Nutritional nursing care for patients undergoing surgery

a personalized approach

Harm H.J. van Noort

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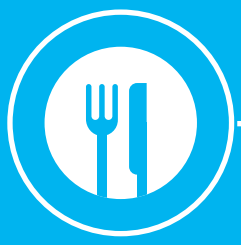

Chapter 1

General introduction

General introduction

Nurses are pivotal to deliver fundamental care to surgical patients. Nurses perform preoperative consultations at outpatient clinics (1) and deliver about 75% of all in-hospital care for patients who undergo surgery (2). The nutritional state of patients is a prognostic factor for recovery after surgery, subsequently influencing physical functioning and patients' perceived quality of life (3-9). Nutritional status involves the balance of nutrient intake and individual requirements. Caring for an optimal nutritional state of patients belongs to essential activities of nursing (10, 11). Through the delivery of essential nursing care activities, nurses ensure patient safety, contribute to general health, and prevent complications (12). As such, nurses fulfil a prominent role which demand evidence-based care activities to optimize the nutritional status of patients when they undergo surgery.

Fundamental nursing care for surgical patients

Historically, the word 'nurse' originates from the Anglo-French word '*nutrice'* and the Latin word '*nutrica'* (13). Both these words mean 'nourish', and that is exactly what nurses do. Florence Nightingale (1820-1910) was one of the first to acknowledge the importance of nutrition. During her experience as a nurse in military hospitals in the Crimean War between 1853 and 1856, she investigated what nursing is about (14). She wrote that attention for recovery should include advanced kitchens to cook the food, and that the delivery of food must have attention (15). With her effort, mortality rates dropped from 42% to 2% among wounded soldiers (14).

During the 20th century, models and theories about nursing were developed by nurses like Henderson's and Nite's (16) and Pearson's and Vaughan's (17). The eating and drinking of patients remained a crucial element of nursing care according to these nurses. In the 21st century, the International Council of Nurses defines that nurses aim to promote health, to prevent illness such postoperative complications, and to care for ill or disabled people (12). Also, Alison Kitson and colleagues synthesized the essential elements of nursing in the Fundamentals of Care (FoC) Framework (10). Central purpose in this internationally embraced framework is the nurse interaction with the patient to establish a relation. Within this relation, personalized care is provided within three dimensions: a physical, psychosocial and relation dimension (see figure 1). Within the physical dimension, eating and drinking of the patients are essential needs. Nutritional nursing care includes management of short fasting periods (18, 19), screening for nutritional care needs (19), monitor food intake (20-22), patients' empowerment to engage in their nutritional care (20), maintenance of oral care, and assisting with eating and drinking (19). As such, nutritional status is defined as an outcome that is sensitive to nursing activities (11, 23). As members

of the multidisciplinary staff, nurses provide outpatient clinic consultations before hospital admission for surgery (1, 24). Regarding preoperative nutritional support for patients with risk for undernutrition, both nurses and dieticians play pivotal roles. Nurses screen the nutritional status with nutritional screening tools such as the Short Nutritional Assessment Questionnaire (SNAQ) or the Malnutrition Universal Screening Tool (MUST) (25). Depending on the outcome of this screening, the patients can subsequently be referred to a dietician. Therefore, patients are supported for their nutritional state by nurses in cooperation with other professionals.

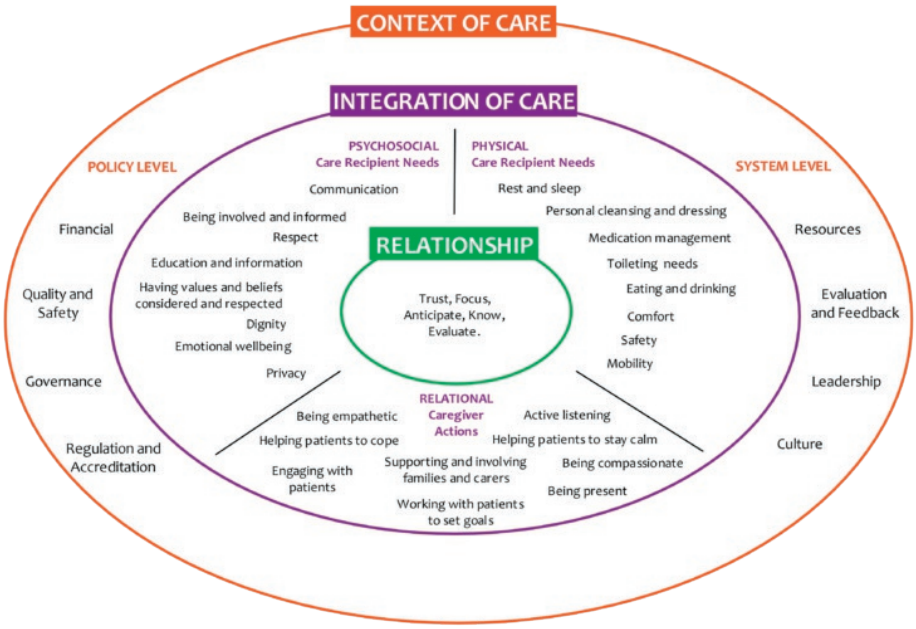

Figure 1 – Fundamentals of Care framework (26)

Image obtained from https://ilccare.org/the-framework/ (17th January, 2022)

Despite research on nursing activities is growing over the past decades (27), many daily fundamental nursing activities are still lacking scientific evidence or are not studied yet, according to the world's leaders in nursing care research (28-31). It is even worse in daily practice, where patients' fundamental needs appear to be unmet which threatens patient safety and quality of care (32-34). Examples of care that is left undone include nutritional care (34, 35), oral hygiene (35, 36) and patient education (37-39). For these reasons, it is time to speak up and transform delivery of fundamental nursing activities (31, 32). This requires systematic and high-quality

investigations to generate evidence for daily practice (31, 32). Subsequently, this will improve patient outcomes, job satisfactions and organisational outcomes (28). Research on daily nursing activities should be close to daily practice. That will inform the content and characteristics of the nursing interventions and ensure the uptake and implementation of the interventions in daily practice (27, 28).
In daily practice, it is known that the uptake of nutritional guidelines and ERAS programs in daily practice can be difficult (40-42). Contributing factors to this include gaps of knowledge and positive attitude of the perioperative team, limited hospital resources, poor communication and collaboration and lack of data and/or education (40). Therefore, to translate current knowledge regarding nutrition for surgical patients, it is important to understand knowledge translation in fundamental nursing care. Experimental designs can provide knowledge on what works and what the mechanisms of effective nursing care are (30), such as the Medical Research Council (MRC) framework (43). The MRC framework guides the development and evaluation of complex interventions can be used to generate the required evidence (28, 43, 44). This framework is a solid foundation to research fundamental nutritional care.

Physical consequences due to surgery

Yearly, more than 1.4 million patients undergo surgery in the Netherlands (45). Surgery induces metabolic stress and an increase of inflammatory factors (46-48). This leads to the release of glucose, free fatty acids, and amino acids which support tissue healing processes (49, 50). The body enters a catabolic state which lead to insufficient protein and glucose reserves especially when the operation is longer or involves high impact techniques (51-55). Risk factors for compromised metabolic response include undernutrition and prolonged fasting behaviour (46, 56). Surgical patients with undernutrition have an increased risk for postoperative complications such as infection (57), delayed gastrointestinal motility (58), delayed wound healing (59), and renal and cardiac impairment (57). Undernutrition is also associated with prolonged length of hospital stay and readmissions in surgical patients (60). The current thinking is therefore that an impaired nutritional status before surgery affects postoperative recovery (51). The opposite is also true: patients who participated in nutritional prehabilitation programs have better recovery outcomes (61-63).

