) to the regional research biobank Biobank1 (Appendix 5). The recruitment process is illustrated in Figure 2. Major reasons for exclusion (n=63) after speaking to the nurses were as follows: having a very bad day, drug abuse, critically ill, does not speak Norwegian or English, severe dementia, alcoholic, preoperative anxiety.

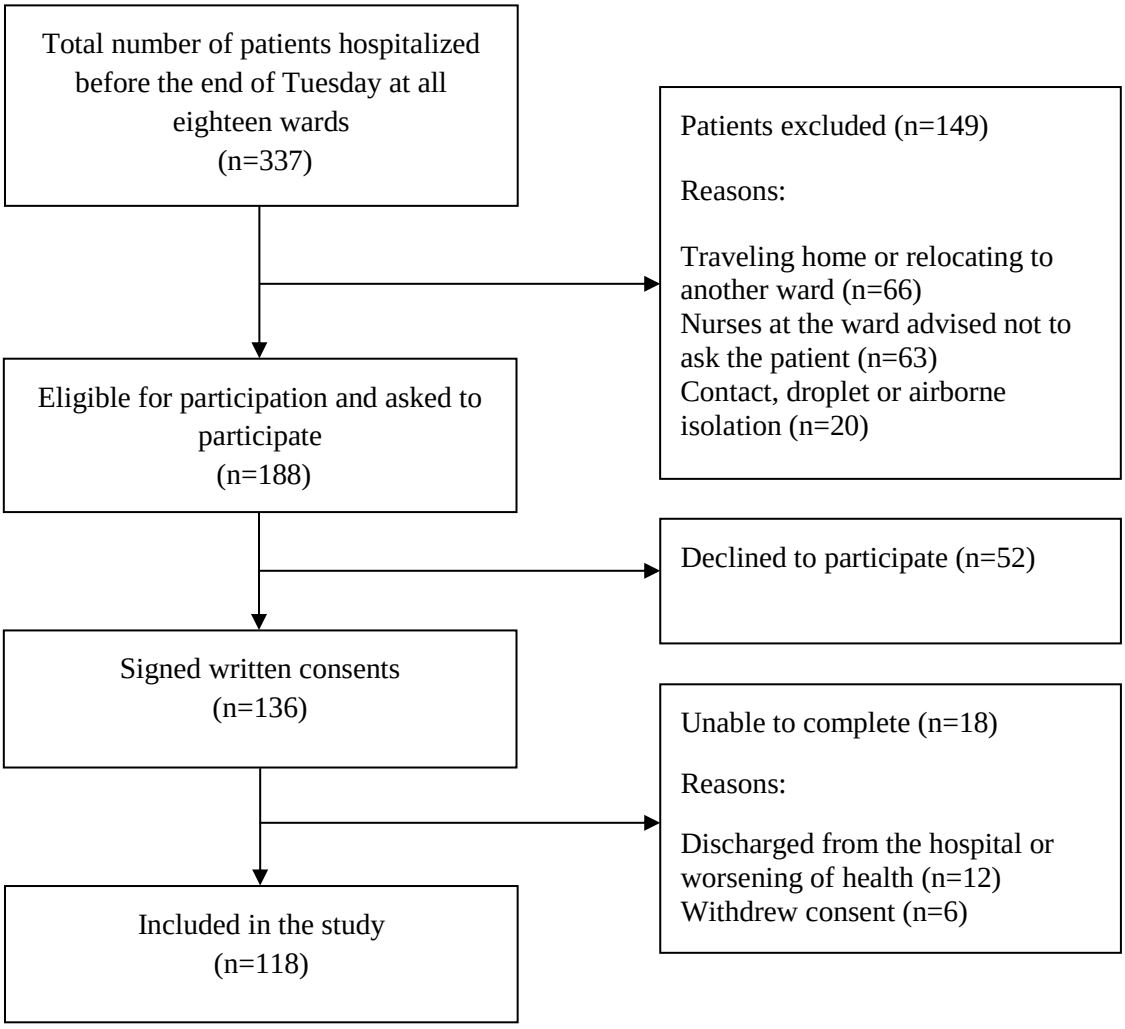

Figure 2. Flow diagram showing the recruitment process. Fifteen somatic and three psychiatric wards were included. In chronological order, the participating wards were: 1) Geriatric Medicine 2) Gynaecological Oncology 3) Infectious Diseases 4) Cardiology 5) Pulmonary Medicine 6) Orthopaedic Surgery 7) Rheumatology 8) Ear Nose Throat & Eye 9) Oncology 10) Gastrointestinal Surgery 11) Nidaros District Psychiatric Center 12) Special Ward 3 (Psychosis) 13) Spinal Cord Injuries 14) Neurology 15) Neurosurgery 16) Cardiothoracic Surgery 17) Vascular-Breast-Endocrine surgery 18) Geriatric Psychiatry.

3.3 Assessment of nutritional status

3.3.1 Patient-Generated Subjective Global Assessment (PG-SGA)

The patient-generated subjective global assessment (PG-SGA) is a validated nutritional assessment tool classifying patients to be well-nourished, moderately/suspected malnourished or severely malnourished. Ottery et al. (77) adapted the PG-SGA from the subjective global assessment (SGA), earlier developed and described by Detsky et al. (78). PG-SGA contains additional questions and was designed so that the four components of the medical history in SGA (weight history, food intake, symptoms and activity level) could be completed by patients using a check box format. A health care professional then completes the professional component of the PG-SGA (physical examination, diagnosis, age and metabolic stress) in order to give the patient a global rating. A scored version of PG-SGA was further developed, incorporating a numerical score in addition to the categorical global rating of well-nourished (PG-SGA A), moderately or suspected malnourished (PG-SGA B) and severely malnourished (PG-SGA C) (79). The total score provides guidelines as to which nutrition intervention is required, while the global rating provides an overall assessment of the patient's nutritional status. The scored PG-SGA with its components and their contribution to the global rating and numerical score is summarized in Figure 3.

Although the PG-SGA was originally developed for use in patients with cancer, it is not an oncology-specific instrument. It covers all domains of the malnutrition definition by ESPEN (2) and has been validated and utilized in both cancer and non-cancer populations (80,81). In the present study, the Norwegian version of the scored PG-SGA (18-004 v03.13.18) was used in the majority of patients (Appendix 6) and the English version (v3.22.15) in a few patients. The professional component (including summing up the total score and classifying each patient according to the global rating) was carried out by the master student, who prior to study start received training from a clinical dietitian experienced with both the SGA and the PG-SGA. The training included a lecture from the dietitian, performing the physical examination on a patient under supervision, and suggestions for relevant literature for the examination (82,83). In worksheet 4 (Figure 3), muscle status, fat stores and fluid status were evaluated by palpation and/or visual inspection of all components listed in the worksheet (e.g. muscle wasting in temples, thigh, scapula; loss of subcutaneous fat in triceps, orbital fat pads; presence of edema in ankles or ascites). The degree of muscle

deficit, fat depletion and fluid excess were individually rated as 0 (no deficit) to 3 (severe deficit), and a total score of 0-3 was awarded based on a subjective evaluation where muscle deficit took precedence over fat depletion and fluid excess.

The Norwegian 2019 edition of ICD-10 includes a rating of PG-SGA B as a criterion for "Moderate malnutrition", as mentioned in Table 1 (6). In light of this, a patient who received a rating of PG-SGA B (moderately malnourished/suspected malnourished) is hereafter referred to as (moderately) malnourished, and not suspected malnourished.

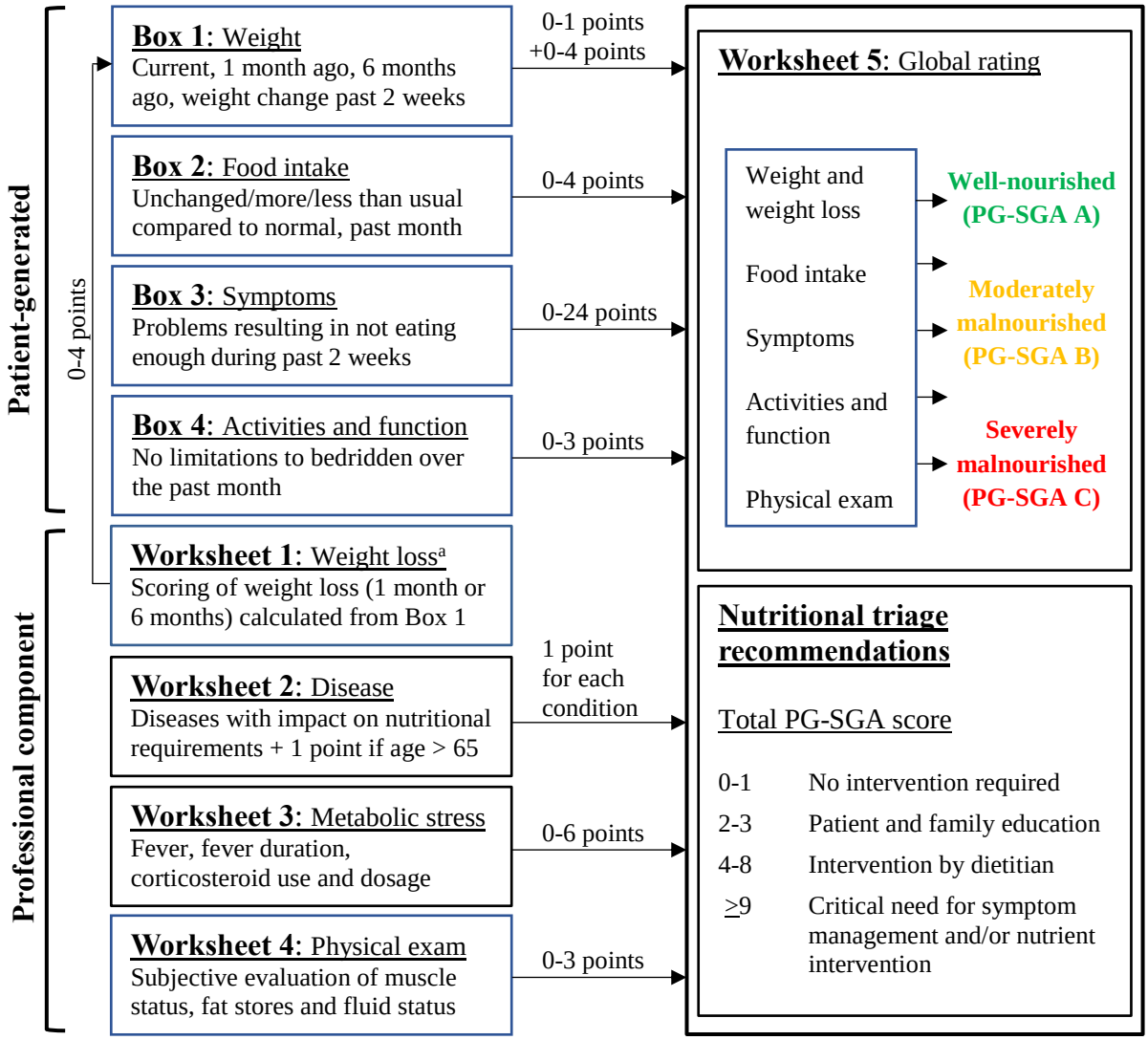

Figure 3. The Patient-Generated Subjective Global Assessment. Page 1 of the instrument contains the patient-generated component, where patients are asked to write down their height and weight development in Box 1 and to check all relevant boxes in Box 2-4. The master student handed out page 1 to the patients and helped fill out the form if anyone was not able to do it themselves. Page 2 contains the professional component and was filled out by the master student after collecting the patient-generated component. A global rating and total PG-SGA score was then awarded based on both components.
[a] When calculating the score for weight loss in Worksheet 1, 6-month data is only used if no 1-month data are available.

3.3.2 Anthropometric measurements

Four anthropometric measurements were obtained: weight, height, triceps skinfold (TSF) thickness and mid-upper arm circumference (MUAC). Weight and height were measured by the study nurses. Weight (kg) was measured using a seca 877 flat scale for mobile use, with patients wearing light hospital clothing and no shoes. Height (cm) was measured using a seca 217 stable stadiometer for mobile height measurement. Weight and height were used to calculate BMI (weight[kg]/height^2[m^2]). When unable to obtain measurements at the ward (e.g. patient not able to stand up), BMI was calculated from recent weight and height measurements obtained from the medical records. When classifying patients according to BMI, the classification by the WHO was used (84,85). TSF and MUAC on the nondominant side of the body were measured by the master student at the same time as the physical examination in PG-SGA was performed. TSF was measured by a conventional Holtain caliper. Three measurements were taken of the TSF and one measurement of MUAC, midway between the tip of the acromion process and the olecranon. Mean TSF was used together with MUAC to calculate the mid-arm muscle circumference (MAMC), using the formula: MAMC (cm) = MUAC (cm) − (TSF (mm) × 3.14). Values of MAMC below the tenth percentile (p10) and the fifth percentile (p5) of a reference population (86) were classified as moderately malnourished and severely malnourished, respectively.

3.3.3 Nutrition risk screening 2002 (NRS 2002)

Nutrition Risk Screening 2002 (NRS 2002) is a standardized screening tool recommended for use in hospitals when screening patients for nutritional risk (7,87,88). It is divided into two main parts (89). The first part is the introductory screening and consists of four questions: (1) is BMI <20.5? (2) has the patient lost weight within the last 3 months? (3) has the patient had a reduced dietary intake in the last week? (4) is the patient severely ill? If the answer is “Yes” to any of these questions, the formal screening is carried out. In the formal screening, the patient is given a score of 0-3 for nutritional status and 0-3 for disease severity according to a scoring system. In patients older than 70 years 1 score is added to the total score, for a final score of 0-7. Patients with a score $\geq$3 is considered at nutritional risk and need a plan for nutritional support.

A modified version of the original NRS 2002 is used at St. Olavs hospital. It includes one additional question in the formal screening, where symptoms affecting food intake is

assessed and included in the scoring when evaluating the disease severity. NRS 2002 data from patients included in the study were obtained from medical records by the master student, and data on diagnoses and number and types of orally administered medications on the day before the saliva test for each patient were collected at the same time (Appendix 7).

3.4 Assessment of oral health status

3.4.1 Unstimulated salivary flow rate

Unstimulated whole saliva was collected by the study nurses according to a standardized protocol (Appendix 8). The technique used for collecting saliva was the spitting method (section 1.2.2), where the patient is allowed to spit into a collecting vessel 1-2 times per minute instead of letting saliva passively drain into a funnel (34). Collecting vessels were Sarstedt tubes (30 ml, 107 x 25 mm, conical base with smear edge) and collections were made between 09.00 and 14.00 (the majority before 12.30). The standardized protocol required patients to not put anything in their mouth (food, fluid, chewing gum, medications) 30 minutes before the test. Saliva was collected for 5 minutes and measured by comparing the volume of spit in the sample with calibration tubes. Saliva samples for biobanking were placed on ice until they were sent via pneumatic tube for biobanking to Biobank1.

To obtain the salivary flow rate, saliva volume was divided by collection time (5 minutes in all patients). Patients with an unstimulated salivary flow rate $\leq$0.1 ml/min were classified as having hyposalivation, while patients with a value >0.1 ml/min was classified as without hyposalivation. Patients without hyposalivation were also classified according to Table 2: a value between 0.1-0.25 ml/min was classified as low salivation and a value >0.25 ml/min was classified as normal salivation (33,42).

3.4.2 Revised Oral Assessment Guide-Jönköping (ROAG-J)

The Revised Oral Assessment Guide (ROAG) is an internationally standardized instrument for non-dental professionals that can be used to investigate, assess and document oral health-related problems (57). The Oral Assessment Guide (OAG) was originally developed by Eilers et al. to be used in patients undergoing bone marrow transplantation, receiving high-dose radiation and/or chemotherapy (87), but was later revised by Andersson et al. to be

used among elderly patients (56). The revised version is reported to be a reliable and clinically useful tool (90). The ROAG-J, used in the present study with permission from Pia Andersson, has been further developed in Jönköping and is presented in Table 3. Recommendations for healthcare professionals on which measures should be taken when oral health problems are detected is listed in the ROAG-J manual (91).

Table 3. The Revised Oral Assessment Guide-Jönköping. Adopted from (91).

	Grading[a]			
Category	0	1	2	3
Voice	Not applicable	Normal	Dry, hoarse, smacking	Difficulty speaking
Swallowing	Not applicable	No problems	Some swallowing problems	Severe swallowing problems
Lips		Soft, pink, moist	Dry, cracked or angular cheilitis	Ulcerated, bleeding
Mucous membranes		Pink, moist, no sores	Red, dry, colour changes or coating	Sores or blisters
Tongue		Pink and moist	Red or dry, with or without coating	Sores and/or blisters
Saliva		No friction between lower end of tooth-brush[b] and oral mucosa	Increased friction Between lower end of toothbrush and oral mucosa	Significantly increased friction between lower end of toothbrush and oral mucosa
Gums	No gums	Pink and firm	Oedematous and red	Spontaneous bleeding
Teeth	No natural teeth	Clean, no debris	Plaque or debris on some teeth	Plaque or debris on most teeth, or severely damaged teeth
Dentures	No partial or complete dentures	Clean, working fine	Unclean with debris, does not fit well	Does not use them

[a] A grade of 2 or 3 on one of the nine categories indicates a problem for that particular category and are to be treated by nursing staff (grade 2) or a dentist/physician (grade 3). A grade of 0 or 1 indicates no problems and does not require any clinical intervention.
[b] A mouth mirror can also be used.