Preoperative nutritional therapy for patients with undernutrition

At preoperative nurse-led outpatient clinics, nurses apply evidence-based screening instruments to assess patients' preoperative health status (1). Beside assessment of vital signs, medication use, and oral prosthesis status, this also includes assessment of nutritional status (1, 24, 25, 64). Weight loss is a preoperative risk factor for

postoperative mortality (65), and is classified as a phenotypic criterion for malnutrition (66). A state of undernutrition means a disbalance of the use and availability of nutrients for basic metabolism in the body (67). It is also described as protein-energy malnutrition (67). It appears that 5 to 45% of the patients who undergo surgery have a risk for undernutrition (3, 4, 7). Undernutrition rates for surgical specialties were 13% for Ear-Nose-Throat-surgery, 10% for general surgery, and 8% for vascular surgery (7). Upon hospital admission, prevalence of undernutrition (17.5%) and being at risk for undernutrition (24.1% and 45.2%) was even higher according to German and Italian studies (3, 4). For those with (risk for) undernutrition, nutritional support should be initiated.

Nutritional support for undernourished surgical patients aims for sufficient nutritional status and nutrient intake which can be delivered either orally, enteral, or parenterally (46). Nutritional support is required during pre-, peri-, and post-operative course. In 1946, Koop and Rhoads were among the first to report the benefits of preoperative forced feeding for patient undergoing major abdominal surgery (68). In the 90's, a multimodal approach to reduce the metabolic stress caused by surgical trauma and at the same time support restoration of functions called 'Enhanced Recovery After Surgery' (ERAS) was proposed by Kehlet (69-71). During the last decades, adequate adherence to ERAS programs resulted in improved recovery with lower complications rates, higher survival rates, and shortened hospital stay (72). More recently, preoperative optimization of the physical and psychosocial functions of patients became of interest in prehabilitation programs (61-63). Preoperative nutritional treatment may lead to improved perioperative functional capacity (61, 73-75), which can be done in the longer preoperative period (i.e., up to four weeks) and the direct preoperative phase (i.e. up to twelve hours before).

Fasting from oral intake to prevent pulmonary aspiration

In the direct preoperative phase, patients are requested to fast from solid foods and clear liquids (76). Fasting is required for surgical patients to prevent pulmonary aspiration during the administration of anaesthesia. Aspiration of gastric content into the lungs is associated with mortality and pulmonary morbidity (77). Preoperative fasting guidelines have been applied and changed over time (78). Since the 1960s, it became standard practice to routinely prepare patients with a nil-per-mouth from midnight (41, 79-81). This practical approach contributes to unnecessary long fasting times, along with low flexibility in operation room management (79). Prolonged fasting times induces discomfort in patients and metabolic impairment. Discomfort due to fasting encompasses thirst, hunger, headache, and anxiety (82, 83). Metabolic impairment includes the catabolism of glycogen and insulin resistance (49,

50, 84). Prolonged fasting should be avoided, which requires everyone involved who have a role in perioperative settings. Since 1992, anaesthetic guidelines recommend patients to stop eating solid foods within 6 hours and stop drinking clear liquids 2 hours before surgery (78). International guidelines also recommend encouraging of patients to eat and drink as long as possible (46, 76, 85). The adherence to these guidelines is important which are of interest in this thesis.

Patient education

The modern definition of health focusses on health instead of illness (86, 87). This definition inspires health care workers to empower their patients with know-how to live healthy with their illness. In today's health care delivery, care is appropriate when it is designed with and around the patients have a central role for patients (33). Moreover, fundamental to nursing care is the interaction between the patient and the nurse (10). In order to recognise the patient as an individual and as a partner to participate in the healthcare team, effective communication and interaction is required between the patient and the healthcare team (88, 89). Patient participation involves the engagement in the patients' care through a dialogue attuned to his preferences and values and the professional' expertise (90, 91). Numerous researchers have already found that effort for enhanced patient participation has positive outcomes, such as lower levels of patients' anxiety and enhanced adherence to treatment and advices (92, 93), and increased patient-centred care with patients feeling empowered (91, 94). Patient participation is therefore also part of nursing care and nursing strategy (95, 96). A crucial element for patients to manage their health and to make treatment decisions is patient education (97). Unfortunately, patient education is an element of fundamental nursing care that is frequently left undone (37-39, 98). Therefore, nurses to need to educate their patients.

Aims and outline of the thesis

This thesis aims to address the lack of scientific evidence of outpatient preoperative nursing care for patients who undergo surgery to improve daily care for the nutritional state. The first aim of this thesis is to develop and evaluate an outpatient nursing nutritional intervention for undernourished surgical patients. Chapters 2-4 describe the development and evaluation of a nursing nutritional intervention to be delivered at an outpatient clinic following the MRC framework. In chapter 2 a systematic review was undertaken to evaluate the effects of oral nutritional support. In chapter 3, an intervention to improve the preoperative nutritional status of patients was systematically developed following the Intervention Mapping approach. This intervention was

evaluated on its feasibility and effectiveness using a two-centre cluster-randomised pilot study design which is described in Chapter 4.

The second aim of this thesis is to evaluate the adherence to evidence-based fasting recommendations during the direct preprocedural period. Chapter 5 describes the adherence to preoperative and postoperative fasting recommendations up to 20 years after the introduction of the guidelines. In Chapter 6, fasting education including the encouragement to eat up to six and drink up to two hours before was provided to patients undergoing esophago-gastro-duodenoscopy. In a controlled pilot study, its applicability and efficacy were evaluated.

Chapter 7 discusses the main findings, the strengths and limitations of this thesis, and implications for future innovations, research and for daily practice.

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Chapter 2

Outpatient preoperative oral nutritional support for undernourished surgical patients: A systematic review

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Abstract

Aims and objectives: To evaluate the effects of preoperative nutritional support using a regular diet for undernourished surgical patients at the outpatient clinic.

Background: Undernutrition (or malnutrition) in surgical patients has severe consequences i.e. more complications, longer hospital stay, and decreased quality of life. While systematic reviews show the effects of oral nutritional supplements (ONS), enteral and parenteral nutrition in surgical patients, the effects of normal foods and regular diets remain unclear.

Design: A systematic review.

Methods: PubMed, CINAHL, Web of Science, PsycInfo, Cochrane Library, and Embase were searched up to July 24th, 2017. Studies on undernourished patients receiving nutritional support using regular or therapeutic diet, performed preoperatively at the outpatient clinic, were considered eligible. Risk of bias was assessed using the Cochrane Risk of Bias tool. Two reviewers independently performed study selection, quality assessment, and data extraction.

Results: Six studies with moderate risk of bias were included. Interventions were preoperatively performed in mainly oncological outpatients by dieticians and aimed to reach nutrient requirements. Interventions included consults for counselling and advice, follow-up meetings and encouragements, and ONS. Nutritional status, nutrient intake, and quality of life improved in supported patients. Improvements were better in counselled patients compared to patients using supplements. Unsupported patients experienced worse outcomes.

Conclusion: Frequent consults with counselling and advice as nutritional support for undernourished patients before surgery result in improvements to nutritional status, intake, and quality of life. This statement is supported by weak evidence due to few studies and inadequate methods.

Relevance to clinical practise: Nutritional support should be provided to all undernourished surgical patients during preoperative course. Nurses are in key position to provide nutritional support during outpatient preoperative evaluations.