Nine categories are included in the assessment: voice, swallowing, lips, mucous membranes, tongue, saliva, gums, teeth and dentures. The categories are evaluated and given a grading of 0 = not relevant to assess; 1 = healthy or normal condition; 2 = moderate changes/deviations; 3 = severe changes/deviations. A person who scores 2 or 3 on at least one category is considered to have an oral health problem, with a 3 being more serious. The grading for each of the 9 categories can be added together, for a maximum score of 27 points and a total number of 9 oral health problems. The ROAG-J also contains additional observations regarding number of teeth in the upper and lower jaw (more or fewer than 6 teeth) and the presence of denture or implants (upper jaw, lower jaw or both).

The ROAG-J assessment was carried out by the four study nurses after the unstimulated salivary flow test had been performed. Before the study, they attended a lecture on how to use the ROAG-J and received training from the dentist who held the lecture. The dentist (from TkMidt) also assisted the nurses in performing the ROAG-J on several geriatric patients on the first day of the study. One of the study nurses had the main responsibility for the ROAG-J in the present study and carried out most of the assessments (about 80-85% of all patients). Equipment was brought to the ward and consisted of a form to fill in the results from the salivary flow test and anthropometric and clinical measurements (weight, height, temperature) (Appendix 9), the ROAG-J form (Appendix 10) and the required equipment for performing the oral assessment in a hygienic manner (Appendix 11). Plastic toothbrushes were used for assessing the category “saliva” in the ROAG-J by sliding the lower end of the toothbrush against the patient’s oral mucosa (Table 3).

3.4.3 Questionnaire on oral health

Prior to study start, a questionnaire was developed to obtain self-reported data on oral health (Appendix 12). The questionnaire included questions used in the HUNT4 Oral health questionnaire (permission given by HUNT) and additional questions commonly used to assess xerostomia/hyposalivation (92). Four of the additional questions were developed by Fox et al. for assessing the severity of dry mouth and identifying those with a reduced unstimulated salivary flow rate (38). They were as follows: (1) Does the amount of saliva in your mouth seem to be too little? (2) Do you have difficulties swallowing any foods? (3) Does your mouth feel dry when eating a meal? (4) Do you sip liquids to aid in swallowing

dry foods? All four questions can individually be regarded as single (global) items used in assessing xerostomia.

Patients were given the questionnaire on oral health by the master student, at the same time as receiving the patient-generated part (page 1) of the PG-SGA. When needed, the master student assisted patients fill out the forms.

3.5 Statistical analyses

All statistical analyses were performed using SPSS (IBM SPSS Statistics 25). Analyses were performed by the master student, with input from two statisticians from TkMidt during two meetings in March 2019. *P*-values (2-sided) < 0.05 were regarded as statistically significant.

All data were plotted into WebCRF throughout the study. When exporting the data, the electronic database presented the results in an SPSS file. Continuous data were checked for normality with the Kolmogorov-Smirnov test and interpreted in conjunction with visual inspection of Q-Q plots and histograms. Normally distributed data were presented as means and standard deviations, and non-normally distributed data as medians and interquartile range (25^{th}–75^{th} -percentiles). For categorical data, frequencies and percentages were presented. Descriptive analyses were carried ouwort, followed by bivariate analyses between different groups. For categorical data, group differences were explored using the chi-square test, or Fisher's exact test when not all cells had expected values >5. When one category contained ordinal data (2x*k* table) and the expected cell count was not >5 for at least 80% of the cells, the linear-by-linear association test was used instead of the chi-square test. For continuous variables, the independent samples t-test was used to explore differences in means between groups with normally distributed data. The Mann-Whitney test was used to explore differences in medians between groups with non-normally distributed data.

Binary logistic regression analyses were performed to explore associations with nutritional status. The ratings in PG-SGA were dichotomized and included as the dependent variable: 0 = well-nourished (PG-SGA A), 1 = malnourished (PG-SGA B or C). The categories in the ROAG-J were also dichotomized: 0 = no problem (grade 0 or 1), 1 = problem (grade 2 or 3). Seven of the nine categories in the ROAG-J and the unstimulated salivary flow rate (0 = normal salivation, 1 = hyposalivation) were examined one by one as independent variables in univariate logistic regression analyses. A hierarchical method was then used by first

entering age (continuous variable) into the model as an independent variable (model 1), and then entering both age and gender (0 = man, 1 = woman) into the model as independent variables (model 2). The category saliva in ROAG-J was excluded and not entered as an independent variable due to few patients having problems (grade >1) with this category, the category dentures was excluded because few of the patients had partial or complete dentures. Binary logistic regression analyses were also performed to explore associations between salivary gland function and medication intake. Unstimulated salivary flow rate was included as the dependent variable (0 = normal salivation, 1 = hyposalivation), independent variables entered into the model (forced entry) were age, gender and number of orally administered medications on the day before the saliva test (continuous variable). The residuals for the logistic regression models and influence statistics (Cook's distance, DFBeta, leverage) were examined in order to assess if the models were a good fit of the data and if any cases exerted undue influence on each model (93).

Because of the pilot nature of the study, no classic sample size calculation was performed. It was expected that 13 wards had been included in the project by the end of week 4 in 2019. If around 10 people (50% of average number of hospital beds per ward) consented to participate at each ward, the sample size would end up being close to 130.

4 Results

4.1 Subject characteristics and participating wards

One hundred and eighteen patients from 18 different wards were included in the study. Subject characteristics and participating wards are presented in Table 4.

Median age was 68 years (range 21-94 years). Age distribution was 10% < 30 years, 43% 30-69 years and 47% ≥70 years. Age and age distribution did not differ between gender (56% men and 44% women). Mean (± SD) weight and BMI was 78.8 (± 20.4) kg and 26.5 (± 6.1) kg/m^2, respectively. BMI did not differ between gender. Fifty-seven percent of the patients were classified as either overweight or obese, 36% as normal weight and 7% as underweight. Weight and height were measured in 89 patients by the study nurses, data on weight and height for the remaining 29 patients were collected from the medical records.

The 18 wards are presented chronologically in Table 4 according to the number of participants. Eighty-six percent of patients came from somatic wards, the remaining 14% from psychiatric wards. The three wards with the biggest number of participants were the respiratory (n=12), orthopaedic (n=10) and gastrointestinal surgery (n=10) wards.

Table 4. Characteristics of the study population.

	All participants (n=118)	Men (n=66)	Women (n=52)	*P*-value[a]
Age[b], median years (IQR[c])	68 (49-75)	67 (49-74)	70 (46-78)	0.35[d]
Age categories				0.19[e]
18-29 years, n	12	7	5	
30-69 years, n	51	33	18	
≥70 years, n	55	26	29	
Weight, mean, kg (SD)	78.8 (20.4)	83.7 (20.6)	72.7 (18.5)	0.003[f]
Height, mean, m (SD)	1.72 (9.9)	1.78	1.64	<0.001[f]
BMI[g], mean, kg/m^2 (SD)	26.5 (6.1)	26.2 (5.9)	26.8 (6.4)	0.60[f]
Somatic wards	*n=101*	*n=57*	*n=44*	0.40[h]
Pulmonary Medicine, n	12	7	5	
Gastrointestinal Surgery, n	10	7	3	
Orthopaedic Surgery, n	10	2	8	
Oncology, n	9	2	7	
Rheumatology, n	9	5	4	
Geratric Medicine, n	8	5	3	
Cardiology, n	7	5	2	
Infectious Diseases, n	7	6	1	
Spinal Cord Injury, n	7	5	2	
Neurology, n	6	4	2	
Neurosurgery, n	6	4	2	
Ear Nose Throat & Eye, n	3	1	2	
Cardiothoracic Surgery, n	3	2	1	
Gynaecological Oncology, n	2	0	2	
Vascular-Breast-Endocrine Surgery, n	2	2	0	
Psychiatric wards	*n=17*	*n=9*	*n=8*	0.77[h]
Geriatric Psychiatry, n	9	5	4	
Nidaros District Psychiatric Center, n	5	2	3	
Special Ward 3 (Psychosis), n	3	2	1	

[a] Significance level $p<0.05$.
[b] Mean age was 62 years.
[c] Interquartile range (25^{th}–75^{th} -percentiles).
[d] Mann-Whitney test between men and women.
[e] Chi-square test between men and women.
[f] Independent samples t-test between men and women.
[g] Body mass index.
[h] Linear-by-linear test between men and women.

4.2 Nutritional and oral health status among participants

4.2.1 Malnutrition

The nutritional status of the study patients is presented in Figure 4. In total, 43% were categorized as well-nourished (n=51), 51% as moderately malnourished (n=60) and 6% as severely malnourished (n=7) (Figure 4a). The categories moderately (B) and severely malnourished (C) are grouped together and presented as the total number of malnourished patients in the results of this thesis, and will be compared with the category well-nourished (A) (Figure 4b). Compared with well-nourished patients, malnourished patients were older (p=0.002), with a median age of 70 years versus 62 years for well-nourished patients.

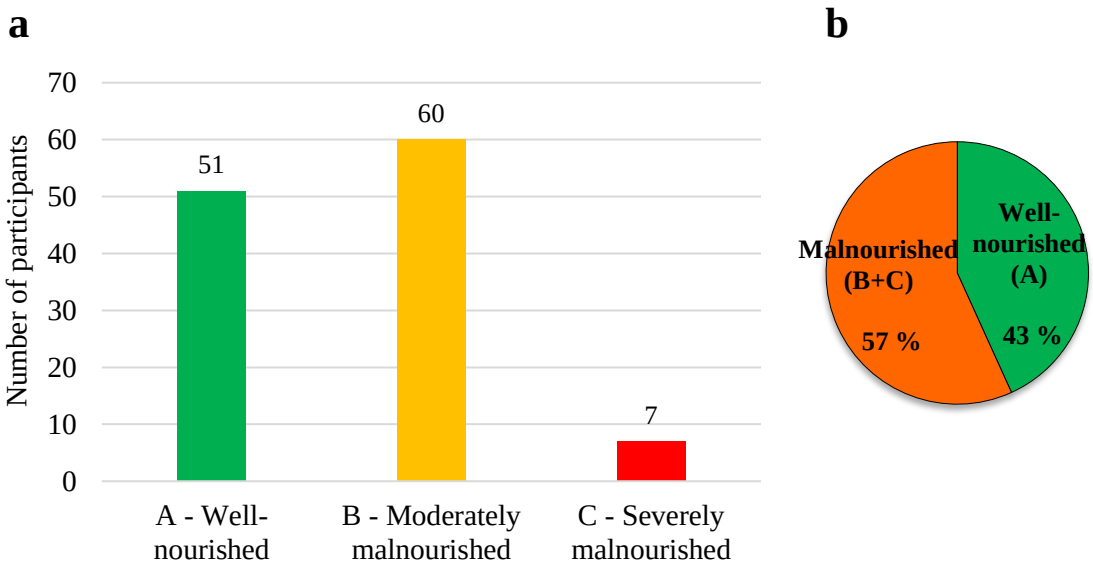

Figure 4. Nutritional status in participants. a) Global rating category measured by the Patient-Generated Subjective Global Assessment (PG-SGA) (n=118). b) Category B and C are combined into one category representing malnourished patients.

Regarding the scoring system of the PG-SGA (Figure 3, page 14), in total and 31% (both well- and malnourished) had a score in the range of 4-8 indicating a need for an intervention by a dietitian, and 38% (malnourished only) had a score ≥9 indicating a critical need for nutritional intervention and improved symptom management.

Data from the patient-generated component of the PG-SGA were further analyzed in more detail. Most importantly, 15% of all patients reported a weight loss of 5% or greater the last month, and 36% reported weight loss during the past two weeks. Furthermore, 42% reported a reduced food intake the last month, and 51% reported having at least one problem that had kept them from eating enough during the past two weeks.

Details of anthropometric measurements are presented in Table 5. Malnourished patients had lower values for all measurements. Regarding BMI categories, 46% overweight and 38% obese patients were classified as malnourished, as were all underweight patients. According to the mid-arm muscle circumference (MAMC), five patients were classified as moderately malnourished and eight patients as severely malnourished. The PG-SGA classified all these 13 patients as malnourished (B or C). Furthermore, the physical examination in PG-SGA identified 12 of these 13 to have a mild to severe total body deficit.

Table 5. Anthropometric measurements according to malnutrition[a].

	All participants (n=118)	Well-nourished (A) (n = 51)	Malnourished (B or C) (n = 67)	*P*-value[b]
Weight, mean, kg (SD)	78.8 (20.4)	86.7 (17.5)	72.9 (20.4)	<0.001[c]
BMI[d], mean, kg/m^2 (SD)	26.5 (6.1)	28.7 (5.3)	24.7 (6.2)	<0.001[c]
BMI categories				<0.001[e]
Underweight (BMI <18.5), n	8	0	8	
Normal (BMI 18.5-24.9), n	43	12	31	
Overweight (BMI 25-29.9), n	35	19	16	
Obese (BMI ≥30), n	32	20	12	
MUAC[f], mean, cm (SD)	30.4 (5.0)	32.9 (4.6)	28.5 (4.4)	<0.001[c]
TSF[g], mean, mm (SD)	16.2 (7.3)	19.3 (7.8)	13.8 (6.0)	<0.001[c]
MAMC[h], mean, cm (SD)	25.3 (3.8)	26.9 (3.8)	24.2 (3.4)	<0.001[c]
MAMC percentiles[i]				0.002[e]
Severely malnourished (p5), n	8	0	8	
Moderately malnourished (p10), n	5	0	5	
Well-nourished (>p10), n	105	51	54	

[a] Measured by the Patient-Generated Subjective Global Assessment (PG-SGA).
[b] Significance level $p<0.05$.
[c] Independent samples t-test between well- and malnourished patients.
[d] Body mass index.
[e] Linear-by-linear test between well- and malnourished patients.
[f] Mid-upper arm circumference.
[g] Triceps skinfold thickness.
[h] Mid-arm muscle circumference.
[i] Limit values for malnutrition is set at the 5 and 10-percentile for severe and moderate malnutrition, respectively, from reference data by Symreng (86).

4.2.2 Hyposalivation

The salivation status of the study patients is presented in Figure 5. In total, 19% of patients had hyposalivation (n=22). Six of the 22 patients with hyposalivation produced 0 ml of saliva during the test. The mean unstimulated salivary flow rate in study patients was 0.35 ml/min. Compared with patients with low or normal salivation, patients with hyposalivation tended to be older (p=0.06), with a median age of 67 for patients with low and normal salivation versus 70 years for those with hyposalivation.

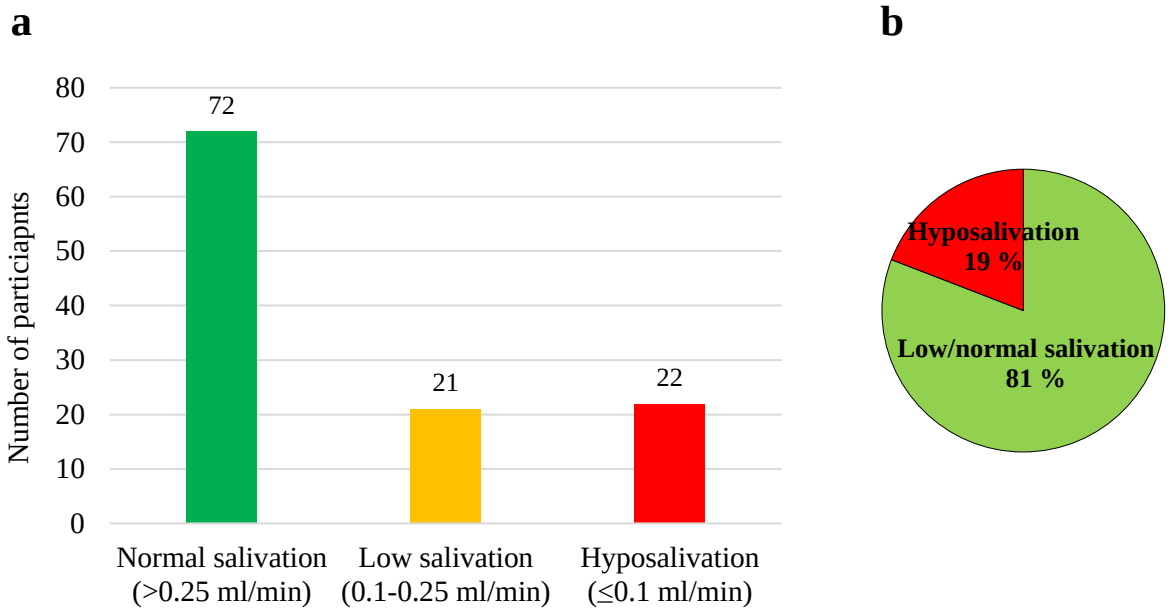

Figure 5. Salivary gland function in participants. Measured by the unstimulated salivary flow test. a) Salivation status of the participants (n=115). b) Normal and low salivation are combined into one category.

4.2.3 Oral health problems

Of the 118 patients, 93% were assessed as having at least one moderate or severe oral health problem (grade 2 or 3) by the ROAG-J (n=110). Eight patients had no problems (grade 0 or 1), while number of problems in the remaining 110 patients ranged from 1 to 7. For the patients having one or more problems, the most frequently occurring number of problems was 3, assessed in 33 patients. Further details of the distribution are presented in Figure 6.