Keywords

Nutritional support, Preoperative Care, Undernutrition, Outpatients, Malnutrition, Surgery, Systematic review, Regular diets, Nutrition Therapy

What does this paper contribute to the wider global clinical community?

- Disease-related undernutrition is a worldwide problem which hampers health, and quality of life even in surgical patients in developed countries.
- This review shows that preoperative nutritional support using a regular or therapeutic diet for undernourished outpatients consists of consults, follow-up and additional provision of supplements and results in an improved nutritional status, nutritional intake and quality of life.
- Besides the lack of studies, the heterogeneity of interventions, settings and patient population, and the variety of definition of outcomes, undernourished surgical patients should receive nutritional support during their preoperative course.

Introduction

Undernutrition in surgical patients affects their postoperative recovery. Undernutrition is defined as 'a disorder of nutritional status resulting from reduced nutritional intake or impaired metabolism' and is often described as protein energy malnutrition (1). Treatment-related factors, such as required episodes of fasting before surgery, side effects of medication like vomiting or diarrhea, and surgery-induced inflammation and metabolic stress response, may contribute to undernutrition(2, 3). Surgical patients with undernutrition face longer hospital stays with subsequent increases in costs (4-9), more postoperative complications, i.e., infections, renal and cardiac complications, delayed recovery of gastrointestinal functions, and fistula or wound healing troubles (10-12). They also have a higher risk of mortality and morbidity (13, 14), and experience a decreased quality of life (15). This long list of the consequences of undernutrition among surgical patients indicate the urgency for adequate nutritional support.

Timely recognition of undernutrition and initiation of nutritional support may lead to a nutritionally better starting position for surgery. Health status, including nutritional status, is evaluated during an outpatient preoperative evaluation by both anaesthesiologists and nurses before a planned surgery (16-18). In the case of undernutrition identified during these evaluation sessions, nurses should provide nutritional support to decrease nutritional risk and prevent deterioration of nutritional status before hospitalization. Nutritional support, or nutritional therapy, is defined as the provision of nutrition either orally, including regular or therapeutic diet and oral nutritional supplements (ONS), enteral, or parenteral (EN/PN)(3). Systematic reviews and meta-analyses on perioperative use of ONS, EN, and PN have been shown to positively impact postoperative recovery (19-22). Complications were significantly reduced in patients nutritionally supported with EN or PN, and length of hospital stay was effectively shortened in these patients. Nutritional support using a regular

or therapeutic diet are not addressed in these reviews but could be started early, e.g. during outpatient preoperative evaluation by nurses. Nurses should have an very important role in nutritional support because undernutrition is both a nursing sensitive outcome (23) and a fundamental element of nursing (24-26). However, the effects of nutritional support using a regular or therapeutic diet during preoperative courses remain unclear. Therefore, this review aims to evaluate the effects of early outpatient preoperative oral nutritional support using regular or therapeutic diet in undernourished surgical patients.

Aims

The aims of this review were 1) to identify intervention studies on early outpatient preoperative oral nutrition support using regular or therapeutic diet in undernourished surgical patients and 2) to evaluate effectiveness of oral nutrition support using regular or therapeutic diet. This overview will contribute to the body of fundament nutritional care.

Methods

This review was undertaken in accordance with the PRISMA guidelines (27) and the Cochrane Handbook (28).

Search strategy

A comprehensive systematic search strategy was performed in PubMed, CINAHL, Web of Science, PsycInfo, Cochrane Library and EMBASE from the starting dates of the databases until July the 24th, 2017. The structure of the search strategy followed the well-known PICO scheme whereby only terms related to the population (e.g. preoperative care, outpatients), and intervention (e.g. nutritional support, nutrition therapy, nursing care, dietetics, nutritionists) were defined (28). Outcomes were not defined in the search strategy since the effects of interest are wide and measured differently. The full search strategy is shown in appendix 1. Additionally, reference lists of included articles and related reviews were searched.

Eligibility criteria

Articles were eligible when they were primary research studies, included patients of at least 18 years of age, included at least 30% undernourished patients and were written in Dutch, German, or English. Studies of interest evaluated oral nutritional supportive interventions that used a regular or therapeutic diet, were performed in the outpatient setting, and took place before a planned hospital admission for sur-

gery. Oral nutritional supplements as part of the intervention were accepted if these were part of an intervention or if these were compared with oral nutritional support without supplements. Studies should report on effects of an intervention. There were no limitations regarding methodological quality and publication date. Conference articles were not included.

Study screening process

Each database was searched separately, and search results were transported to Endnote X7.2. After duplicate removal, the selection process was performed in three phases by two reviewers (HN and GHdW) independently. First, they assessed the titles of the records. Secondly, abstracts of relevant titles were assessed. Finally, full-text articles were read. Additionally, reference lists of the selected full text articles and a review regarding preoperative nutritional support (20) were assessed during the three phases. After each phase, differences in assessment were discussed by the reviewers until a consensus was achieved. A third reviewer (HV) was available in case of discrepancies.

Quality appraisal

The risk of bias in randomised studies was assessed using the risk of bias tool of the Cochrane Collaboration (28). The Newcastle-Ottawa Scale (NOS) for Assessing the Quality of Nonrandomized Studies was used for case-control studies (29). All assessments were independently performed by two reviewers (HN, MtM). A third reviewer was available for discussions and disagreements to reach a consensus (GHdW). The risk of bias was used for interpretation during the synthesis of the data.

Data extraction and synthesis

Data collection was facilitated by a structured data collection form. Two reviewers (HN, RE) undertook the process of data extraction, and any discrepancies were discussed with a third reviewer (GHdW). Data included the first author; year of publication; country; study design; time points of measurements; details of study participants, i.e., number of participants, age, gender, diagnoses, nutritional status and type of assessment; details of the intervention, i.e., professionals involved, intervention period, study groups, and intervention components; and effectiveness with regard to the outcomes of nutritional intake, weight, nutritional status, quality of life, length of hospital stay, postoperative complications; patients' satisfaction with care; and cost effectiveness.