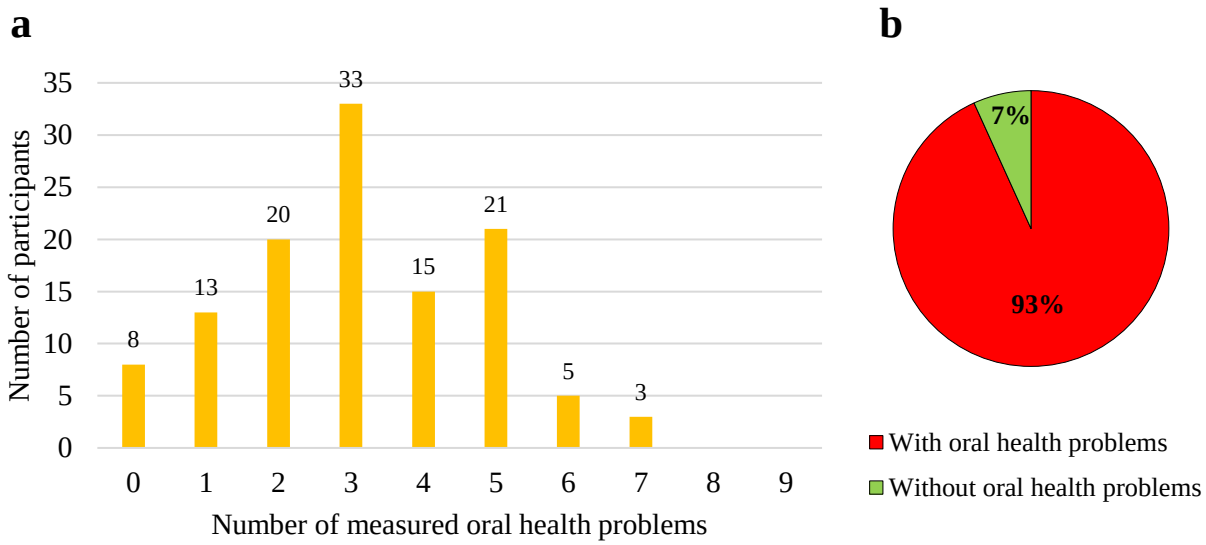

Figure 6. Oral health problems in participants. a) Number of problems measured by the Revised Oral Assessment Guide-Jönköping (ROAG-J) (n=118). A grade of 2 or 3 on one of the nine categories indicates a problem for that particular category. b) Patients with at least one problem are combined into one group.

The number of individual oral health problems is presented in Table 6. The highest proportion of oral health problems in patients was found regarding teeth (67%), lips (66%), dentures (56%) and the tongue (53%), respectively. The most severe problems (grade 3) were within teeth and the oral mucosa. Unclean or poorly functioning dentures was found in 56% of patients wearing dentures. Low saliva flow was the least frequent oral health problem, as only four patients were assessed to have increased friction when sliding the lower end of the plastic toothbrush along their buccal mucosa. All 22 patients identified with hyposalivation had at least one other oral health problem when assessed by the ROAG-J, with four problems being the most common.

The present study also included self-reported data of oral health. Results are presented in Table 7.

Table 6. Measured[a] oral health problems.

	Problem[b]		Grade 2 Moderate changes	Grade 3 Severe changes
Category	n	*%*	n	n
Voice	36	*31*	35	1
Swallowing	18	*15*	17	1
Lips	78	*66*	77	1
Mucous membranes	46	*39*	34	12
Tongue	62	*53*	61	1
Saliva	4	*3*	4	0
Gums	37	*31*	36	1
Teeth[c]	73	*67*	49	24
Dentures[d,e]	14	*56*	13	1

[a] By the Revised Oral Assessment Guide-Jönköping (ROAG-J), n=118.
[b] A grade of 2 or 3 on one of the nine categories indicates a problem for that particular category, while a grade of 0 (not relevant to assess) or 1 (healthy condition) indicates no problems.
[c] n= 109.
[d] n=25.
[e] Sixteen patients had partial dentures and 9 had complete dentures. Some participants had both dentures and teeth (n=16).

Table 7. Self-reported[a] oral health problems.

	Yes	
Question	n	*%*
1. Does the amount of saliva in your mouth seem to be too little?	35	*30*
2. Do you have difficulties swallowing any foods?	24	*21*
3. Does your mouth feel dry when eating a meal?	26	*22*
4. Do you sip liquids to aid in swallowing dry foods?	50	*43*
5. Are you bothered by dry mouth?	42	*36*
6. Are you able to chew all kinds of foods?	101	*86*

[a] Reported in the self-administered questionnaire on oral health. Missing data in one patient, n=117.

4.2.4 Malnutrition, hyposalivation and oral health problems in individual wards

An overview of the prevalence of malnutrition, hyposalivation and oral health problems in somatic wards, psychiatric wards and each separate ward is presented in Table 8. No differences between malnutrition, hyposalivation or oral health problems in somatic wards versus psychiatric wards were found (*p*-values between 0.38 and 1).

Table 8. Prevalence of malnutrition, hyposalivation and oral health problems in individual wards.[a]

	All participants (n=118)	Well-nourished (n = 51)	Mal-nourished (n = 67)	Low or normal salivation (n = 67)	Hypo-salivation (n = 22)	Without oral health problems (n =8)	With oral health problems (n = 110)
Somatic wards, n	101	42	59	79	19	8	93
Psychiatric wards, n	17	9	8	14	3	0	17
Separate wards							
Pulmonary Medicine, n	12	3	9	9	3	12	0
Gastrointestinal Surgery, n	10	2	8	7	2	10	0
Orthopaedic Surgery, n	10	4	6	7	3	9	1
Oncology, n	9	4	5	8	1	9	0
Rheumatology, n	9	9	0	7	1	5	4
Geriatric Psychiatry, n	9	3	6	7	2	9	0
Geratric Medicine, n	8	0	8	5	2	8	0
Cardiology, n	7	3	4	5	2	6	1
Infectious Diseases, n	7	4	3	6	1	5	2
Spinal Cord Injury, n	7	4	3	7	0	7	0
Neurology, n	6	2	4	6	0	6	0
Neurosurgery, n	6	4	2	5	1	6	0
Nidaros District Psychiatric Center, n	5	4	1	4	1	5	0
Ear Nose Throat & Eye, n	3	1	2	3	0	3	0
Cardiothoracic Surgery, n	3	1	2	2	1	3	0
Special Ward 3 (Psychosis), n	3	2	1	3	0	3	0
Gynaecological Oncology, n	2	0	2	0	2	2	0
Vascular-Breast-Endocrine Surgery, n	2	1	1	2	0	2	0

[a] Malnutrition measured by the Patient-Generated Subjective Global Assessment (PG-SGA) and defined as PG-SGA B or C; hyposalivation measured by the unstimulated salivary flow test and defined as salivary flow rate $\leq$0.1 ml/min (missing data in three patients); oral health problems defined as at least one problem (grade 2 or 3) on one of the nine oral health factors examined in the Revised Oral Assessment Guide-Jönköping (ROAG-J).

4.3 Associations between oral health and malnutrition

4.3.1 Hyposalivation and malnutrition

Salivation status for patients categorized as well- versus malnourished are presented in Table 9. Among the 22 participants measured to have hyposalivation, 77% were categorized as malnourished compared with 53% in patients without hyposalivation (p=0.04).

Table 9. Hyposalivation according to malnutrition[a].

	Well-nourished (A) (n = 51)	Malnourished (B or C) (n = 67)	*P*-value[b]
Unstimulated salivary flow[c]			0.04
Hyposalivation (≤0.1 ml/min), n=22	5	17	
Low/normal salivation (>0.1 ml/min), n=93	44	49	

[a] Measured by the Patient-Generated Subjective Global Assessment (PG-SGA).
[b] Chi-square test between well- and malnourished patients. Significance level p<0.05.
[c] Missing data in three of 118 patients, n=115.

4.3.2 Oral health assessment and malnutrition

Problems with different oral health factors were more common in malnourished patients (Table 10). This included problems regarding the lips, mucous membranes and teeth. Each category in the ROAG-J is graded, and the total score and number of patients scoring a 2 or 3 at least once was higher in malnourished patients compared with well-nourished patients (p<0.001 for both). Problems with dentures tended to be more common in malnourished patients (p=0.08), as did the presence of less than 12 teeth in the mouth (p=0.07) when compared to those well-nourished.

As shown in Figure 6a, eight of the 118 patients were assessed to have no oral health problems. All eight were well-nourished, whereas 67 of the remaining 110 patients with at least one oral health problem were malnourished (p=0.001). For the categories voice, swallowing, lips, tongue, gums and dentures, a grade of 3 (severe changes/problems) was given to malnourished patients only. The majority of patients who received grade 3 for the mucous membranes and teeth were also malnourished.

Table 10. Oral health problems[a] according to malnutrition[b].

Category[c]	Well-nourished (A) (n = 51)	Malnourished (B or C) (n = 67)	*P*-value[d]
Voice, n	13	23	0.30[e]
Swallowing, n	8	10	0.91[e]
Lips, n	26	52	0.002[e]
Mucous membranes, n	11	35	0.001[e]
Tongue, n	25	37	0.50[e]
Saliva, n	0	4	0.13[f]
Gums, n	13	24	0.23[e]
Teeth[g], n	25	48	0.001[e]
Dentures[h], n	2	12	0.08[f]
Total score[i], median (IQR[j])	11 (9-12)	12 (11-14)	<0.001[k]
With oral health problems[l], n	43	67	<0.001[f]

[a] Measured by the Revised Oral Assessment Guide – Jönköping (ROAG-J), n=118.
[b] Measured by the Patient-Generated Subjective Global Assessment (PG-SGA).
[c] Dichotomised categories, where a score of 2 or 3 indicates a problem for each of the nine categories.
[d] Significance level $p<0.05$.
[e] Chi-square test between well- and malnourished patients.
[f] Fisher's exact test between well- and malnourished patients.
[g] n=109.
[h] n=25.
[i] Obtained by summarizing each grade (0, 1, 2 or 3) for all 9 categories, maximum 27 points.
[j] Interquartile range (25^{th}–75^{th} -percentiles).
[k] Mann-Whitney test between well- and malnourished patients.
[l] Participants scoring a 2 or 3 at least once on the ROAG-J.

4.3.3 Self-reported oral health and malnutrition

The associations between oral health and malnutrition when the former was self-reported are presented in Table 11. Answering "Yes" to needing liquids to aid in swallowing dry foods and "No" to being able to chew all kinds of foods was associated with malnutrition. Answering "Yes" to being bothered by dry mouth tended to be associated with malnutrition.

Among the seven patients categorized as severely malnourished (PG-SGA category C, Figure 4b), the majority answered "Yes" to questions 1-5 and "No" to question 6 (Table 11). With nutritional status divided into three categories (PG-SGA A, B and C), a linear association was found for perception of too little saliva in the mouth (p=0.047), dryness in the mouth while eating (p=0.038), needing liquids to aid in swallowing dry foods (p=0.009), being bothered by dryness in the mouth (p=0.016) and not being able to chew all kinds of foods (p=0.008).

Table 11. Self-reported[a] oral health problems according to malnutrition[b].

Question	Well-nourished (A) (n = 50)	Mal-nourished (B or C) (n = 67)	*P*-value[c]
1. Does the amount of saliva in your mouth seem to be too little?			0.23[d]
Yes[e]	12	23	
No[e]	38	44	
2. Do you have difficulties swallowing any foods?			0.30[d]
Yes[e]	8	16	
No[e]	42	51	
3. Does your mouth feel dry when eating a meal?			0.34[d]
Yes[e]	9	17	
No[e]	41	50	
4. Do you sip liquids to aid in swallowing dry foods?			0.02[d]
Yes[e]	15	35	
No[e]	35	32	
5. Are you bothered by dry mouth?			0.05[d]
Yes[e]	13	29	
No[e]	37	38	
6. Are you able to chew all kinds of foods?			<0.01[d]
Yes[e]	48	53	
No[e]	2	14	

[a] Reported by the patients with the self-administered oral health questionnaire. Missing data in one of the 118 participants, n=117.
[b] Measured by the Patient-Generated Subjective Global Assessment (PG-SGA).
[c] Significance level $p<0.05$.
[d] Chi-square test between well- and malnourished patients.
[e] All cells contain number of participants answering "Yes" or "No" to each respective question.

4.4 Medication intake

4.4.1 Number of medications

Medication intake in patients is presented in Figure 7. Median number of different administered medications on the day before the saliva test in patients was 5 (IQR 3-8). Polypharmacy, defined as taking ≥5 medications per day, was present in 53% of patients (n=55). Excessive polypharmacy, defined as taking ≥10 medications, was present in 14% of patients (n=16) (Figure 7b).

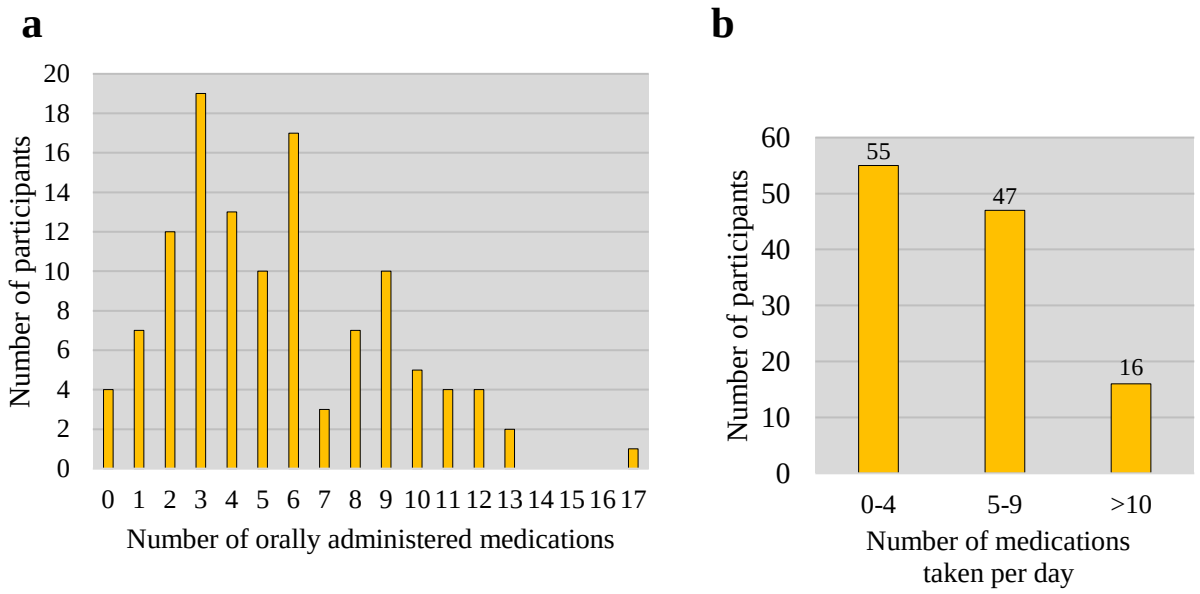

Figure 7. Medication intake in participants. a) Number of different medications administered orally in patients on the day before the saliva test (n=118). b) Concurrent use of multiple orally administered medications grouped into three categories.

4.4.2 Associations between medication intake and hyposalivation

The intake of orally administered medications per day was higher in patients with hyposalivation (median number 8) compared with patients without hyposalivation (median number 4) (Figure 8a). Furthermore, the prevalence of hyposalivation increased with increasing medication intake (Figure 8b).

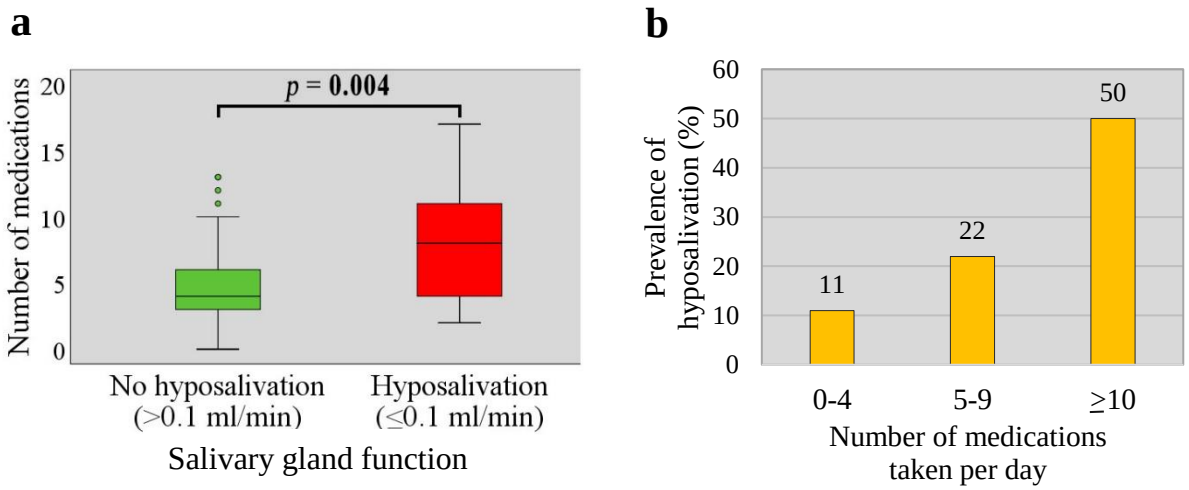

Figure 8. Number of medications per day according to salivary gland function. a) Boxplots show the number of different orally administered medications on the day before the saliva test for those without and with hyposalivation (n=118). Statistics were performed with the Mann-Whitney test, significance level $p<0.05$. b) Prevalence of hyposalivation in patients, shown according to medication intake grouped into three categories.

Among the 22 patients with hyposalivation, 73% (n=16) received polypharmacy (≥5 medications). In patients without hyposalivation, polypharmacy was present in 48% (p=0.04 compared with patients with hyposalivation). Excessive polypharmacy (≥10 medications) was present in 36% of patients with hyposalivation and 9% of patients without hyposalivation (p=0.003).The most common medications in patients with hyposalivation were analgesics (16 patients), hypnotics (13 patients), antihypertensives (11 patients), cardiac medications (10 patients), anticoagulants (9 patients), antacids (8 patients) and nutritional supplements (8 patients).

4.5 Nutritional risk and malnutrition

4.5.1 Screening of nutritional risk at the hospital

Results of the data collection process from patients' nutritional risk screening in their medical records is presented in Figure 9. Out of all 118 patients, 21 had not been screened at the hospital during either the last seven days or the next seven days after consenting to participate in the study. Among the 97 patients screened with the NRS 2002 tool, 11 patients had a score of 3 or higher. In other words, 11% of the 97 participants screened at the hospital were found to be at nutritional risk.

Some flaws in the hospital screening were detected. In eight patients, the formal screening in NRS 2002 had been performed even though the answer to all four questions in the introductory screening was "No". In 21 patients, the formal screening had not been performed even though the introductory screening contained at least one "Yes". In 30 patients, many of the four introductory questions remained unanswered, e.g. 26 nutrition screenings contained three unanswered question. The only question answered in the majority of these 26 screenings was the first out of the four questions ("Is BMI <20.5?"), which was calculated automatically when the values of weight and height were registered.

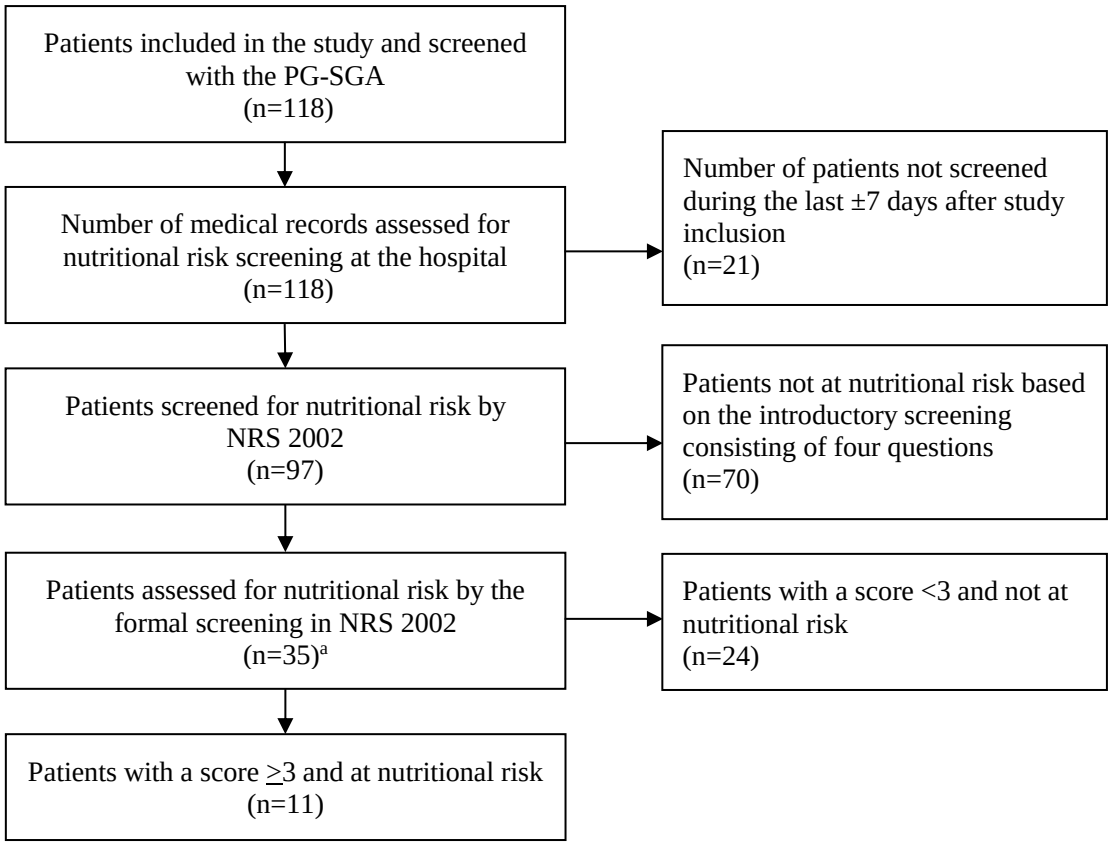

Figure 9. Nutritional risk screening of patients. Flow diagram showing number of patients at nutritional risk based on the Nutritional risk screening (NRS 2002) results collected from 118 medical records.
[a] The formal screening was carried out in eight patients even though the answer was "No" to all four questions in the introductory screening. None of these patients got a score ≥3.

4.5.2 Associations between malnutrition and nutritional risk

In total, 67 of the study patients were categorized as malnourished (PG-SGA B or C). Of the 67 patients with malnutrition, 58 had been screened for nutritional risk at the hospital. Among these 58 inpatients, 11 were screened to be at nutritional risk (score >3). The proportion of malnourished patients (PG-SGA B or C) screened and classified as at nutritional risk by NRS 2002 used at the hospital, was therefore 19%.

All well-nourished patients (PG-SGA A) screened at the hospital were classified as not at nutritional risk by the NRS 2002, but the negative predictive value was 45%, meaning that a patient screened to not be at nutritional risk at the hospital had a probability of 55% of being malnourished.

4.6 Logistic regression analyses

4.6.1 Associations between oral health and malnutrition

Oral health factors and their association with malnutrition according to binary logistic regression analyses is presented in Table 12. The four factors significantly associated with malnutrition in the univariate analyses were hyposalivation measured by the unstimulated salivary flow test, and problems with the lips, mucous membranes and teeth measured by the ROAG-J.

Table 12. Odds ratios[a] for malnutrition[b] in relation to oral health problems.

	Unadjusted		**Adjusted, model 1**[c]		**Adjusted, model 2**[c]	
Independent variable[d]	Odds ratio (95% CI)	*P*-value[e]	Odds ratio (95% CI)	*P*-value[e]	Odds ratio (95% CI)	*P*-value[e]
Hyposalivation[f,g]	3.05 (1.04, 8.96)	0.04	2.34 (0.77, 7.10)	0.13	2.26 (0.74, 6.87)	0.15
Voice	1.53 (0.68, 3.42)	0.30	1.11 (0.47, 2.61)	0.82	1.05 (0.44, 2.55)	0.91
Swallowing	0.94 (0.34, 2.59)	0.91	0.80 (0.28, 2.31)	0.68	0.85 (0.29, 2.47)	0.76
Lips	3.33 (1.51, 7.38)	0.003	3.98 (1.71, 9.25)	0.001	4.22 (1.78, 9.94)	0.001
Mucous membranes	3.98 (1.75, 9.05)	0.001	4.50 (1.86, 10.84)	0.001	4.67 (1.92, 11.36)	0.001
Tongue	1.28 (0.62, 2.66)	0.50	1.27 (0.59, 2.72)	0.54	1.22 (0.57, 2.64)	0.61
Gums	1.63 (0.73, 3.65)	0.23	1.88 (0.80, 4.42)	0.15	1.85 (0.78, 4.37)	0.16
Teeth[h]	3.38 (1.65, 8.94)	0.002	3.65 (1.53, 8.72)	0.004	3.62 (1.51, 8.72)	0.004

[a] Binary logistic regression.
[b] Measured by the Patient-Generated Subjective Global Assessment (PG-SGA), n=118.
[c] Model 1 adjusted for age, model 2 adjusted for age and gender. Age was entered as a continuous variable. Reference category for the dependent variable is well-nourished (PG-SGA A).
[d] Hyposalivation measured by the unstimulated salivary flow test, and 7 dichotomised categories from the ROAG-J (no problem = 0 set as a reference).
[e] Significance level $p<0.05$.
[f] Statistics for the adjusted model 2 with hyposalivation as the independent variable: $R^2 = 0.10$ (Cox–Snell), 0.13 (Nagelkerke). Model $\chi^2(3) = 12.04$, $p=0.007$. Hosmer and Lemeshow goodness-of-fit statistic, $p=0.90$.
[g] Missing data in three patients.
[h] Missing data in nine patients.

Compared to patients without hyposalivation, patients with hyposalivation had 3.05 higher odds of malnutrition in the univariate analysis (95% CI 1.04-8.96). After adjusting for age and gender in model 2, the odds ratio (OR) decreased to 2.26 (95% CI 0.74-6.87). The variables included in the model explained 13% of the variance according to Nagelkerke's R^2. Problems related to the mucous membranes (OR 4.67), lips (OR 4.22) and teeth (OR 3.62) remained significantly associated with malnutrition after adjusting for age and gender (p<0.01 for all three categories).

4.6.2 Associations between medication intake and hyposalivation

By adjusting for age and gender, the number of orally administered medications per day was still significantly associated with increased risk of hyposalivation. The outcome of the final logistic regression model is presented in Table 13. As the number of different medications increased by one, the odds of hyposalivation increased with 22% (95% CI 1.05-1.42). Age also tended to be associated with risk of hyposalivation, as the odds increased by 4% with each unit increase in age (p=0.05). The variables included in the model explained 23% of the variance according to Nagelkerke's R^2.

Table 13. Regression model predicting whether a patient had hyposalivation[a] based on medication intake[b].

				95% CI for Odds ratio	
Predictors[c]	*B* (SE)	*P*-value[d]	Odds ratio	Lower	Upper
Number of medications[e]	0.20 (0.08)	0.01	1.22	1.05	1.42
Age	0.04 (0.02)	0.05	1.04	1.00	1.09
Gender	-0.52 (0.55)	0.35	0.60	0.20	1.76

R^2 = 0.14 (Cox–Snell), 0.23 (Nagelkerke). Model $\chi^2(3) = 17.56$, p=0.001. Hosmer and Lemeshow goodness-of-fit statistic, p=0.86.

[a] Defined as an unstimulated salivary flow rate ≤0.1 ml/min (n=22).

[b] One case excluded from the final model after analyzing the residuals (standardized residual of 4.6) and influence statistics (Cook's distance substantially larger than the rest at 0.6). Reason for case being unusual: recent abuse of drugs causing hyposalivation. N=114.

[c] Number of medications and age were entered as continuous variables. Gender was coded as: male = 0, female = 1.

[d] Significance level p<0.05.

[e] Number of different medications administered orally on the day before the saliva test.

5 Discussion

5.1 Methodology

5.1.1 Nutritional assessment methods

The tool used to assess malnutrition in this study was the PG-SGA, a widely used method that is quick and noninvasive. Originally developed for use in an oncologic setting and demonstrated to predict clinical outcomes in cancer patients (81,94–96), the PG-SGA can also be used as a prognostic tool in non-cancer patients (97–99). As such, it is not only applicable in an oncology setting but can be used in the general hospital setting as in the present study, where the tool was chosen primarily to diagnose malnutrition. The PG-SGA has recently been shown to be one of the few assessment tools that covers all three domains within the definitions of malnutrition as defined by ESPEN (4) and the American Society for Parenteral and Enteral Nutrition (1) (ASPEN) (100). The domains include 1: nutrient balance; 2: body weight, body area and body composition; 3: function. PG-SGA Category B or C were also recently added as criteria for malnutrition in the Norwegian edition of ICD-10 in 2019 (101).

Compared to a number of other screening tools, PG-SGA can not only be used for early detection of malnutrition, but has been described as a 4-in-1 instrument capable of both screening patients, assessing nutritional status, triaging interventions and monitoring intervention outcomes (80). The screening tool NRS 2002 used as a St. Olavs hospital on the other hand, was not designed as an assessment instrument capable of diagnosing malnutrition, but as a tool to identify patients at nutritional risk and in need of nutritional support (87). NRS 2002 is quick and easy to use, making it an ideal tool in the hospital setting when the goal is to identify patients at nutritional risk (102). The national guidelines specify that all patients are to be screened when admitted to a hospital (7), and as such, information on the patients was collected from the medical records of the hospital NRS 2002 screening, in order to assess whether participants categorized as malnourished by the PG-SGA had been screened to be at nutritional risk.

The most recent Norwegian version of PG-SGA was used in the present study. This version has been translated and culturally adapted, and the previous version was shown to have a clear comprehensibility and to be easy to complete by a group of cancer patients (103). A qualitative study in a group of cancer patients showed that the majority had no problems understanding how to complete and fill out the questionnaire (104). A few challenges were noted, however. Patients tended to read and respond quickly to some of the questions, resulting in them not noticing which time period the questions were referring to when asking about changes in food intake. To overcome this and hopefully minimize response errors in the present study, each patient had the opportunity to ask the master student questions if anything was unclear. When collecting each form, the answers were also briefly reviewed by the student to see if any questions were unanswered or incorrectly filled out. All of the physical examinations performed as part of the professional component was carried out by the master student, strengthening the reliability of the assessments.

Additional measurements were taken for both TSF thickness and the MUAC when performing the physical examination in PG-SGA, in order to obtain an objective measure of muscle mass in the form of the MAMC. The measurements of TSF thickness and the MUAC were chosen as they are quick to perform and can easily be completed by the bedside of patients (105). Although not as accurate as a method such as bioelectrical impedance analysis (BIA), MAMC is a non-invasive and inexpensive method that can function as an early indicator of depletion of muscle protein stores. Lower values have been associated with increased risk of mortality in different clinical and public health settings (106), and reference values can be used to classify patients as moderately or severely malnourished (19). In support of obtaining an objective estimation of muscle mass, a recent study found low agreement between PG-SGA global category and reduced fat free mass index (FFMI) measured by BIA in patients with colorectal cancer (107). Only 50% of patients with a low FFMI were categorized as malnourished. The authors further found that the physical examination in the professional component was not sensitive enough to detect muscle mass depletion, particularly in overweight and obese individuals. The authors concluded by recommending that the PG-SGA should be supplemented with a method capable of assessing muscle mass in order to identify low FFM in their patient group.

Portable weight and height scales were brought to each ward in order to obtain standardized weight and height measurements. When measurements could not be performed at the ward,

data were collected from the medical journals in order to obtain data of all patients. The BMI could then be calculated for each patient. A BMI under 18.5 kg/m^2 is the cut-off for underweight as advocated by the WHO and one of the accepted criterions by ESPEN to diagnose malnutrition (4,84). The BMI value does however not differentiate between subcutaneous fat, visceral fat and fat free mass, and studies utilizing computed tomography have demonstrated that sarcopenic patients classified as overweight or obese may have an equally low muscle mass as underweight patients (108,109). The BMI may therefore not be sensitive enough to detect muscle mass depletion. By measuring weight and height however, the BMI classification of the participants could be used to explore the relationship with the PG-SGA, e.g. how many malnourished patients were classified as overweight and obese.

5.1.2 Oral health assessment methods

Sialometry is a commonly used method in academic settings, as it is a non-invasive and reliable method that can identify patients with salivary hypofunction (110). The method is also used among dentists to identify patients with salivary gland disorders and hyposalivation(110). In the present study, the unstimulated salivary flow test was performed by using the spit method, as the draining method where patients drools into a funnel is often perceived as unpleasant (46). Unlike the draining method were saliva is crystal clear, however, the sample tends to be somewhat opalescent with the spit method, indicating that the sample is not performed completely unstimulated and may somewhat overestimate the salivary flow rate. A standardized protocol was followed by the study nurses performing the test. Standardization is important, as small deviations from a standard can lead to large differences in volume (42). Unstimulated saliva is significantly influenced by different factors such as the position of the body, temperature, previous stimulation, hydration status and time of day. Except for after an overnight fast, the best time for collecting saliva is said to be between 08.00-11.00. Because of the study design and the study nurses' schedule, most collections were made between 08.00-12.30. It is recommended that patients should refrain from eating or drinking preferably 90 minutes prior to the test (34), but due to the hospital setting and design of the study 30 minutes were chosen as a minimum, as having patients refrain from putting anything in their mouth for one and a half hours or more would not be feasible. The collection time was set to 5 minutes, which is the minimum time for obtaining reliable results. Ten to fifteen minutes would have been even better, but since the

anthropometric measurements (weight and height) and the ROAG-J had to be performed after the saliva test this would have added too much time to each patient visit.

The ROAG-J assessment covers a wide range of oral health factors, can be used by the hospital bed and is relatively easy to use. Other alternative tools such as the Oral Health Assessment Tool (111) is also available for assessing oral health, but in Sweden, the ROAG is commonly used within daily nursing care (112) and has been demonstrated to be a useful tool for identifying oral health problems in geriatric patients (56). It has also been shown to have a moderate to very good inter-rater reliability for all categories, with a high percentage agreement between a registered nurse and a dental hygienist in all categories (70-91%) except for the combined category of teeth/dentures (58%) (90). The study nurses in the present study received training from a dentist in the form of a lecture, training session and assistance at the first ward. Most of the assessments (80-85%) were carried out by one of the study nurses, and a visual guide consisting of oral pictures matched to the different gradings in ROAG was also brought to each ward. A previous study showed that the inter-rater reliability for all the categories was considered either poor or fair according to Cohen's Kappa coefficient (113), but nurses performing the assessment received no training prior to study start. High intra-rater reproducibility was observed between community health workers (CHW) in another study for all categories except saliva, teeth and dentures (114). In addition, CHWs and a dentist independently evaluated individuals in order to assess the validity, showing a good specificity for all categories (range 0.69 to 0.98) and a good sensitivity for most categories (1.0 for swallow) except oral mucosa (0.33), lips (0.25) and saliva; the saliva test performed using a gloved finger had a sensitivity of only 0.17, and a sensitivity of 0 when performed with a mouth mirror (114).