RESULTS

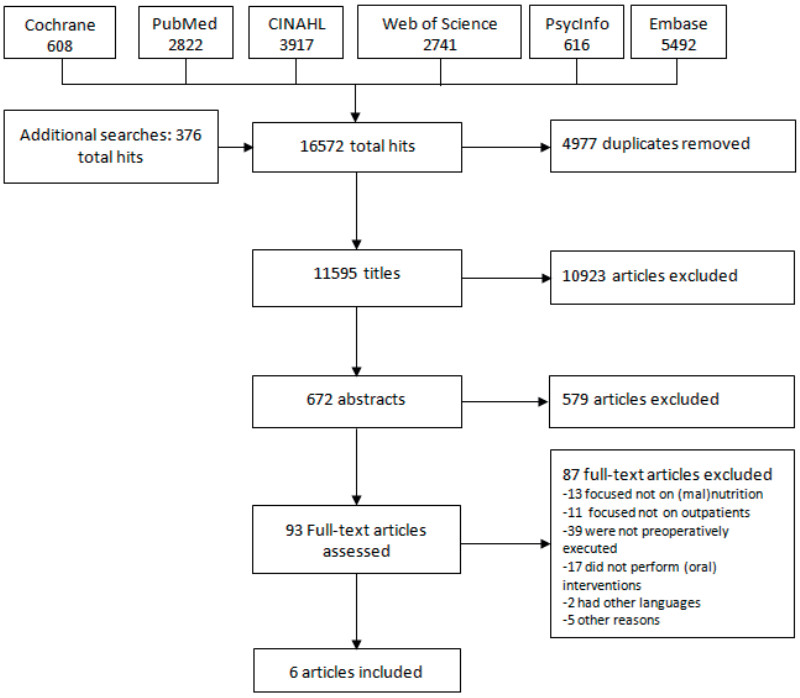

Figure 1 – Article flow during the selection process of the studies

Description of the articles

The literature search resulted in 11.595 hits of which six articles finally met the inclusion criteria (see article flow in figure 1). The included studies were published between 1987 and 2015. Five articles describe a (pilot) randomised study design, and one describes a case-controlled study (30) (see table 1). Of the articles on RCTs, one three-armed study is described in two articles, one on the short term effects (31) and one on the long term effects (32)). Data were collected in all studies at three points in time: the first visit to the outpatient clinic during or soon after diagnosis; the period before surgery, and, after surgery. The third point could be during hospitalisation (33), at discharge (34), or after discharge (30-32, 35). Study outcomes include nutritional outcomes (nutritional intake (31-33), nutritional status (31, 32, 35), weight (30, 35)), quality of life (31, 32, 35), length of hospital stay and complications (30, 33, 34), patient satisfaction (35), and cost effectiveness (34).

Table 1 – Summary of study characteristics and interventions regarding oral nutritional support using a regular diet

Author (year), Country	Design	Participants	Nutritional assessment	Intervention period (mean)	Study group	Intervention components
Flynn et al. (1987) United States of America	RCT	*Patients* (n=36) with squamous cancer of the upper aerodigestive tract scheduled for operative resection *Age* (mean): 64 years *Undernutrition*: 100%	Weight change, antropometric features and relevant laboratory parameters	10-21 days between outpatient visit and surgery	IG (n=19)	*Consults:* Nutritional counselling and suggestions to cope with eating problems; specific recommendations: to meet their individual nutrient requirements or a nutritional supplement to fulfil their intake needs *Follow up meetings*: contact determined independently by the dietician to determine nutritional status and encourage compliance to the protocol *Supplements*: if indicated to fulfil intake need
					CG (n=17)	Nutritional counselling and suggestions to cope with eating problems
Le Cornu et al., 2000, United Kingdom	RCT	*Patients* (N=81) with ESLD scheduled for orthotopic liver transplantation Age (median): 51 years *Male* (%): 73% *Undernutrition*: 100%	mid-arm muscle circumference (MAMC) <25 percentile	IG: median 77 (1–395) days CG: median 45 days (1-424) between initial assessment and surgery	IG (n=42, S: n=39)	*Consults:* Advice to adapt usual intake to increase intake and to achieve individual protein requirements, tailored to their underlying medical condition and symptoms; to eat small, frequent meals and snacks, late evening snack; discouraged from following guidelines of healthy eating, food diary 5 days before outpatient visit *Supplements*: 500ml supplements each day until surgery *Follow up meetings:* no contact in between
					CG (n=40, S: n=32)	*Consults:* as described above

Table 1 *(Continued)*

Author (year), Country	Design	Participants	Nutritional assessment	Intervention period (mean)	Study group	Intervention components
Ravasco et al., 2005, Portugal	RCT	*Patients* (N=111) with colorectal cancer *Age* (mean):64 years *Male* (%): 59% *Undernutrition*: 38%	BMI and PG-SGA	6 wks	IG1 (n=37)	*Consults*: weekly individualized dietary counselling on the prescription of therapeutic diets using regular foods
					IG2 (n=37)	*Supplements*: consumption of 400ml high-protein supplements each day in addition to regular foods
					CG (n=37)	instruction to maintain and consumption ad libitum intake
Ravasco et al., 2012, Portugal	RCT, follow-up median 6.5 (range 4.9–8.1) years Ravasco et al., 2005	*Patients* (N=89) with colorectal cancer *Age* (mean):64 years *Male* (%): 54% *Undernutrition*: 38%	BMI and PG-SGA	6 wks	IG1 (n=34)	*Follow-up after consults*: weekly individualized dietary counselling on the prescription of therapeutic diets using regular foods before and during the hospital admission
					IG2 (n=29)	*Follow-up after supplements*: consumption of high-protein supplements each day in addition to their regular foods before and during the hospital admission
					CG (n=26)	*Follow-up after* instruction to maintain and consumption ad libitum intake
Silvers et al. (2014) Australia	Pilot RCT	*Patients* (N=21) with esophageal or stomach cancer *Age* (mean): 68 years *Male* (%): 57% *Undernutrition*: 90%	PG-SGA	18 wks with start immediately after diagnoses	IG (n=10)	*Consults*: Weekly 15-30 min telephone calls or face-to-face interviews with tailored, symptom-directed treatment approach based on the taxonomy of behaviour change techniques of Abraham and Michie *Supplements*: oral nutritional supplement samples if indicated

Table 1 *(Continued)*

Author (year), Country	Design	Participants	Nutritional assessment	Intervention period (mean)	Study group	Intervention components
					CG (n=11)	*Consults:* assessment and intervention 6-10 weeks after diagnoses, if nursing or medical staff made a referral; intervention had a similar tailored, symptom-directed approach, and varied for amount and timing
Leistra et al. (2015), The Netherlands	Case- control study	*Patients* (n=190) with head and neck cancer planned for surgery (n=78), radio- (n=38) or chemoradiotherapy (n=84) *Age*(mean): 61years *Male* (%): 71% *Undernutrition*: 55%	SNAQ and BMI	Pretreatment period: 4 wks, start within 1 wk after first outpatient visit	IG (n=95, S: n=34)	*Consults*: Dietary assessment in the pretreatment period including current intake of energy, nutrients and alcohol, evaluation of oral symptoms using the FAACT A/CS12; counselling according to most recent Dutch guidelines; aimed to improve dietary patterns with normal food intake, protein and/or energy enrichment, modified texture for dysphagia patients, alleviation of oral pain or chewing problems *Follow-up meetings:* weekly by telephone or face to face during outpatients visit *Supplements:* oral nutritional supplements (ONS) or tube feeding were provided if patients did not meet their goals with normal food (n=11 of the surgical patients[#])
					CG (n=95, S: n=34)	*Consults*: during pretreatment period only on referral by a physician *Supplements:* ONS (standard of 4 packages a day) prescribed by a nurse in case of SNAQ score ≥3 or severe swallowing problems

RCT: Randomized Controlled Trial; IG: intervention group; CG: control group; S: patients who received surgery; ESLD: End-stage Liver Disease; BMI: Body Mass Index; PG-SGA: patient-generated Subjective global assessment; wks: weeks; SNAQ: Short Nutritional Assessment Questionnaire; FAACT A/CS12: Functional Assessment of Anorexia/Cachexia Therapy; #: this information is received out of personal communication with the author of this study, E. Leistra, PhD, RD.

Table 2 – Quality assessment of the included studies

Cochrane Risk of Bias tool	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Total items at low risk
Flynn et al., 1987	-	-	-	-	-	/	/	5/7
Le Cornu et al., 2000	-	-	+	/	-	/	/	3/7
Ravasco et al., 2005	-	-	/	/	-	/	/	3/7
Ravasco et al., 2012	-	-	+	/	-	/	/	3/7
Silvers et al., 2014	-	-	+	+	/	/	/	2/7
Newcastle-Ottawa Scale (NOS)	Selection		Comparability		Exposure			Total stars
Leistra et al., 2015	----		--		---			8/9

-=low risk of bias; += high risk of bias; /=unclear risk of bias; ¯=each star indicate a high quality choices for the items per domain of the Newcastle-Ottawa Scale

Quality

The overall quality of the studies appeared to be moderate (table 2). Of the five randomised studies, one study meets the criteria for a low risk of bias for five of seven items (34), the other studies only meet these criteria for two or three of the items. One study did not perform blinding at all, resulting in two items at high risk of bias (35). An unclear risk of bias was determined due to lack of clearly described procedures. The case-control study meets eight of the nine NOS -items.