The self-administered questionnaire used in the present study was developed by combining several questions from HUNT4 questionnaires and the literature, such as the four simple yes/no questions (Table 7) from the questionnaire by Fox et al. (38) intended for use in detecting hyposalivation. More comprehensive questionnaires to assess dry mouth have been developed and would have been valid alternatives to the four selected questions, such as the Xerostomia Inventory, consisting of an eleven-item summated rating scale assessing the severity of xerostomia (39). In the end, the questions from Fox et al. were chosen based on their simplicity, strong association with hyposalivation and relevance with regard to nutrition related problems (e.g. “do you sip liquids to aid in swallowing dry foods”).

Considered the most important risk factor for dry mouth, medication use was collected from the medical journals by the master student. For every patient, information on orally administered medications ingested on the day before the saliva test were written down and transferred to WebCRF. As such, this provided a comprehensive snapshot in time of what the patients were ingesting and the overall number of different medications. Some limitations with this approach are apparent, as the hospital setting could result in an increased number and type of prescribed medications compared to the out-of-hospital situation. At the same time, depending on the time of admission and the xerogenic effect of each medication, some medications may not have been ingested long enough to have an effect on the salivary output.

5.1.3 Study design and generalizability

The cross-sectional study design is advantageous in that it provides a relatively quick method when combined with the validated instruments to assess the prevalence of malnutrition and oral health problems at the hospital. Associations between any of the collected variables can be described, but at the same time no causality can be inferred since temporality is not known, i.e. malnutrition and an oral health factor may be associated but since the outcomes were measured simultaneously it is difficult to infer whether one or the other came first.

All data were plotted into WebCRF. In this database, each physical questionnaire had been converted into digital questionnaires consisting of checkboxes, radio buttons and text fields prior to study start. This allowed for easy transfer of data into a digital form, and greatly minimized the risk of errors when transferring the dataset to SPSS for statistical analysis.

Based on previous studies (56,57), a sample size of >100 was preferred. Of the 188 patients asked to participate in the study, 130 ended up consenting and 118 ended up completing the assessments (Figure 2). Almost 150 patients could not be included due to either disease isolation, hospital discharge/transfer or exclusion as a result of talking with the nurses at the wards. As no information about the excluded patients was available, this is a limitation of the study since these patients could have differed from the ones who were included (selection bias). Still, the several included wards in the study are a major strength, as the study ended up including patients from 18 different wards. A wide variety of patients with different diseases were therefore assessed, including patients from both somatic and

psychiatric wards, meaning the results of the assessments should have good generalizability to the hospital as a whole.

5.2 Discussion of results

5.2.1 Prevalence of malnutrition and oral health problems

According to the PG-SGA Global rating results obtained in this study, 57% of a sample of 118 hospitalized patients were malnourished. The highest prevalence was found in the wards of Geriatric Medicine, Gynaecological Oncology and Gastrointestinal Surgery, respectively. The unstimulated salivary flow test showed that 19% of patients had hyposalivation, with the highest prevalence found in the wards of Gynaecological Oncology, Cardiothoracic Surgery, Orthopaedic Surgery, Geriatric Medicine and Cardiology, respectively. According to the ROAG-J assessment, oral health problems were found in 93% of patients. In 14 of 18 wards all patients were found to have problems. The most frequent oral health problems were related to lips, teeth and the tongue, respectively. Subjective oral health problems were also reported, with the most prevalent problems being the need to sip liquids to aid in swallowing dry foods in 43% of patients and being bothered by dry mouth in 36% of patients.

Considering the number of malnourished patients in hospitals ranges from 20-60% (10,115), the number of patients with malnutrition in the present study was relatively high. In comparison to recent studies in Norwegian hospitals it was even higher, with estimates of malnutrition or risk of malnutrition usually reported to 30% (11,12). In hospitalized patients with a mean age of 80 years compared to 62 years in the present study, the prevalence of patients at nutritional risk was reported to be 45% (14). Studies performed over a decade ago reported estimates between 50-75% (13,116), among them a study performed at St. Olavs hospital in cancer patients where 65% of patients were malnourished (73). In the present study the prevalence was 55% in the ward of Oncology, albeit with a smaller sample size.

In comparison to a previous study performed at the hospital where 41% reported problems that had kept them from eating enough during the past weeks (72), a slightly higher proportion of patients (51%) reported problems in the present study. Weight loss during the last two weeks was reported in 36% of patients, similar to a point-prevalence study performed at Oslo University Hospital and University Hospital of Northern Norway where 37% of

patients reported losing weight within the last three months (11). The high prevalence of weight loss and problems related to food intake in patients indicate a great need for nutritional support, and by calculating the PG-SGA total score is was found that 69% of patients in the present study were in need for a nutrition intervention by a clinical dietitian.

Unsurprisingly, all anthropometric measurements were lower in malnourished patients. Every underweight patient (BMI <18.5 kg/m^2) was malnourished, but of the 67 malnourished patients only 8 were underweight, indicating that routine weighing alone is not sufficient to detect malnourished patients. Malnutrition was common in overweight and obese patients too, with 24% of patients with BMI $\geq$25 kg/m^2 classified as malnourished. This is in line with a previous study at Haukeland University hospital, where 23% of overweight and obese patients were found to be at nutritional risk (12). According to the reference values for the MAMC (86), all 13 malnourished patients (below the 10-percentile) were classified as malnourished by the PG-SGA. This is in contrast to Ræder et al. (107), where 50% of cancer patients with low FFMI were classified as malnourished by the PG-SGA. Although MAMC is not an ideal measurement of fat free mass, it can be used as a surrogate of total body muscle mass and has been shown to correlate well (r = 0.54) with dual-energy X-ray absorptiometry measured lean body mass in hemodialysis patients (117). A high agreement was therefore found in the present study between the PG-SGA and low muscle mass in patients with a variety of diseases. In addition, of the 13 patients classified as malnourished according to the MAMC, 12 were identified to have a mild to severe total body deficit (score 1-3) by the physical examination in PG-SGA, with only one patient below the 10-percentile classified as having no deficit (score 0).

One in five patients were measured to have hyposalivation, in line with the range of 5-47% estimated in older institutionalized and non-institutionalized adults (47). Few studies have been performed on hospitalized patients, however. One study reported a prevalence of 17% and 27% in hospitalized elders for unstimulated and stimulated saliva, respectively (62). Another study in long-term hospitals found 43% of patients to have hyposalivation, measured by the stimulated salivary flow test (118). A third study also measured stimulated saliva, and reported hyposalivation in 58% of hospital patients (119). Although the prevalence was under twice as low in the present study, the result was similar to the first study measuring unstimulated saliva. Still, the number of patients with reduced salivary flow may have been underestimated due to the aforementioned problem with the unstimulated

spit method possibly causing some stimulated saliva to be secreted in the collecting vessel. In line with the salivary test result, 21-43% of the patients answered “Yes” to one or more of the four questions from Fox et al. (38) (Table 7). This is also within the known range of 20-40% for xerostomia prevalence in institutionalized and non-institutionalized adults, where older adults tend to lie toward the higher end of the range (33,46). Together with the salivary flow test, these results indicate that dry mouth is a common problem at the hospital.

The main finding from the assessment performed by the study nurses (ROAG-J) was that 93% of all patients had moderate or severe oral health problems. This is higher compared to many other studies, where the prevalence in the elderly has been reported in the range of 29-85% (56,57,59,112,120,121). Contrary to the prevalence of hyposalivation and xerostomia in the present study, only 3% of patients were evaluated to have a low saliva flow by the ROAG-J. This finding was similar to a recent study where the prevalence was approximately 5% in individuals receiving elder care (112), but in contrast to previous studies where the prevalence in elderly patients ranged from 19-64% (56,57,120). There may be several reasons for this, e.g. different populations or varying degrees of experience with the assessment in staff conducting the examination. Another explanation is methodological differences, as the instrument used to evaluate saliva in the present study was a plastic toothbrush, used by sliding its lower end against the buccal mucosa in patients. A mouth mirror or spoon is also recommended (91), which may adhere more strongly to the mucosa due to the larger surface area. Despite this, the mirror method has been shown to have lower sensitivity (0) compared to evaluating saliva with a gloved finger (0.17) when trained community health workers and a dentist performed independent oral examinations (114). Excluding the mirror method, the gloved finger method still had the lowest sensitivity out of all categories in the ROAG-J. Another study showed moderate inter-rater agreement between a trained registered nurse and a dental hygienist using the mouth mirror (90), indicating that staff performing the saliva flow evaluation should be aware of these discrepancies and receive sufficient training and education beforehand.

The remaining oral health problems measured by the ROAG-J ranged from 15% (swallowing) to 67% (teeth). Problems related to the lips were found in 66% of patients, a relatively high proportion as findings from other studies have ranged from 5-29% (56,112,120,122), with the exception of Andersson et al. who reported a prevalence of 55% (57). The most severe problems were found regarding the teeth, with 20% of patients

receiving a grade of 3 and found to have plaque/generalized debris or severely damaged teeth. This is concerning, as poor teeth status may cause pain, loss of self-esteem and dysfunction (123). In patients with hyposalivation the situation is even worse, as the reduced salivary output can lead to a rapid worsening of caries development, tooth loss and eventually edentulism if not treated (37).

5.2.2 Associations between oral health problems and malnutrition

When studying the association of malnutrition and poor oral health in hospitalized patients, this study found a positive association between malnutrition and the presence of at least one oral health problem. Poor nutritional status was furthermore associated with several individual oral health factors. Specifically, hyposalivation and problems with the lips, oral mucosa and teeth were associated with malnutrition. When adjusting for age and gender, associations for all problems except for hyposalivation remained significant. In addition, malnutrition was higher in patients reporting a need to sip liquids to aid in swallowing dry foods and in patients who reported not being able to chew all kinds of foods. Taken together, these findings reveal that oral health may be a neglected health area for many patients at the hospital and that oral health assessments should be included in the general care of patients.

Three in four patients with low unstimulated salivary flow rate were malnourished, compared to two in four patients without hyposalivation. This indicate that malnutrition is prevalent in hospital patients with reduced salivary gland function, and that hyposalivation is a risk factor for poor nutritional status. Patients with hyposalivation had 3.1 higher odds of malnutrition compared with patients without hyposalivation, but after adjusting for age and gender in logistic regression analyses the association disappeared (OR 2.26, 95% CI 0.74-6.87). However, the wide confidence interval suggests that there may still be an association, but that the sample size was too small in order to detect a significant difference. Unfortunately, few other studies in Norwegian hospitals have measured salivary gland function of inpatients, making comparisons difficult. Dormenval et al. found that malnutrition (defined as BMI <21) was more common in Swiss hospital patients with hyposalivation compared to those without (62), and Srinivasulu et al. found a significantly decreased stimulated salivary flow rate in malnourished (mean 0.5 ml/min) compared to well-nourished (mean 0.9 ml/min) institutionalized Indian elderly assessed with the MNA screening tool (124). In elderly and in visually impaired elderly Thai, subjects with

hyposalivation had significantly lower scores when assessed with the MNA (125,126). Among Finnish elderly assessed with the MNA, however, no relationship was found between malnutrition and hyposalivation (OR 1.3, 95% CI 0.5–3.9) (127). The researchers noted that saliva was collected at different times of the day, and this may have affected the results since circadian rhythms are known to influence the secretion of saliva, with the highest values obtained in the afternoon (128).

The strongest associations with malnutrition was found for problems with the oral mucosa, lips and teeth, respectively. It is plausible that a compromised oral status with mucosal sores, cracked/ulcerated lips or poor dental status can contribute to a reduced food intake, and these findings are in accordance with previous studies assessing oral health with the ROAG, where problems with the oral mucosa (120), lips (56,120) and teeth (120) were found to be associated with malnutrition. However, in contrast to the present study these studies reported associations for some of the remaining six categories too. Andersson et al. found problems related to the voice, swallowing function, tongue and saliva flow to be associated with malnutrition in the elderly patients (56), and Lindmark et al. found associations for all the nine categories in elderly adults (120). Surprisingly, the strongest association with malnutrition in these two studies was found for swallowing function, the category which had the weakest association in the present study. Poor oral status is known to adversely affect swallowing in older individuals, as wearing dentures or having dry mouth can impair the swallowing process (129). Indirectly, problems with the teeth can impair swallowing too by affecting chewing ability. As such, it would be expected that patients with swallowing difficulties had higher risk of malnutrition considering the high proportion of oral health problems and especially teeth-related problems in the study. The inter-rater agreement and sensitivity for swallowing in the ROAG-J has been demonstrated to be very good (90,114), but it is possible that identifying patients with problems still requires a more thorough evaluation. According to the assessment, 18 patients had trouble swallowing. In contrast, 24 patients reported having difficulties swallowing foods in the self-administered questionnaire on oral health, although no differences were found between malnourished and well-nourished patients there either. Differences were found regarding the need to use liquids to aid in swallowing dry foods, so one possible explanation may be that malnourished patients compensated for a reduced swallowing function by utilizing liquids to make the chewing and swallowing process easier. As such, they may not have felt the need to report any problems with swallowing foods. The higher need to sip liquids when eating dry foods in

malnourished patients compared to well-nourished patients further indicated that saliva production was reduced, and was consistent with the results from the unstimulated salivary flow test. Problems in the saliva flow assessment in the ROAG-J was however not associated with increased risk of being malnourished in the present study, in contrast to all three aforementioned studies (56,57,120) where one of them reported an OR of 2.7 between saliva problems and risk of malnutrition (57). This again reinforces the importance of sufficient training and appropriate assessment instruments, as discussed in section 5.2.1.

Only 25 patients wore partial or complete dentures, but of the 14 patients assessed to have problems with them the majority were malnourished. Poorly fitted dentures or denture discomfort because of dry mouth can make eating difficult, and problems related to dentures showed the strongest association with malnutrition in a study in nursing home residents (65). Although the sample size was much smaller, the present study indicates that increased attention should be given to elderly patients wearing dentures at the hospital.

5.2.3 Medication intake and hyposalivation

By obtaining data from the medical records, the median intake of orally administered medications per day was found to be 5, with polypharmacy (≥5 medications per day) present in 53% of patients. The high prevalence of polypharmacy was expected, since median age of included participants was 68 years and use of multiple medications is common in older populations with multimorbidity (53). In line with previous studies, medication use was more prevalent in patients with hyposalivation (127,130). Since age and gender are known to influence the salivary output, i.e. older people and women commonly produce less saliva (34), a regression model adjusting for these confounding variables was constructed. The association between medication use and hyposalivation remained, indicating that the number of different medications was an independent risk factor for low saliva production in patients. Increasing age tended to be significant in the model. Several studies have also investigated the association between xerostomia and medication exposure, and found that the incidence and prevalence of self-perceived dry mouth are strongly associated with number of medications (52,131,132).

However, due to the complex relationship between medication exposure and dry mouth the result in the present study should be interpreted with caution. Analgesics, hypnotics, antihypertensives, cardiac medications, antacids and nutritional supplements were the most

commonly used medications in patients with hyposalivation, and each category is known to be associated with dry mouth (36,45,50). Even so, associations between the overall number of medications taken and hyposalivation does not reveal which medications are actually responsible for the dry mouth (47). Unknown drug-drug interactions complicate things even further, as polypharmacy can cause dry mouth independent of each medications xerogenicity (51). Furthermore, it can be difficult to assess whether medications or the underlying disease conditions are the causative factor.

Still, with so many categories of medications associated with xerostomia and with hyposalivation known to be associated with most of the common medication classes (133), increased attention should be paid to medications' impact on oral health in order to identify patients at risk for dry mouth. Not all persons with hyposalivation will experience xerostomia, and patients with xerostomia may underestimate their symptoms. Consequently, the problem can go unnoticed unless healthcare professionals choose to ask the patients about their symptoms. Particular attention should be given to older patients and patients receiving polypharmacy, especially when the number of medications exceeds ten (Figure 8a). Once diagnosed, appropriate treatment requires an understanding of the underlying cause(s), i.e. whether the cause is medication-related, the result of a health condition, or related to something else (36). Given the many adverse effects of dry mouth, a multi-disciplinary approach adapted to the individual needs of each patient is recommended (133).

5.2.4 Nutritional screening at the hospital

Of the 67 patients categorized as malnourished by the PG-SGA, 9 had not been screened at the hospital. Of the 58 malnourished patients that had been screened, 11 (19%) were found to be at nutritional risk and 47 (81%) were found to not be at nutritional risk by the hospital screening. In other words, four out of every five malnourished patients were not identified as at nutritional risk when screened at the hospital. Upon examination of the screening forms in the medical records several flaws in the screening process were detected. Tangvik et al. has pointed out the heterogeneity of patients at nutritional risk, suggesting that identification of patients at risk is not possible without performing a nutritional risk screening or assessment according to guidelines (12). Identification of patients at nutritional risk is furthermore a prerequisite for initiation of individualized nutritional support. No data were collected on the number of referrals to a dietitian in the present study, but because of the low prevalence of

patients being assigned diagnosis codes for malnutrition at the hospital in 2006-2009 (74) it is likely that many patients are underdiagnosed and undertreated. In a study performed at Haukeland University Hospital, only 53% of patients at nutritional risk received nutritional treatment and 5% were seen by a dietitian (134). Data from nutritionDay 2014 showed that 59% of malnourished patients at Oslo University Hospital and University Hospital of Northern Norway did not receive any nutritional treatment (11).

A randomized clinical trial recently found strong support for systematic screening of nutritional risk and subsequent initiation of nutritional support in hospital patients at-risk (135). Compared to patients receiving standard hospital food, patients receiving individualized nutritional support to reach caloric and protein goals had better quality of life and lower risk of adverse outcomes. In the present study, the finding that few malnourished patients were detected by the hospital screening is concerning and suggests that factors affecting food intake and causing poor nutritional status are less likely to be identified. Oral problems were shown to be very common in patients and associated with malnutrition, adding support to the body of evidence suggesting poor oral health to be an important risk factor for poor nutritional status. As with nutritional interventions, oral health interventions have also been demonstrated to have an effect. Screening for oral health problems in geriatric patients was performed using the ROAG and followed by taking measures when problems were detected (136); the prevalence of problems was found to be significantly lower at discharge (51%) compared to at admission (86%). In elderly home care clients who had xerostomia and were malnourished or at risk of malnutrition, a combined nutritional and xerostomia counseling intervention resulted in a 30% decrease in xerostomia and a 61% decrease in malnutrition or risk of malnutrition (137).

In the hospital setting, the responsibility for screening patients for nutritional risk falls upon the nurses. Routines in nutritional practice among nurses and doctors in Norway were demonstrated to have improved from 2004 to 2014, but several barriers to nutrition therapy including nutritional screening were still prevalent (138,139). The findings from the present study supports this and may therefore serve to increase awareness around nutrition-related challenges at the hospitals. In addition, the findings suggest that increased attention should be given to oral health problems, and that the relationship between malnutrition and poor oral health in hospital patients may be underappreciated.

6 Conclusion

This thesis explored the nutritional and oral health status in 118 patients from 18 different wards at St. Olavs hospital. Malnutrition and oral health problems were prevalent, with

- one in two patients found to be malnourished
- one in five patients measured to have hyposalivation
- nine in ten patients assessed to have at least one oral health problem
- one in three patients reporting having a dry mouth.

Hyposalivation and problems regarding the lips, oral mucosa and teeth showed the strongest association with malnutrition. By assessing the number of orally administered medications per day, medication intake was found to be positively associated with hyposalivation. Several study patients had not been screened for nutritional risk at the hospital, and only one in five malnourished patients were found to be at nutritional risk when they had been screened. As such, nutritional practice was poor. In summary, these findings add to the growing body of evidence showing that malnutrition is a serious problem in hospitalized patients, and demonstrates that oral health problems are very common and associated with poor nutritional status in a Norwegian hospital.

The implications are several. Since individualized nutritional support is demonstrated to improve clinical outcomes in hospital patients at nutritional risk, the high prevalence of malnutrition and poor nutritional screening practice strengthens the findings from previous studies and show that an improvement in nutritional routines is needed. More attention should also be directed towards oral health problems and their relationship with malnutrition in the hospital setting, particularly in the elderly and in patients receiving polypharmacy. Assessment of oral health status should be included as a natural part of nursing practice, and dietitians should also be able to evaluate the oral health of patients when performing nutritional assessments. Presuming sufficient education and training is given, a screening tool like the ROAG-J appears to be a useful tool for assessing oral health. In conclusion, there is a need for more research to investigate the prevalence of oral health problems in hospitals, and the relationship between nutritional status and oral health should be explored further in future studies.

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8 Appendices

Appendix 1. Consent form

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

ERNÆRINGSSTATUS OG MUNNHELSE HOS INNELIGGENDE PASIENTER VED ST. OLAVS HOSPITAL

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å kartlegge ernæringsstatus og munnhelse blant voksne inneliggende pasienter ved St. Olavs hospital. Du er blant de rundt 500 pasientene som blir tilfeldig forespurt om å delta i prosjektet. St. Olavs hospital og Tannhelsetjenestens kompetansesenter Midt-Norge (TkMN) er ansvarlig for å gjennomføre prosjektet.

God munnhelse har betydning for næringsinntak og dermed den generelle helsen vår. Vi ønsker å øke kunnskapen og bevisstheten om munnhelsens betydning for ernæringsstatus og spesielt underernæring. I denne studien vil vi kartlegge sammenhenger mellom ernæringsstatus og munnhelse hos inneliggende pasienter ved St. Olavs hospital. Det vil også bli kartlagt antall og type per orale medikamenter og sammenhengen med munntørrhet og ernæringsstatus. «Per orale» betyr at de tas inn gjennom munnen, altså tabletter eller flytende medisin som svelges.

HVA INNEBÆRER PROSJEKTET?

Å delta i prosjektet innebærer at du skal besvare spørreskjema om ditt næringsinntak/matvaner og om din munn- og tannhelse. Vi vil hjelpe deg å fylle ut spørreskjema om nødvendig. Det vil også bli utført en fysisk undersøkelse for å kartlegge din ernæringsstatus og din munnhelse. Vi vil be om lov til å innhente opplysninger fra din legejournal om hvilke medisiner du bruker som kan påvirke munnhelsen din. Ernærings- og munnhelseundersøkelsen vil foregå på sengepost (altså på pasientrommet ditt), og innebærer at det vil bli tatt en spyttprøve for å vurdere om du er munntørr eller ikke. Undersøkelsen vil ta cirka 20-25 minutter.

MULIGE FORDELER OG ULEMPER

De fysiske undersøkelsene du vil gjennomgå er ikke forbundet med smerte eller ubehag for deg. Hvis undersøkelsene avdekker forhold som krever videre utredning eller behandling, vil prosjektarbeiderne i samråd med deg, kontakte ansvarlig lege på sengeposten og/eller tanntemaet på St. Olavs hospital, og du vil få beskjed.

De langsiktige fordelene av at du deltar i dette prosjektet er at vi vil få økt kunnskap om sammenhenger mellom ernæring, munnhelse, munntørrhet og medikamentbruk. Det kan føre til at helsevesenet på sikt kan tilby en mer persontilpasset oppfølging og dermed bedre behandling.

HVA SKJER MED INFORMASJONEN OM DEG?

Alle som behandler helseopplysninger, er underlagt taushetsplikt i henhold til norsk lov. Informasjon som samles inn i dette prosjektet vil lagres etter de til enhver tid gjeldede lovpålagte retningslinjer. Alle opplysninger blir avidentifisert når de lagres, og forskere kan derfor ikke spore noen opplysninger tilbake til deg. Senest fem år etter prosjektslutt vil koblingsnøkkelen slettes slik at materialet som er samlet inn i forbindelse med ernærings- og munnhelseprosjektet, blir anonymisert.

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Tannhelsetjenestens kompetansesenter Midt-Norge

HVA SKJER MED PRØVER SOM BLIR TATT AV DEG?

Hvis du samtykker i å delta i ernærings- og munnhelseprosjektet, vil spyttprøven som tas av deg brukes til å måle om du er munntørr eller ikke.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Hvorvidt du samtykker eller ikke, har ingen betydning for den medisinske behandlingen du får mens du er innlagt på St. Olavs hospital. Dersom du samtykker, kan du når som helst kreve å få vite hvilken informasjon og materiale som finnes fra deg, hva det har vært brukt til, og hvilke resultater som har kommet ut av forskningen.

Dersom du ønsker å delta, undertegner du samtykkeerklæringen på neste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Ingrid Løvold Mostad, Klinikk for kliniske servicefunksjoner, St. Olavs hospital HF, Postboks 3250 Torgarden, 7006 Trondheim, epost: ingrid.lovold.mostad@stolav.no, mobiltelefon 93411419, eller Astrid Jullumstrø Feuerherm, Tannhelsetjenestens Kompetansesenter Midt-Norge (TkMN), Klæbuveien 70, 7030 Trondheim, epost: astrid.j.feuerherm@tkmidt.no, mobiltelefon 98637364.

Appendix 2. REC approval number 1

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Marit Hovdal Moan	73597504	15.05.2018	2018/621/REK midt
			Deres dato:	Deres referanse:
			20.03.2018	

Vår referanse må oppgis ved alle henvendelser

Ingrid Løvold Mostad
St. Olav

2018/621 Ernæringsstatus og munnhelse hos inneliggende pasienter ved St. Olavs hospital

Forskningsansvarlig: St. Olavs Hospital HF
Prosjektleder: Ingrid Løvold Mostad

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK midt) i møtet 25.04.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Komiteens prosjektsammendrag
Hensikten med prosjektet er å undersøke munnhelsens betydning for ernæringsstatus og spesielt underernæring. Man ønsker også å kartlegge antall og type perorale medikamenter og sammenhengen med munntørrhet og ernæringsstatus. Deltakere: ca. 500 tilfeldig utvalgte inneliggende pasienter som representerer alle sentra og klinikker ved St. Olavs hospital. Studien er designet som en tverrsnittsundersøkelse av forekomst og sammenhenger. Data samles inn ved bruk av et spørreskjema om næringsinntak/matvaner og munn- og tannhelse, en fysisk undersøkelse for å kartlegge deltakernes ernæringsstatus og deres munnhelse, samt en tannhelseundersøkelse tilsvarende rutinekontroll hos vanlig tannlege. Data om hvilke medisiner deltakerne bruker som kan påvirke munnhelsen deres hentes fra pasientjournal. Det vil bli tatt en spyttprøve som planlegges lagret i Biobank 1s tematiske forskningsbiobank for oral helse, for framtidig forskning på sammenhenger mellom munnhelse og generell helse. En master i klinisk ernæring ved UiO inngår i studien. Samtykke skal innhentes.

Vurdering

Forsvarlighet
Komiteen har vurdert søknad, forskningsprotokoll, målsetting og plan for gjennomføring. Komiteen har en kommentar til det vedlagte informasjonsskrivet, men har ellers ingen forskningsetiske innvendinger til prosjektet. Under forutsetning av at vilkårene nedenfor tas til følge, framstår prosjektet som forsvarlig og hensynet til deltakernes velferd og integritet er ivaretatt.

Forbedring av informasjonsskriv
Komiteen ber om at informasjonsskrivet revideres i samsvar med følgende punkter:

1. Komiteen oppfatter at Biobank1 har utarbeidet en mal for bredt samtykke som med fordel kan brukes for innhenting av samtykke til lagring av spyttprøven i Biobank 1s generelle forskningsbiobank for oral helse.
2. Komiteen ber om at samtykkeskrivet knyttet til det spesifikke prosjektet det her er søkt forhåndsgodkjenning for revideres slik at informasjon knyttet til fremtidig lagring av spyttprøven

Besøksadresse:
Fakultet for medisin og helsevitenskap Mauritz Hansens gate 2, Øya helsehus

E-post: rek-midt@mh.ntnu.no
Web: http://helseforskning.etikkom.no/

tas ut.

Vilkår for godkjenning

1. Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og protokollen. Prosjektet må også gjennomføres i henhold til REKs vilkår i saken og de bestemmelser som følger av helseforskningsloven (hfl.) med forskrifter.
2. Vi ber om at det reviderte informasjonsskrivet knyttet til den spesifikke studien, samt informasjonsskrivet knyttet til lagring av spyttprøver i Biobank 1 sendes komiteen til orientering. Vennligst benytt e-postadressen post@helseforskning.etikkom.no og "REK midt 2018/621" i emnefeltet. Prosjektet kan ikke igangsettes før REK midt bekrefter at informasjonsskrivene er mottatt.
3. Komiteen forutsetter at ingen personidentifiserbare opplysninger kan framkomme ved publisering eller annen offentliggjøring.
4. Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Av kontrollhensyn skal prosjektdata oppbevares i fem år etter sluttmelding er sendt REK. Data skal derfor oppbevares til denne datoen, for deretter å slettes eller anonymiseres, jf. hfl. § 38.
5. Prosjektleder skal sende sluttmelding til REK midt når forskningsprosjektet avsluttes. I sluttmeldingen skal resultatene presenteres på en objektiv og etterrettelig måte, som sikrer at både positive og negative funn fremgår, jf. hfl. § 12.

Vedtak
Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge godkjenner prosjektet med de vilkår som er gitt.
Komiteens beslutning var enstemmig.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK midt på eget skjema senest 31.08.2023, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK midt dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK midt. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Vibeke Videm
Professor dr.med. / Overlege
Leder, REK Midt

Marit Hovdal Moan
seniorrådgiver

Kopi til:*lise.lundbom.stoylen@stolav.no; rek-midt@mh.ntnu.no; personvernombudet@stolav.no*

Appendix 3. REC approval number 2

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Marit Hovdal Moan	73597504	21.09.2018	2018/621/REK midt
			Deres dato:	Deres referanse:
			19.09.2018	

Vår referanse må oppgis ved alle henvendelser

Ingrid Løvold Mostad
St. Olavs Hospital

2018/621 Ernæringsstatus og munnhelse hos inneliggende pasienter ved St. Olavs hospital

Forskningsansvarlig: St. Olavs Hospital HF
Prosjektleder: Ingrid Løvold Mostad

Vi viser til søknad om prosjektendring datert 19.09.2018 for ovennevnte forskningsprosjekt. Søknaden ble behandlet av sekretariat for REK midt på fullmakt, med hjemmel i helseforskningsloven § 11 og forskrift om behandling av etikk og redelighet i forskning § 10.

Prosjektleder søkte om følgende endringer:

1. Redusere antall undersøkelser av deltakerne: man har valgt å ta ut tannhelseundersøkelsen som skulle foregå i tannklinikk ved Tannteamet på St. Olavs hospital. Tannteamet vil likevel være involvert i prosjektet som tilkallingsinstans hvis det oppdages forhold i munnhule som ansees være behandlingskrevende.
2. Oppdatert informasjons -og samtykkeskriv i tråd med endring beskrevet under punkt 1.

Vurdering
REK midt har vurdert søknad om prosjektendring, og har ingen forskningsetiske innvendinger mot endringen av prosjektet. Hensynet til deltakernes velferd og integritet er fremdeles godt ivaretatt.

Vi ber likevel om at dere i informasjonsskrivet knyttet til det spesifikke prosjektet setter inn en setning om at materialet som samles inn i forbindelse med dette konkrete prosjektet vil anonymiseres (det vil si at koblingsnøkkel slettes) eller destrueres senest fem år etter prosjektslutt. Se REK sin oppdaterte mal for informasjonsskriv til voksne på våre nettsider. Vi ber om at et oppdatert informasjonsskriv sendes oss til orientering.

Vi minner forøvrig om at prosjektet må gjennomføres i henhold til tidligere vedtak i saken.

Vedtak
Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge godkjenner søknad om prosjektendring.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK midt. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Besøksadresse:
Fakultet for medisin og helsevitenskap Mauritz Hansens gate 2, Øya helsehus

Telefon: 73597511
E-post: rek-midt@mh.ntnu.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK midt og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK midt, not to individual staff

Hilde Eikemo
sekretariatsleder, REK Midt

Marit Hovdal Moan
seniorrådgiver

Kopi til: *lise.lundbom.stoylen@stolav.no; post@stolav.no; personvernombudet@stolav.no*

Appendix 4. REC approval number 3

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Ramunas Kazakauskas	73597510	03.10.2018	2016/1155/REK midt
			Deres dato:	Deres referanse:
			26.09.2018	

Vår referanse må oppgis ved alle henvendelser

Haakon Robin Skogseth
Forskningsavdelingen

Vi viser til søknad om endring av forskningsbiobanken "Generell forskningsbiobank for oral helse" (2016/1155). Søknaden ble behandlet av sekretariat for REK midt på fullmakt, med hjemmel i helseforskningsloven § 11 og forskrift om behandling av etikk og redelighet i forskning § 10.

Endringer
Ansvarhavende for biobanken søker om en endring i utvalg og rekruttering. Det er ønskelig å forespørre pasienter som også skal bli invitert til å delta i prosjektet "Ernæringsstatus og munnhelse hos inneliggende pasienter ved St. Olavs hospital" (vår referanse: 2018/621). Materiale som skal samles inn er spyttprøver. Rekruttering skal skje gjennom 26 sengeområder på følgende klinikker: Kirurgisk klinikk, klinikk for hjertemedisin, klinikk for lunge- og arbeidsmedisin, klinikk for ortopedi, revmatologi og hudsykdommer, Klinikk for øre-nese- hals, kjevekirurgi og øyesykdommer, Kreftklinikken, Kvinneklinikken, Medisinsk klinikk, Divisjon Psykisk helsevern og Nevroklinikken. Pasientene skal forespørres gjennom eget informasjonsskriv for biobanken.

Vurdering
REK midt har vurdert søknad om biobankendring, og har ingen forskningsetiske innvendinger mot endringen. Hensynet til deltakernes velferd og integritet er fremdeles godt ivaretatt. Vi minner om at godkjenningen er gitt under forutsetning av at biobanken forvaltes i henhold til tidligere vedtak i saken.

Vedtak
Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge godkjenner søknad om biobankendring.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningslovens § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK midt. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Hilde Eikemo
Sekretariatsleder, PhD
REK midt

Ramunas Kazakauskas
rådgiver

Besøksadresse:
Fakultet for medisin og helsevitenskap Mauritz Hansens gate 2, Øya helsehus

E-post: rek-midt@mh.ntnu.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK midt og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK midt, not to individual staff

Kopi til: *post@tkm-n.no; postmottak@helse-midt.no; biobankregisteret@fhi.no; rek-midt@mh.ntnu.no*

Appendix 5. Biobanking consent form

FORESPØRSEL OM Å GI BIOLOGISK MATERIALE TIL BIOBANK1

TEMATISK FORSKNINGSBIOBANK FOR ORAL HELSE

Helse Midt-Norge RHF har etablert den regionale forskningsbiobanken og infrastrukturen Biobank1®. Underlagt denne er innsamlinger fra flere ulike pasientgrupper.