Participants

Sample sizes ranged from 21 to 190 with a total of 327 patients in this review. Patients had been diagnosed with cancer in five of the six studies. The other study included patients with end-stage liver disease (ESLD) that were scheduled for orthotropic liver transplantation. Most of the patients were male (57-73%) and the mean age ranged from 51 to 68 years. To address nutritional status, the patient-generated subjective global assessment (PG-SGA) score, Short Nutritional Assessment Questionnaire (SNAQ), weight change, BMI, laboratory parameters, and mid-arm muscle circumference (MAMC) were used. Undernutrition rates were 100% (two studies), 90%, 55%, and 38% (two studies) (table 1).

Interventions

Five interventions are evaluated in the six studies (table 1). The intervention periods range from two to 18 weeks. All interventions were performed by dieticians and aimed to improve dietary intake (energy and protein) to meet patients' nutrient requirements using a regular or therapeutic diet. The interventions were consults consisting of counselling and advice, follow-up meetings, and oral nutritional supplements if indicated or provided separately.

Consults

Patients had consults with dieticians at an early time in their treatment period. During these consults, patients received counselling and were advised about their nutritional status and nutritional behaviour, i.e., eating patterns. Counselling was based on personal eating patterns and preferences (30-32, 35). In two studies, guidelines and theoretical approaches were used. In other studies, patients received advice only.

One study followed the Dutch guidelines for nutritional care specified for patients with cancer (30). Another study used the taxonomy of behaviour change techniques of Abraham and Michie (36) as a base for a tailored, symptom-directed treatment (35). In this approach, behaviour change techniques were translated into treatment

for undernutrition. During the treatment, information about consequences and causes of undernutrition was provided, barriers to adapt dietary modifications were identified, and nutritionally healthy behaviour was instructed and encouraged.

In the other studies, dieticians gave advice that was tailored to patients' medical conditions, symptoms, and their eating patterns (31-34). Based on their personal eating patterns and preferences, patients with cancer received a prescription for a therapeutic diet of regular foods. The prescription included the type of food, amount, and frequency of feeding, specified the required caloric and protein level, and included any restrictions (31, 32).

Advice as a nutritional intervention was tailored to patients' underlying medical condition and symptoms and aimed to alter usual eating patterns to increase intake and achieve protein requirements (33, 34). In one study, specific recommendations were to eat small, frequent meals and snacks and a late evening snack (33). Another study provided suggestions to cope with eating problems, however, these suggestions and eating problems were not specified (34).

Overall, consults aimed to reach nutrient requirements and were tailored to the condition and eating patterns of the individual patient. Counselling was based on theoretical frameworks, such as the taxonomy of behaviour change and guidelines for nutritional care.

Follow-up meetings

During follow-up meetings, dieticians encouraged patients by telephone or during face-to-face contact (30-32, 34, 35). Contact was weekly or independently determined per patient by the dietician. Encouragements included positive feedback on weight, compliance with dietary modifications, the previous week's nutritional goals, trying one change at a time, and compliance with the study protocol. Patients were discouraged from following current healthy eating guidelines in one study however, healthy eating guidelines were not specified. Patients were instructed to record usual food intake once, it remains unclear whether this was an element of the intervention or an outcome measurement (33).

Supplements

In all studies, oral nutritional supplements (ONS) were provided. Two intervention studies provided ONS systematically to patients in one intervention group separately or along with advice and counselling (31-33). During the first consult, patients received instructions on the supplements, such as number per day and moment of consumption during mealtimes. Other studies provided ONS if needed to reach intake needs (30, 34, 35), while patients received advice or counselling as well.

Effects on outcomes

The following outcomes were evaluated in the studies: nutritional intake (31-33) and nutritional status in three of the studies (31, 32, 35), length of hospital stay and complications in three (30, 33, 34), quality of life (31, 32, 35) and weight in two of the studies (30, 35), and patient satisfaction (35) and cost effectiveness (34) in one study (see table 3).

Nutritional outcomes

Nutritional risk, indicating nutritional status, significantly decreased in supported patients while it increased in patients without this support ($p<0.001$) (35). Nutritional status deteriorated more frequently in supplemented patients than in counselled patients ($p<0.001$). In addition, this deterioration was even more severe and more present in controlled patients ($p=0.008$) (31, 32). At long-term follow-up, controlled patients were found to not even be able to maintain or improve nutritional status (32). However, results for weight were inconclusive. Patients who received counselling gained more weight compared to patients in control or supplemented groups (31). However, in another study concerning patients with head and neck cancer, both groups lost weight over the study period (30).

Supported patients improved their nutrient intake. Energy and protein intake was similar for patients provided with supplements and counselling and patients provided with counselling only (33). Patients who received counselling only ate more regular foods in comparison to patients, who received supplements, for whom supplements contributed 20-25% to their total nutrient intake (33). Ravasco and colleagues (31) reported significant improvement of energy and protein intake before surgery compared with the study onset for both the counselled and the supplemented groups compared to the control group. Energy intake increased significantly more for the group that received counselling in comparison with the supplemented group while protein intake was lower. In conclusion, nutritional status and nutrient intake improved with nutritional support. Results suggest that supplements are not necessary to achieve the required nutrient intake when counselling is provided.

Table 3 – Outcomes, measurements, and effects of oral nutritional support using a regelar diet

Author, year	Points of measurements	Outcomes	Measurement	Results (number (percentage), mean (SD – range) or main findings))	
Flynn et al., 1987	0) first outpatient office visit (10-21 days before surgery) 1) hospital admission 2) hospital discharge	Complications	*n.s.*	IG CG	n=6 (32%) n=10 (59%)
		Length of hospital stay	Days	IG CG	18 days 21 days
		Cost effectiveness	$766 per patient per day	For the group (n=19) $43.662	
Le Cornu et al., 2000	0) outpatient setting 1) at outpatient clinic before transplantation 2) 9 days after transplantation	Nutritional intake (t=1)	Energy (kcal per day)	IG CG	2419 (157; 1093-4944) 2234 (194; 863-4669) (p>0.05)
			Protein (g per day mean)	IG CG	79.8 (5.99;35.2-183.1) 86.5 (6.22; 11.61-132.5) (p>0.05)
		Length of hospital stay	*n.s.*	no significant differences between groups	
		Complications	Mild acute rejection	IG CG	14 (36%) 10 (31%) (P=0.623)
			Severe rejection	IG CG	15 (38%) 16 (50%) (P=0.377)
Ravasco et al., 2005	0) every week during the 6 weeks of RT (day 7, 14, 21, 28, 35, 42) 1) after surgery and CT 2) every 3 month until 2y	Nutritional intake (onset - day 42)	Energy change (kcal per day)	IG1 IG2 CG	+555 (398-758) (P=0.002) +296 (286-401) (P=0.04) -285 (201-398) (P=0.01)
			Protein change (g per day)	IG1 IG2 CG	+27 (20-35) (P=0.007) +30 (20-40) (P=0.001) -10 (7-15) (P=0.01)