FORMÅL

Biobank1® samler inn og lagrer biologisk materiale, i dette tilfellet tenner, saliva (spytt), slimhinneprøver, vevsbiopsier og blodprøver til medisinsk forskning, som har til formål å gi kunnskap om årsaker og mekanismer ved sykdom relatert til tann- og munnhelse, for å forbedre forebygging, diagnostikk og behandling.

INNSAMLING AV BIOLOGISK MATERIALE OG HELSEOPPLYSNINGER

Vi spør deg med dette om å gi materiale til medisinsk forskning i forbindelse med den undersøkelsen og/eller den behandlingen du får. Dette innebærer at du ikke skal utsettes for ekstra inngrep, men at det taes noe ekstra materiale som kan brukes til forskning. Prøvetakingen er således ikke forbundet med noen risiko, ubehag eller ulempe for deg utover det som den ordinære pasientundersøkelsen og/eller behandlingen innebærer. Vi ber også om å få bruke opplysninger fra din pasientjournal når dette er nødvendig.

BEHANDLING AV OPPLYSNINGER

Innsamlede opplysninger og resultat av analyser av det biologiske materialet blir lagret i helseregisteret Biobank1®, og gjenbrukt i nye medisinske forskningsprosjekt så lenge de vurderes som nyttige for formålet. Alle som behandler biologisk materiale og helseopplysninger, er underlagt taushetsplikt i henhold til norsk lov. Alle opplysninger blir avidentifisert når de lagres, og forskere kan derfor ikke se at opplysningene gjelder deg. I enkelte tilfeller kan det være nødvendig å overføre deler av materialet til samarbeidspartnere i andre land, men Biobank1® vil aldri utlevere identifiserbare personopplysninger til forskere eller institusjoner i utlandet.

BRUK AV BIOLOGISK MATERIALE OG HELSEOPPLYSNINGER

Biologisk materiale og helseopplysninger vil bli brukt i prosjekter som er forhåndsgodkjent av Regional komité for medisinsk og helsefaglig forskningsetikk (REK), i samsvar med Helseforskningsloven og annen norsk lov. Prosjektene vil ta sikte på å vinne ny kunnskap om sykdomsmekanismer relatert til tann- og munnhelse. Materialet kan også brukes som kontroll ved forskning på andre tilstander. Det kan være aktuelt å gjøre genetiske analyser av det innsamlede materialet, inkludert genomsekvensering. Dette er analyser som er under stadig utvikling og som i dag kan avdekke nærmest all informasjon som finnes på den enkeltes arveanlegg. Denne informasjonen kan igjen knyttes sammen med kunnskap om sykdomsutvikling. Biobank1® vil kunne samarbeide med helseindustrien, for utvikling av varer, tjenester, legemidler eller diagnostiske tester. Dette betyr at de vil kunne få opplysninger og materiale fra deg, som kun kan brukes til utvikling av ovennevnte. Slike samarbeidsprosjekter vil, som all annen helseforskning, alltid trenge godkjenninger fra REK før de kan igangsettes.

Materialet vil bli oppbevart og brukt så lenge det er noe igjen. REK vil kunne bestemme at deltakere må gis nærmere informasjon om bruken av materialet og/eller at det må innhentes nytt samtykke.

Tannhelsetjenestens kompetansesenter Midt-Norge · Biobank1 · ST. OLAVS HOSPITAL UNIVERSITETSSYKEHUSET I TRONDHEIM · HELSE MIDT-NORGE

Tematisk forskningsbiobank for oral helse — Desember 2016 #1

KOBLING TIL REGISTRE

I enkelte prosjekt kan det være nødvendig å sammenstille resultatene med data fra store befolkningsundersøkelser (for eksempel Helseundersøkelsen i Nord-Trøndelag). Noen ganger kan det være nødvendig å innhente tilleggsinformasjon som finnes i nasjonale registre. Vi ber om din tillatelse til dette.

FORMELLE GODKJENNINGER

Biobank1® eies av Helse Midt-Norge RHF, og er godkjent av REK. Datatilsynet har gitt Biobank1® konsesjon til å behandle helseopplysninger for forskningsformål.

DINE RETTIGHETER

Det er helt opp til deg om du vil tillate at biologisk materiale fra deg kan bli brukt til forskning eller ikke. Dersom du samtykker, kan du senere når som helst trekke tilbake ditt samtykke og få fjernet og destruert gjenværende materiale, uten å måtte begrunne dette ønsket nærmere. Hvorvidt du samtykker eller ikke, har ingen betydning for den medisinske behandlingen du får. Dersom du samtykker, kan du når som helst kreve å få vite hvilket materiale som finnes fra deg i Biobank1®, hva det har vært brukt til, og hvilke resultater som har kommet ut av forskningen. Ønsker du å få slike opplysninger eller trekke tilbake et avgitt samtykke, kan du benytte følgende kontaktinformasjon:

BIOBANK1®

St. Olavs Hospital
Medisinsk teknisk forskningssenter (MTFS)
Olav Kyrres gate 9
7481 Trondheim

Tlf: 72 57 13 44 / 72 57 18 04
E-post: biobank1@helse-midt.no
Web: www.biobank.no

Dersom du samtykker til deltakelse, signer denne erklæringen.

SAMTYKKEERKLÆRING

Jeg har lest informasjonsskrivet og har hatt anledning til å stille spørsmål. Jeg samtykker til å avgi materiale til Biobank1®, og at innsamlede opplysninger og resultater fra analyser kan lagres i helseregisteret Biobank1. Jeg samtykker til at det kan innhentes opplysninger fra min pasientjournal, og at data kan kobles mot helseregistre.

Sted: .....

Dato: .....

Underskrift: .....

Navn (med blokkbokstaver): .....

Fødselsnummer (11 siffer) .....

Appendix 6. The Patient-Generated Subjective Global Assessment (PG-SGA)

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Boks 1 - 4 skal fylles ut av pasienten

(Boks 1 - 4 heter PG-SGA Short Form (SF))

ID: **Rom:** **Dato:**

1. Vekt:

Oppsummering av min nåværende og tidligere vekt

Jeg veier nå ca. _____ kilo
Jeg er ca. _____ cm høy

For én måned siden veide jeg ca. _____ kilo
For seks måneder siden veide jeg ca. _____ kilo

I løpet av de siste to ukene har vekten min:

☐ gått ned (1) ☐ ikke endret seg (0) ☐ økt (0)

(Se arbeidsark 1) **Boks 1** ☐

2. Matinntak: Sammenlignet med mitt vanlige inntak vil jeg anslå matinntaket den siste måneden som

☐ uendret (0)
☐ mer enn vanlig (0)
☐ mindre enn vanlig (1)

Jeg spiser nå

☐ *vanlig mat,* men mindre mengder enn jeg pleier å spise (1)
☐ lite fast føde (2)
☐ bare væske (3)
☐ bare næringsdrikker (3)
☐ svært lite av noe som helst (4)
☐ bare sondeernæring eller intravenøs ernæring (0) **Boks 2** ☐

3. Symptomer: Jeg har følgende problemer som har hindret meg i å spise nok de siste to ukene (kryss av for alt som passer)

☐ ingen problemer med å spise (0)
☐ ingen matlyst, følte ikke for å spise (3)
☐ kvalme (1)
☐ forstoppelse (1)
☐ sår i munnen (2)
☐ mat/drikke smaker rart eller ingenting (1)
☐ problemer med å svelge (2)
☐ smerter; hvor? (3) _____
☐ annet** (1) _____
☐ oppkast (3)
☐ diaré (3)
☐ munntørrhet (1)
☐ lukter plager meg (1)
☐ føler meg raskt mett (1)
☐ utmattethet (1)

Eksempler: depresjon, økonomiske problemer, tannproblemer **Boks 3 ☐

4. Aktiviteter og funksjon: I løpet av den siste måneden vil jeg beskrive aktivitetsnivået mitt som

☐ normalt uten begrensninger (0)
☐ ikke mitt vanlige jeg, men i stand til å være oppe og gjøre normale aktiviteter (1)
☐ føler meg ute av stand til det meste, men ligger i sengen eller sitter i en stol mindre enn halve dagen (2)
☐ liten evne til å utføre aktiviteter, og tilbringer det meste av dagen i sengen eller i en stol (3)
☐ stort sett sengeliggende, er sjelden ute av sengen (3)

Boks 4 ☐

Resten av dette skjemaet skal fylles ut av helsepersonell. Tusen takk!

Sammenlagt skår for Boks 1 - 4 ☐ **A**

email: faithotterymdphd@aol.com or info@pt-global.org

Scored Patient-Generated Subjective Global Assessment (PG-SGA) Sammenlagt poengskår fra Boks 1 - 4 (side 1) ☐

Arbeidsark 1 – Poengskår for vekttap

Bruk poengene nedenfor for å skåre vektendringen ved å bruke vekttap for 1 måned, hvis tilgjengelig. Bruk data for 6 måneder bare hvis det ikke finnes vektdata for 1 måned siden. Legg til ett poeng hvis pasienten har tapt vekt i løpet av de siste to ukene og overfør den totale skåren (maksimalt 5 poeng) til boks 1 (side 1).

Vekttap på 1 måned	Poengskår	Vekttap på 6 måneder
10% eller mer	4	20% eller mer
5 – 9,9%	3	10 – 19,9%
3 – 4,9%	2	6 – 9,9%
2 – 2,9%	1	2 – 5,9%
0 – 1,9%	0	0 – 1,9%

Poengskår fra Arbeidsark 1 ☐

5. Arbeidsark 2 – Sykdom og dens påvirkning på ernæringsbehov

Ett poeng gis for hver av de følgende tilstander:

- ☐ Kreft
- ☐ AIDS
- ☐ Pulmonal eller kardial kakeksi
- ☐ Kronisk nyresvikt
- ☐ Liggesår, åpent sår eller fistel
- ☐ Traume
- ☐ Alder over 65 år

Andre relevante diagnoser (spesifiser) _____

Stadium av hovedsykdom (sett en ring rundt hvis kjent) I II III IV Annet _____

Poengskår fra Arbeidsark 2 ☐ **B**

ID:

Rom:

Dato:

6. Arbeidsark 3 – Metabolsk behov

Poengskår for metabolsk stress bestemmes av flere variabler som er kjent for å øke protein- og kaloribehov. Poengskåren for feber og kortikosteroider legges sammen (maks 6 poeng). **NB:** Ved feber gis bare den høyeste skår av febervarighet eller temperatur (maks 3 poeng). For eksempel en pasient som har feber på > 38,8 °C (3 poeng) i < 72 timer (1 poeng) og er på 10 mg prednisolon fast (2 poeng), vil få en sammenlagt skår på 5 poeng.

Stress	ingen (0)	lavt (1)	moderat (2)	høyt (3)
Feber	ingen feber	> 37,2 og < 38,3	≥ 38,3 og < 38,8	≥ 38,8 °C
Febervarighet	ingen feber	< 72 timer	72 timer	> 72 timer
Kortikosteroider	ingen kortikosteroider	lav dose (< 10 mg prednisolon-ekvivalenter/dag)	moderat dose (≥ 10 og < 30 mg prednisolonekvivalenter/dag)	høy dose (≥ 30 mg prednisolon-ekvivalenter/dag)

Overarmsomkrets (cm):	Tricepshudfold (mm):
_____	1. _____ 2. _____ 3. _____

Poengskår fra Arbeidsark 3 ☐ **C**

7. Arbeidsark 4 – Fysisk undersøkelse

Fysisk undersøkelse omfatter 3 aspekter ved kroppssammensetning: fett, muskel og væske. Undersøkelsen er subjektiv, hvert aspekt av undersøkelsen er vurdert i grader. Underskudd/tap av muskel påvirker poengskåre mer enn underskudd/tap av fettmasse. Definisjon av grader: 0 = ingen underskudd, 1+ = lett, 2+ = moderat, 3+ = alvorlig. Skåren legges ikke sammen. Man gjør en subjektiv klinisk vurdering av totalt underskudd, inkludert forekomst av væskeoverskudd/ødem. **Maks total poengskår for fysisk undersøkelse er 3 poeng.**

Muskelstatus					Fettlager				
tinninger (temporalis)	0	1+	2+	3+	orbitalt fettdepot	0	1+	2+	3+
krageben (pektoralis & deltoid)	0	1+	2+	3+	triceps hudfold	0	1+	2+	3+
skuldre (deltoid)	0	1+	2+	3+	fett over nedre ribben	0	1+	2+	3+
interosseus i hånd	0	1+	2+	3+	**Vurdering fettunderskudd**	**0**	**1+**	**2+**	**3+**
skulderblad (latissimus dorsi, trapezius, deltoid)	0	1+	2+	3+	**Væskestatus**				
lår (quadriceps)	0	1+	2+	3+	ankeløedm	0	1+	2+	3+
legg (gastrocnemius)	0	1+	2+	3+	sakralt ødem	0	1+	2+	3+
Vurdering muskelstatus	**0**	**1+**	**2+**	**3+**	ascites	0	1+	2+	3+
					Vurdering væskestatus	**0**	**1+**	**2+**	**3+**

Poengskåren for den fysiske undersøkelsen bestemmes av en total subjektiv klinisk vurdering.
Muskelstatus har større effekt på poengskåren enn fettmasse eller væskestatus.

Ingen underskudd	0 poeng
Lett underskudd	1 poeng
Moderat underskudd	2 poeng
Alvorlig underskudd	3 poeng

Poengskår fra Arbeidsark 4 ☐ **D**

Total PG-SGA poengskår (Total numerisk skår for A+B+C+D) ☐

PG-SGA global kategori (A, B eller C) ☐

Klinikers underskrift _____ Yrke _____ Dato _____

Arbeidsark 5 –PG-SGA globale kategorier

Kategori	Kategori A Velernært	Kategori B Moderat underernært/ mistenkt underernært	Kategori C Alvorlig underernært
Vekt	Ingen vekttap **ELLER** vektøkning som ikke **skyldes væskeretensjon**	≤ 5% vekttap på 1 måned (≤ 10% på 6 måneder) **ELLER** progressivt vekttap	> 5% vekttap på 1 måned (> 10% på 6 måneder) **ELLER** progressivt vekttap
Matinntak	Ikke redusert inntak **ELLER** nylig forbedring	Noe redusert inntak	Sterkt redusert inntak
Symptomer	Ingen **ELLER** nylig forbedring som gir adekvat matinntak	Symptomer (PG-SGA Boks 3)	Symptomer (PG-SGA Boks 3)
Funksjon	Normalt funksjonsnivå **ELLER** nylig forbedring	Moderat redusert funksjonsnivå **ELLER** nylig forverring	Alvorlig redusert funksjonsnivå **ELLER** nylig forverring
Fysisk undersøkelse	Ingen mangel **ELLER** nylig forbedring	Mild til moderat tap av muskelmasse /subkutant fett/muskeltonus ved palpering	Alvorlig tap av muskelmasse eller subkutant fett eventuelt ødemer

Ernæringstiltak: Den sammenlagte poengskåren brukes til å definere spesifikke ernæringstiltak. Dette inkluderer symptombehandling og opplæring av pasienter og familie. Symptombehandling kan inkludere farmakologisk behandling og/eller egnet ernæringstiltak (mat, ernæringstilskudd, sonde- eller intravenøs ernæring).

Førstelinje ernæringstiltak inkluderer optimal symptombehandling.

Ernæringstiltak basert på poengskår for PG-SGA

0-1	Ingen tiltak er nødvendig nå. Ernæringsstatus må revurderes regelmessig under behandling.
2-3	Krever opplæring av pasient og familie av klinisk ernæringsfysiolog, sykepleier eller annet helsepersonell. Farmakologisk behandling ved behov som indikert ved symptomene (Boks 3) eller laboratorieverdier.
4-8	Krever tiltak av klinisk ernæringsfysiolog i samarbeid med sykepleier eller lege som indikert ved symptomene (Boks 3).
≥ 9	Indikerer et kritisk behov for ernæringstiltak og forbedret symptombehandling.

email: faithotterymdphd@aol.com or info@pt-global.org

Appendix 7. Data collection form for medical records (NRS 2002, medication use)

Registreringsark å krysse av i fra SCREENING ERNÆRINGSRISIKO i Doculive.
Skal deretter punches inn i WEB-crf.

Merk at noen variabler er identiske med noen på registreringsarket for studiesykepleierne. Det er et poeng at de også registreres her, slik de er innhentet av «tilfeldige sykepleiere» i sengeposten.

Kvinne____, Mann_____, IDnr_____

Dato uthenting fra Doculive _____

Undersøkelsesdato i Doculive_____ Skjemaet er godkjent_____ Skjemaet står i kladd_____

Tidspunkt: Ved innleggelse __, Før innleggelse__, Under innleggelse__, Ved utskriving__, Poliklinisk___

Vekt _____ (kg), Høyde _____(cm), BMI_____ *(står med to desimaler, skriv dem inn, men punche inn med kun én desimal i WEB-crf)*

Innledende screening

Er BMI <20,5? ja____, nei____

Har pasienten tapt vekt de siste 3 mnd? ja____, nei____

Har pasienten hatt redusert næringsinntak de siste ukene? ja____, nei____

Er pasienten kritisk syk? ja____, nei____

(en sjekk på om sengeposten gått videre til risikovurderingen:

Står minst ett ja på «innledende screening»?_____. Er risikovurderingen utført? ja____, nei____)

Risikovurdering

Symptomer som reduserer matinntaket:

Appetittløshet_____, Kvalme/brekninger_____, Munntørrhet_____, Tygge/svelgeproblem_____, Lukt/smaksendringer_____, Sårhet i munn/svelg____, Rask metthet_____, Obstipasjon_____, Diaré_____, Subileus_____, Smerter_____, Ødem____, Hypoalbuminemi_____

Fri tekst_____

Vekttap i %_____ *(merk fortegnet her. Hvis det står minus foran tallet, er det en vektøkning)*

Endring ernæringsstatus: 0_____, 1_____, 2_____, 3_____

Det er følgende svaralternativer til denne variabelen:

0 = Normal ernæringsstatus

1= Vekttap >5% siste 3 mnd / Matinntak 50-75% siste uke

2= Vekttap >5% siste 2 mnd (>10% siste 3 mnd) / BMI 18,5-20,5 + nedsatt allmenn / Matinntak 25-50% siste uke

3= Vekttap >5% siste 1 mnd (>15% siste 3 mnd) / BMI <18,5 + nedsatt allmenn / Matinntak 0-25% siste uke

Skår for sykdommens alvorlighetsgrad: 0_____, 1_____, 2_____, 3_____

Det er følgende svaralternativer til denne variabelen:

0= ikke syk og ingen symptomer som reduserer matinntak

1=Kronisk sykdom eller gjennomgått mindre kirurgiske inngrep og/eller 1-2 sympomer

2=Tydelig redusert allmenntilstand på grunn av sykdom og/eller 3 symptomer eller flere

3= Er kritisk syk

Er pasienten over 70 år, gi ett skår: 0_____, 1_____

Total skår for ernæringsmessig risiko:

0_____, 1_____, 2_____, 3_____, 4_____, 5_____, 6_____, 7_____

Dato for spyttprøve: _____ *(antall og type medikamenter hentes fra dagen før)*

Antall medikamenter: _____

Navn medikament	**Dose**	**Antall doser den _____**

Appendix 8. Standardized protocoll for the saliva test

Prosedyre: Spyttprøve i MUMS

Vi ber om en spyttprøve for å kunne måle spyttproduksjonen. Nedsatt spyttproduksjon og munntørrhet er uheldig både for tygge- og svelgefunksjon, for tannhelsa og allmenn velvære.

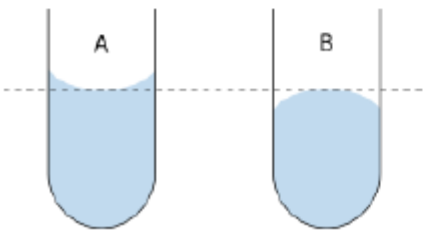
1. Spyttprøven skal tas *før* ROAG-undersøkelsen.
2. Spør om pasienten har spist, drukket, pusset tenner, skylt munnen, tygget tyggegummi, røkt eller inntatt medisiner gjennom munnen den siste halvtimen. Hvis dette er tilfellet, utsett å ta spyttprøven.
3. Forklar at det skal samles spytt i munnhulen i 5 minutter, uten å svelge. Pasienten spytter i røret underveis i løpet av de 5 minuttene, etter hvert som det samler seg spytt.
4. Pasienten kan sitte på stol eller sitte oppreist i sengen, avslappet. Hodet kan gjerne lute litt framover så spyttet samler seg foran i munnhulen. Pasienten skal ikke prøve å framprovosere spytt, men samle det som naturlig samler seg i munnen.
5. La pasienten svelge en gang før tidtakingen starter. Ta tiden med en timer/stoppeklokke. La pasienten spytte godt ut i prøverøret etter 5 minutter. Hvis pasienten må svelge før det har gått 5 minutter, vurdér å ta prøven på nytt eller registrer prøven som den er med angivelse av faktisk medgått tid. Pasienten kan gjerne drikke etter at prøve er avgitt.
6. Sett prøven i stativ i en isoporboks med is fram til den skal måles og evt. sendes til Felles prøvemottak for biobanking.

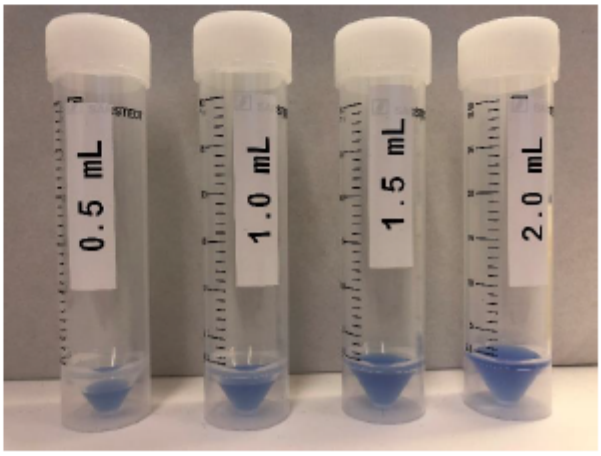
Måling av prøven.

Sammenlikn volum spytt i prøven med kalibrator. Kalibrator er et identisk prøveglass med markering for hver 0.5 mL.

Hold prøverør og kalibratorrør ved siden av hverandre og avles volum. Se bort fra skum som er samlet på toppen, avles menisk av væskeoverflaten mot væske i kalibratorrør eller mot gradering (se figur 1).

Angi volum som <0.5 hvis mindre enn 0.5 mL, angi ellers volum med én desimal .0 eller .5 for volum inntil 2.0 mL.





Figur 1. Måling av spyttvolum.

Rekvirering av prøve i ROS.

Hvis pasienten har samtykket til at vi kan lagre prøven for fremtidig forskning så skal prøven rekvireres i ROS. Fremgangsmåte:

Velg medisinsk enhet ADM, pleieenhet BIOBA1 og ressurskode ORAL helse. Rekvirere analysekode ORAL spytt.

Hold spyttprøven på is.

Merk prøverøret med ROS-etikett og send prøven med rørpost så snart som mulig og helst innen en time etter prøvetaking.

Appendix 9. Assessment form used by study nurses

ID:	Rom:
Dato:	

Registreringsark studiesykepleiere (MUMS)

1. Sjekket (med Thomas) at personen har samtykket i å delta i MUMS:

Nei ☐ Ja ☐

2. Høyde og vekt

Notater (med klær og/eller sko):

Høyde: ☐☐☐,☐ cm _____

Vekt: ☐☐☐,☐ kg _____

3. Spørsmål som stilles under måling av høyde og vekt

Har du gått ned i vekt i løpet av de siste 3 månedene?

Nei ☐ Ja ☐

Har du hatt et redusert matinntak de siste ukene?

Nei ☐ Ja ☐

Har det gått minst 30 minutter siden du har spist, drukket, pusset tenner, brukt tyggegummi, røyket/snust?

Nei ☐ Ja ☐

4. Temperatur

Temperatur: ☐☐,☐ °C

5. Spyttprøve

Volum spytt: ☐☐,☐ mL **Tid:** ☐:☐☐ min:sek

Samtykket i å sende spyttprøven til Biobank1:

Nei ☐ Ja ☐

Evt. kommentarer om spyttprøven:

Tannhelsetjenestens kompetansesenter Midt-Norge

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Appendix 10. The Revised Oral Assessment Guide-Jönköping (ROAG-J)

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Tannhelsetjenestens kompetansesenter Midt-Norge

ID: Rom:

Dato:

Observasjon av munnhelse (ROAG-J)

1. Hvordan høres stemmen ut?
(Sett ett kryss)

- Normal ☐
- Tørr, hes, smattende ☐
- Vanskelig for å snakke ☐
- Ikke aktuelt ☐

2. Hvordan er svelgefunksjonen?
(Sett ett kryss)

- Uhindret svelging ☐
- Noe svelgeproblemer ☐
- Store svelgeproblemer ☐
- Ikke aktuelt ☐

3. Hvordan ser leppene ut?
(Sett ett kryss)

- Myke, lyserøde, fuktige ☐
- Tørre/sprukne/sår i munnviken ☐
- Såre, blødende lepper ☐

4. Hvordan ser munnslimhinnene ut?
(Sett ett kryss)

- Lyserøde, fuktige, uten sår ☐
- Røde/tørre/fargeforandringer/belegg ☐
- Sår eller blemmer ☐

5. Hvordan ser tungen ut?
(Sett ett kryss)

- Lyserød og fuktig ☐
- Rød/tørr/med eller uten belegg ☐
- Sår og/eller blemmer ☐

6. Hvordan ser området under tungen ut?
(Sett ett kryss)

- Fuktig, med synlig spytt ☐
- Tørt, uten synlig spytt ☐

7. Hvordan glir tannbørsten mot innsiden av kinnet?
(Sett ett kryss)

- Lett ☐
- Tregt ☐
- Ikke i det hele tatt ☐

8. Hvordan ser tannkjøttet ut?
(Sett ett kryss)

- Lyserødt og fast ☐
- Hovent og rødt ☐
- Spontan blødning ☐
- Har ikke egne tenner/tannkjøtt ☐

9. Egne tenner? (Hvis «nei» gå til spm. 10)

Ja ☐ Nei ☐

Hvis ja:
9a.Hvordan ser tennene ut?
(Sett ett kryss)

- Rene, uten synlig belegg/matrester ☐
- Belegg/matrester på noen tenner ☐
- Belegg/matrester på de fleste tennene, eller svært ødelagte tenner ☐

9b. Antall tenner, løse/bevegelige tenner og rotrester

Flere enn 6 tenner i overkjeven?

Ja ☐ Nei ☐

Flere enn 6 tenner i underkjeven?

Ja ☐ Nei ☐

Er noen av egne tenner løse/bevegelige?

Ja ☐ Nei ☐

Ser du noen rotrester?

Ja ☐ Nei ☐

10 Hel- eller delproteser?

Ja ☐ Nei ☐

Hvis ja:

10a. Protese hvor?

(Sett ett kryss)

I overkjeven ☐

I underkjeven ☐

I både over- og underkjeven ☐

10b. Hvordan ser protesen(e) ut?

(Sett ett kryss)

Ren(e) ☐

Belegg, matrester ☐

10c. Hvordan fungerer protesen(e)?

(Sett ett kryss)

Greit ☐

Dårlig ☐

Bruker de(n) ikke ☐

11. Munnhelseundersøkelsen (ROAG-J) er:

Gjennomført ☐

Delvis gjennomført ☐

Ikke gjennomført ☐

Hvis delvis eller ikke gjennomført:

Deltaker ønsker ikke ☐

Ikke gjort pga deltakers helsetilstand ☐

Annet, evt hva:

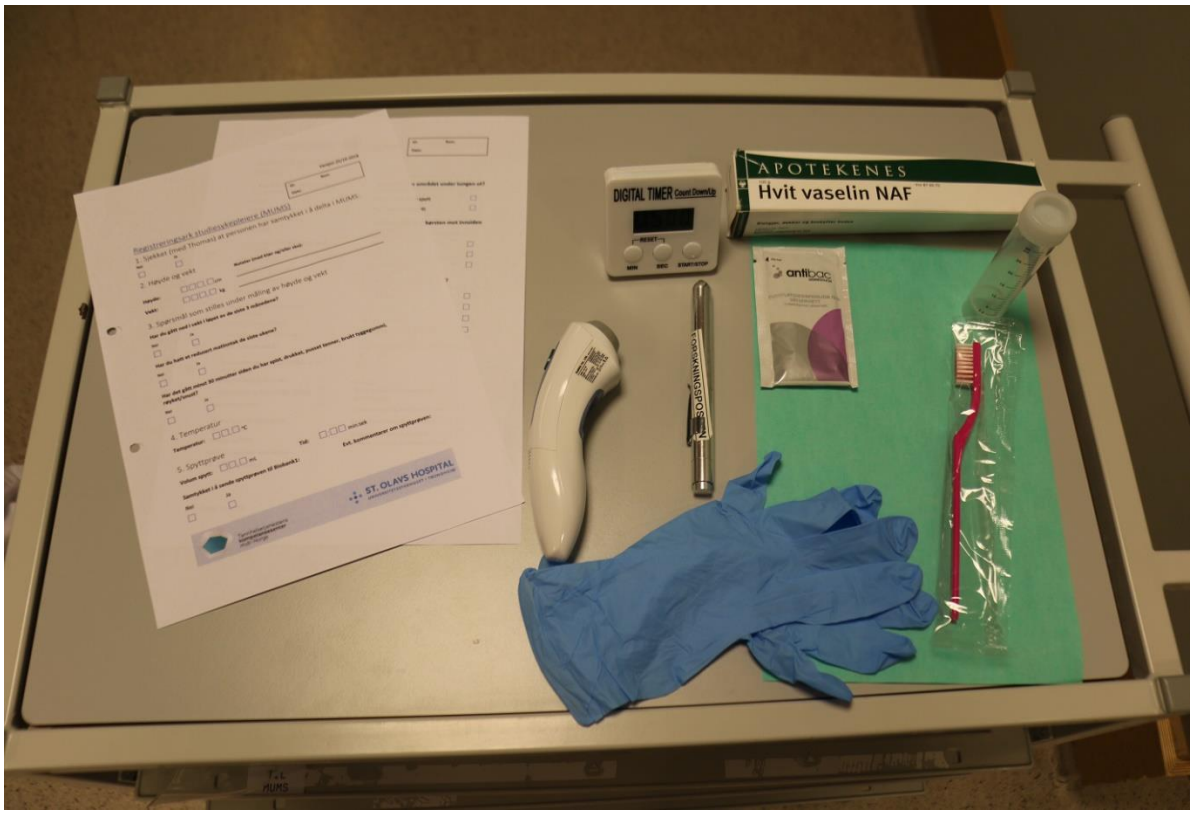
_____

_____

12. Hvis denne observasjon av munnhelse (ROAG-J) vekker mistanke om alvorlig tilstand som ikke blir fulgt opp, er ansvarlig sykepleier/tannteam informert?

Ja ☐ Nei ☐

Appendix 11. Equipment used for performing the ROAG-J assessment



- Digital timer
- Vaselin (for application on lips)
- Disinfectant wipes
- Flashlight
- Disposable plastic toothbrushes
- Medical gloves
- Also depicted: Two forms (assessment form, the ROAG-J), medical forehead thermometer, Sarstedt tube

Appendix 12. The self-administered questionnaire on oral health

ID: Rom:

Dato:

SPØRRESKJEMA OM MUNNHELSE

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Tannhelsetjenestens kompetansesenter Midt-Norge

Takk for at du ønsker å delta i forskningsprosjektet «Ernæringsstatus og munnhelse hos inneliggende pasienter ved St. Olavs hospital». Nå skal du få svare på noen korte og enkle spørsmål om munnhelsen din.

1. Føles det ut som mengden spytt i munnen din er for liten?

Nei ☐ Ja ☐

2. Har du problemer med å svelge noen matvarer?

Nei ☐ Ja ☐

3. Føles munnen din tørr når du spiser et måltid?

Nei ☐ Ja ☐

4. Må du drikke for å få til å svelge tørr mat?

Nei ☐ Ja ☐

5. Plages du med munntørrhet?

Nei ☐ Ja ☐

6. Kan du tygge all slags mat?

Nei ☐ Ja ☐

7. Hvordan vurderer du tannhelsa di?

Meget dårlig ☐ Dårlig ☐ God ☐ Meget god ☐

8. Går du regelmessig til tannlege eller tannpleier?

Nei ☐ Ja ☐

HVIS JA, hvor ofte går du til tannlege eller tannpleier?

Svar: _____

9. Hvilke tannpleiemidler bruker du, og hvor ofte?
(Sett ett kryss per linje)

	Sjelden/aldri	En gang i uken	En gang om dagen	To eller flere ganger daglig
Tannbørste.....	☐	☐	☐	☐
Tannstikker.....	☐	☐	☐	☐
Tanntråd.....	☐	☐	☐	☐
Mellomromsbørste.....	☐	☐	☐	☐
Protesebørste.....	☐	☐	☐	☐
Tannkrem.....	☐	☐	☐	☐
Munnskyll.....	☐	☐	☐	☐
Fluortabletter.....	☐	☐	☐	☐

10. I løpet av de siste 12 måneder, hvor ofte har du på grunn av dine tenner, forhold i munnen eller proteser (gebiss) hatt disse problemene?
(Sett ett kryss per linje)

	Ofte	Ganske ofte	Av og til	Sjelden	Aldri
Vanskeligheter med å uttale ord eller lage spesielle lyder..	☐	☐	☐	☐	☐
Endret/dårligere smaksans.....	☐	☐	☐	☐	☐
Smerter i munn/tenner.....	☐	☐	☐	☐	☐
Opplevd at mat har gitt deg ubehag.....	☐	☐	☐	☐	☐
Hatt en dårligere kost eller kostsammensetning.....	☐	☐	☐	☐	☐
Måttet avbryte måltider.....	☐	☐	☐	☐	☐

11. I løpet av de siste 12 måneder, hvor ofte har dine tenner, forhold i munnen eller proteser (gebiss) bidratt til at du har
(Sett ett kryss per linje)

	Ofte	Ganske ofte	Av og til	Sjelden	Aldri
Følt deg usikker, stresset, irritabel.....	☐	☐	☐	☐	☐
Hatt vanskeligheter med dine vanlige gjøremål..	☐	☐	☐	☐	☐
Følt at livet var mindre tilfredsstillende.....	☐	☐	☐	☐	☐
Ikke kunnet fungere i hverdagen.....	☐	☐	☐	☐	☐