Table 3 *(Continued)*

Author, year	Points of measurements	Outcomes	Measurement	Results (number (percentage), mean (SD – range) or main findings))	
		Nutritional status	Nutritional deterioration at day 42/3 month	-higher in G2 and in G3 relative to G1; (P<0.001) -more severe and incident in G3 relative to G1 and G2 (P=0.008)	
			PG-SGA	IG1	9 of 15 malnourished patients improved their nutritional status
				IG2 CG	no patients improved their nutritional status no patients improved their nutritional status
		Quality of Life	EORTC QLQ-C30	IG1	all QoL function scores improved; (P=0.002) pain worsened in association with -anorexia, P<0.05 -nausea or vomiting, P<0.04 -diarrhea; P<0.03
				IG2	physical, role, and emotional scores improved (P<0.05), and these were proportional to the increase in protein intake (P=0.04)
				CG	all QoL function scores worsened in association with deterioration of -nutritional intake (P<0.0001) -nutritional status (P<0.002)

Table 3 *(Continued)*

Author, year	Points of measurements	Outcomes	Measurement	Results (number (percentage), mean (SD – range) or main findings))	
Ravasco et al., 2012	3)every 6 mo until 5y 4)every year once Mean follow up time 6.5y	Nutritional intake (at long term follow up)	Energy intake (median) (kcal per day)	IG1 IG2 CG	2482 (95%CI: 2210-2685) 1335 (95%CI: 1150-1569) 1332 (95%CI: 1098-1426)
			Protein intake (median) (g per day)	IG1 IG2 CG	74 (95%CI: 69-77) 42 (95%CI: 39-44) 40 (95%CI: 38-42.5)
		Nutritional status (at long term follow up)	Nutritional deterioration (PG-SGA)	IG1 IG2 CG	CG and IG2>IG1 (p<0.001) n=3 (9%) n=27 (93%) n=26 (100%)
		Quality of life (at long term follow up)	EORTC QLQ-C30		CG and IG2 had lower QoL scores than IG1 (p<0.002) IG2 worsened all functional scales significantly
Silvers et al., 2014	0) Baseline assessment/near time of diagnoses 1) midstudy follow-up/ preoperatively 2) final follow-up after 26 wks	Weight (kg)		T=0: 80 (18) (CG) versus 73 (20) (IG) T=1: 71 (20) (CG) versus 78 (18) (IG) T=2: 61 (20) (CG) versus 81 (14) (IG) Preoperatively: similar between groups 26-weeks follow-up: on average 6 kg greater for IG vs CG (p<0.001)	
		Nutritional status	PG-SGA	T=1 IG: six points lower nutritional risk than the CG (p=0.008) T=2 IG: 10 points lower than CG (p<0.001)	
		Health-related QoL	EORTC QLQ-C30	T=1 IG>CG (p<0.001) T=2 IG>CG (p<0.01)	
			EQ-5D	T=1 IG>CG (p=0.003) T=2 IG>CG (p=0.001)	
			EQ-5D VAS	T=1 IG>CG (p=0.003) T=2 IG>CG (p<0.001)	

Table 3 *(Continued)*

Author, year	Points of measurements	Outcomes	Measurement	Results (number (percentage), mean (SD – range) or main findings))	
Leistra et al., 2015	0) At first outpatient visit 1) start of primary treatment 2) end of primary treatment	Weight change[&]	between T=0 and T=1	IG	-0.7% (5,5)
				CG	-0.2% (5,5) (p=0.53)
			Between T=0 and T=2	IG	-6.0%(6.9)
				CG	-5.4 (5.7) (p=0.83)
		Complications	Overall complications*	IC	15 (44%)
				CG	21 (70%) (p=0.04)
			Major complications[#]	IC	4 (12%)
				CG	6 (18%) (p=0.49)
		Length of hospital stay	Mean (SD)	IC	18.5 (11.2)
				CG	19.3 (11.2) (p=0.79)

SD: standard deviation; kcal: kilocalories; g: grams; PG-SGA: Patient-Generated- Subjective global assessment; QoL: Quality of Life; vs.: versus; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire version 3.0 ; EQ-5D: European Quality of Life Instrument; EQ-5D VAS: European Quality of Life Instrument visual analogue scale; n.s.: not specified in the article; IG: intervention group; CG: control group; &: for this outcome, 112 patients treated with (chemo)radiotherapy were included as well; *:pneumonia, oral infection, fistula, other; #: reoperation, readmission <4wk, ICU admission, in hospital mortality;

Quality of life

Patients who were supported reported improvements in their quality of life (QoL). Overall QoL scores were significantly higher in intervention groups compared with the control groups, both at mid-study follow-up and long-term follow-up (31, 32, 35). One study reports that QoL-function scores even worsened in association with a deterioration of nutritional intake and nutritional status in unsupported patients (31).

Length of hospital stay and complications

No significant differences were found in length of hospital stay and complication rates. Head and neck cancer (HNC) patients who received counselling stayed 0.8 days shorter in the hospital. However, this result was not significantly different. The same applies to the results for the liver transplant group (30, 33). Despite the three-day shortened hospital stay for supported cancer patients, no statistical test was performed (34).

Effects of nutritional support on complications were not convincing. Complications occurred in 27% more patients receiving usual care than in patients on nutritional support, however, no statistical test was performed in this study (34). In another study, severe rejection occurred in more control patients than supplemented patients (Δ12%, p=0.377) (33). For surgical HNC patients, counselled patients had less overall complications (i.e. pneumonia, oral infection, fistula, other) than control patients (p=0,04). In this group, major postoperative complications had a low prevalence (12% versus 18%) and were not significantly different for both groups (p=0.49) (30). In conclusion, complications rates tended to be lower in nutritional supported patients, but, not statistically.

Other effects

Patients' satisfaction and cost effectiveness were almost not evaluated. Thematic analyses of experiences with nutritional counselling resulted in reassurance, improved knowledge, and understanding of the behaviour-to-health-outcome link. Furthermore, patients responded positively to the dietician and stated that the counselling was generally helpful (35). Treatment cost decreased with $766 per patient per day shorter hospital stay (34). However, this was calculated in a small sample, with no statistical analysis, and was studied decades ago. In conclusion, patients seems to demonstrate some positive experiences with nutritional counselling and no valid cost analysis was performed.

DISCUSSION

Summary of evidence

This systematic review evaluates the effects of preoperative oral nutritional interventions using regular or therapeutic diet in undernourished surgical patients. A comprehensive search through six databases resulted in five intervention studies reported in six articles of moderate quality. Interventions were performed in patients mostly facing cancer-induced surgery. Intervention elements include consults with counselling and advice, follow-up and encouragements, and supplements. In general, patients who received any kind of support had better outcomes than control patients. The interventions resulted in an improved or maintained nutritional status, an increased intake, and a better quality of life. Counselling and advice during consults showed equal or better outcomes than ONS. No clear effects were found with regard to length of hospital stay, complications, patient satisfaction, and costs.

Comparison with other studies

This review focuses on improving nutritional status at outpatient clinics in the period before hospitalisation. Due to differences in the period between diagnosis and hospital admission, times before surgery vary, and can be both short and prolonged in clinical practise. Elective surgical patients may benefit from very early interventions in primary care settings (37) . Additionally, preoperative nutritional support may also be provided during hospitalisation as is shown in a study in patients with hip fractures (38). Optimal setting of preoperative nutritional support should be further investigated.

In the study on patients with hip fractures (38), nutritional support included oral nutritional supplements as well. Other strategies on nutritional support using a regular diet during hospitalisation may include adequate fasting regimens (39, 40) during surgical procedures and optimal meal conditions after surgery. Strategies for optimal meal conditions include changes to the organisation of nutritional care and feeding environment, modifications to meals, supplementation of meals, and home-delivered meals (41). These strategies also need development and adequate evaluation of their effects to achieve better nutritional support using a regular diet.

We focused on nutritional support to improve nutritional status before surgery. Prehabilitation, an approach that focuses on nutritional and physical improvements before surgery (3, 42), was not fully addressed in our systematic review. Prehabilitation of surgical patients however could be a solution to optimise physical status before surgery and diminish negative postoperative outcomes. Furthermore, we did not address undernutrition-related problems. Undernutrition-related problems are, for instance, taste and smell alterations and poor oral health(43, 44). Effective approach-

es to these problems may also benefit undernourished patients planned for surgery. A recent review showed the need for an effective approach to support patients with taste and smell alterations (45). Oral hygiene to improve poor oral health may prevent oral-health-related pneumonia (46). However, oral health is not yet investigated in relation to undernutrition in surgical patients. Further studies should evaluate preoperative physical prehabilitation and these undernutrition-related problems to improve health statuses among surgical patients.

Limitations

A few considerations should be made with regard to the results. First, only five studies in six articles evaluated our predefined outcomes. Due to this small number of studies, the heterogeneity of patients, the diversity of interventions and measurements, and very few (maximal three) studies per outcome, our conclusions should be considered with caution.

Second, thanks to our comprehensive search strategy, initially, many hits were found. Six databases were searched after evaluating the search terms with a clinical expert (GH-dW) and a clinical librarian (OYC). The fact that our searches resulted in only six studies is in accordance with other reviews that did not identify studies on nutritional support in the outpatient setting before surgery (47) using a regular diet (20).

Third, we could not perform a meta-analysis because outcomes are differently defined thorough the studies included in this review. For example, nutritional status is defined as weight, weight change, intake or intake change, or PG-SGA scores, and complications are defined as intensity of rejection, overall complications, or major complications. For future research, a consensus is needed about a valid way to measure outcomes of nutritional support to enable analysis across studies.

Areas for further research

More and well-designed research is needed on nutritional support using a regular or therapeutic diet, since only a few articles are available. The use of supplements should be reconsidered in this research to define the effects of supplements versus consults. Additionally, research is needed in populations with types of surgery other than cancer-induced surgery, such as orthopaedic and cardiovascular surgery. Effects have not yet been evaluated in these patients, despite the prevalence of undernutrition in these populations (48).

CONCLUSION

In conclusion, we found weak evidence that nutritional support using a regular or therapeutic diet reduces undernutrition and improves nutritional intake and quality of life in surgical patients. Since nutritional support without supplements in this review indicate the same or better outcomes than nutritional support with supplements, we should reconsider the use of oral nutritional supplements. Nutritional support included consults with counselling and advice, follow-up meetings and encouragements, and additional use of oral nutritional supplements. No firm conclusion can be drawn for the effects on complications, length of hospital stay, patient satisfaction, and costs due to few studies and inadequate methods. Most research was performed on patients diagnosed with cancer; therefore, it is necessary to evaluate nutritional support in other surgical patient populations. Consensus is needed for comparable measurements of outcomes. Until these limitations are addressed, undernourished surgical patients should receive nutritional support during their preoperative course.

Relevance to Clinical Practise

Nutritional support using a regular or therapeutic diet should start as early as possible. The small number of studies in this review show promising results for oral nutritional support using a regular or therapeutic diet as this subsequently may result in improved intake, nutritional status, and quality of life. Improvements were better in patients receiving consults than in patients receiving supplements. Despite the fact that the evidence in this review has a moderate quality, we argue that there is no reason to withhold undernourished patients' nutritional support preoperatively.

Undernutrition in surgical patients should be treated by the involved disciplines in a pathway (49). The interventions found in our review were performed by dieticians, however, we know that the patients are also seen by nurses, anaesthesiologists and surgeons (16-18, 42, 50). Surgeons determine the treatment plan and are therefore in key position to coordinate such a treatment pathway. They can underline that nutritional support is of paramount importance for their undernourished patient. Nurses, are in the key position during outpatient preoperative evaluations (16) to provide nutritional support besides consulting dieticians. Additionally, nutrition is a fundament element of basic nursing which is essential for patient outcomes (23-26). Activities in nutritional nursing care include nutritional screening and nutrition care planning (25). Screening has already improved in hospitals, however, interventions for undernourished patients remains less provided. Nurses can take their responsibility and have nutritional consults with their patients. A multidisciplinary path for undernourished surgical patients is not reported in the literature yet. The involved

health care professionals should therefore collaborate to develop and evaluate such a path for nutritional prehabilitation.

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Supplementary materials

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Chapter 3

Using intervention mapping to develop an outpatient nursing nutritional intervention to improve nutritional status in undernourished patients planned for surgery

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Abstract

Background: Undernutrition in surgical patients leads to a higher risk of postoperative complications like infections and delayed recovery of gastrointestinal functions, often resulting in a longer hospital stay and lower quality of life. Nurses at outpatient clinics can deliver nutritional care during outpatient preoperative evaluation of health status to ensure that patients are properly fed in preparation for hospital admission for surgery. However, nutritional nursing care was not determined in research yet. This paper describes the structural development of an Outpatient Nursing Nutritional Intervention (ONNI).

Methods: A project group followed the steps of the Intervention Mapping. The needs assessment included assessment of delivery of nutritional care and nutritional care needs at two anaesthesia outpatient clinics of an academic and a teaching hospital. Also, outpatient clinic nurses and patients at risk for undernutrition were interviewed. Determinants resulted from these methods were matched with theories on behaviour change and nutritional support.

Results: Both patients and nurses were unaware of the consequences of undernutrition, and nurses were also unaware of their roles with regard to nutritional support. The intervention goals were: 1) enabling surgical patients to improve or maintain their nutritional status before hospital admission for surgery, and 2) enabling nurses to deliver nutritional support. The ONNI was developed for outpatients at risk for or with undernutrition. A training was developed for nurses. The ONNI included the five following components: 1) identification of the causes of undernutrition; 2) provision of a nutritional care plan including general and individually tailored advice; 3) self-monitoring of nutrient intake; 4) counselling and encouragement; and 5) support during a telephone follow-up meeting. The intervention and training were tested. A multifaceted implementation strategy was used to deliver the intervention in daily practice.

Conclusions: Despite the unique position of the nurses at outpatient clinics, nurses were unaware of their role with regard to nutritional care. The ONNI was developed and implemented along with a training program for nurses. The test confirmed that the training can improve nurses' knowledge, skills, and sense of responsibility for nutritional support. The intervention may empower patients to actively improve their nutritional status.

Keywords

Nursing, Undernutrition, Nutritional Support, Preoperative Care, Needs Assessment, Health Behaviour Change, Development, Intervention Mapping, Outpatient Clinic, Prehabilitation

Background

Undernutrition is an important prognostic indicator of postoperative complications, such as infections, fistulas or wound-healing problems, and the delayed recovery of gastrointestinal functions (1, 2). Additionally, undernourished surgical patients face more renal and cardiac complications (1), and prolonged hospital stays (3). Undernutrition can be measured timely with screening instruments such as the Malnutrition Universal Screening Tool (MUST) (4) and Short Nutritional Assessment Questionnaire (SNAQ) (5). With these instruments, undernutrition was found among 14% of 564,063 patients admitted to Dutch hospitals (3). An Italian study at medical and surgical units found that 18% (n=60) and 45% (n=155) of surgical inpatients were undernourished or at risk for undernutrition (6). In a sample of gastrointestinal surgical patients in a university hospital in the USA, 19% (n=93) were moderately or severely undernourished based on screening at the time of admission (2). In The Netherlands, preoperative assessment of nutritional status using SNAQ at outpatient clinics demonstrated that 5% (n=49) to 7% (n=67) of surgical patients were moderately to severely undernourished (5, 7). These studies in especially high-income countries signify higher undernutrition rates for surgical inpatients as compared to outpatients. This suggests that undernutrition in surgical patients worsens in the period between outpatient clinic visit and hospital admission. Thus, it is pivotal that patients' nutritional status should be improved as early as possible to benefit their outcomes.

To ensure that surgical patients are properly fed, nutritional prehabilitation is needed. Studies on nutritional support before and after surgery have demonstrated positive effects on infections and length of hospital stay (8, 9). Nutritional support, or nutritional therapy, is defined by the European Society for Clinical Nutrition and Metabolism (ESPEN) as the provision of nutrition – either orally (including regular or therapeutic diet and oral nutritional supplements (ONS)), through enteral (EN) administration, or parenteral (PN) administration (10). The meta-analysis of RCTs by Zhong (8) and Burden's Cochrane review (9) illustrated these effects, through ONS, EN, and PN methods at different periods before, during, and after surgery. Studies evaluating oral nutritional support using regular or therapeutic diet preoperatively were identified in our systematic review and demonstrated improved nutritional status or prevention of further decline of undernutrition (11). The intervention components determined in our systematic review study were education, monitoring of dietary intake, individually tailored advice regarding symptoms, and follow-up. However, only a small number of intervention studies were found (n=5).

In The Netherlands, surgical patients' health status including nutritional screening is evaluated before surgery by both nurses and anaesthesiologists during outpatient preoperative evaluations (5, 7, 12). In this setting of health care service, nurses

are in key positions to provide nutritional support to improve or maintain patients' nutritional status. Systematic reviews of nutritional nursing did not, however, identify intervention studies in which nurses provided oral nutritional support preoperatively during outpatient clinic consults (11, 13). A nutritional supportive intervention to be delivered by nurses should be developed for use in outpatient clinic services for preoperative health evaluation to prehabilitate undernourished surgical patients.

Intervention development

Nutritional prehabilitation of surgical patients can be considered a complex intervention. Complex interventions are the focus of the Medical Research Council (MRC) framework, which provides guidance for development and evaluation (14). Complex interventions encompass several interacting components, numerous and varied outcomes, several behaviours to deliver or receive the intervention, different target groups, and the need for flexibility or tailoring (14). Regarding nutritional prehabilitation, the need of tailoring varies based on the different causes of disease-related undernutrition and amount of time before surgery. Healthcare professionals face different groups of patients based on different classes of nutritional risk, e.g., low risk (well-nourished), medium risk (at risk for undernutrition), or high risk (undernutrition) (4). Furthermore, both patients and outpatient clinic nurses have to change behaviour routines (15). Therefore, development of the complex preoperative nutritional optimization requires a systematic approach (14).

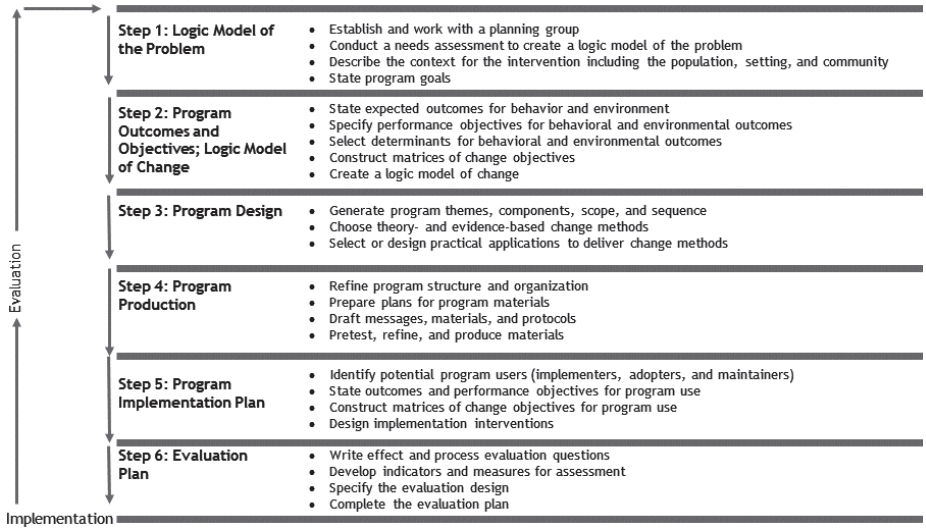

Figure 1 - The six steps of Intervention Mapping

Table 1 – Methods used to develop and implement ONNI† following the six steps of Intervention Mapping

Six steps of Intervention Mapping	Study objectives	Methods used during the development
Step 1: Logic Model of the Problem		
Aim: to examine a specific health problem in the target population	To examine the behavioural and environmental determinants of undernourished patients planned for surgery seen at anaesthetic outpatients clinics	• Interviews with patients and nurses, observations of nutritional care, survey among patients (see table 2)
Step 2: Program Outcomes and Objectives – Logic Model of Change		
Aim: to develop matrices of change objectives	To define program outcomes, performance objectives, change objectives	• Panel discussion and definition session • Matrix of program objectives (see table 3 & 4)
Step 3: Program Design		
Aim: to generate program ideas, including change methods and practical applications	To generate program idea's with methods for change	• Theory of undernutrition and nutritional support • Theory of behaviour change • Implementation strategies (see table 5)
Step 4: Program Production		
Aim: to produce a programme that matches the previous steps	To produce a program for undernourished patients during outpatient preoperative evaluation at anaesthetic outpatient clinic	• Development of the ONNI† (see table 6) • Development of a nursing nutritional training • Pre-test of the ONNI† and the training
Step 5: Implementation Plan		
Aim: to develop an implementation plan to enable adoption, implementation, and maintenance	To develop an implementation plan of the ONNI†	• Identification of implementation barriers and process evaluation (see table 7) • Literature on implementation strategies and evaluation of complex interventions

†=Outpatient Nursing Nutrition Intervention

Systematic intervention development of new interventions is defined by Bartolomew and colleagues in the Intervention Mapping (IM) approach (16). Intervention Mapping is a framework (17) that includes a systematic, iterative six-step process, which helps researches and healthcare professionals to develop or adapt an intervention based on theoretical, empirical, and practical information (16). This framework has been used widely for health promotion, e.g., nutrition (18, 19), as well as in other basic nursing care programs (20, 21). The steps in IM are as follows: 1) Logic Model of the Problem; 2) Program outcomes and Objectives – Logic Model of Change; 3) Program Design; 4) Program Production; 5) Program implementation plan; and 6) Evaluation plan (16) (see figure 1 and table 1). Each step encompasses clear tasks and a clear end product. We used the IM to structure the development of an Outpatient Nursing Nutritional Intervention (ONNI). In this paper we describe the methods that are used during the development and the end products that were developed. The methods and results are presented for each step are presented separately. This development is part of the Basic Care Revisited Research program (22).

Step 1: Logic Model of the Problem - Methods

A project group was established to participate in the development of the intervention. The group was made up of a nurse, a nurse specialist, a dietician (MvA), a gastroenterologist, two researchers (GHdW, MH), and an external dietetic expert (HK).The specific context included two anaesthesia outpatient clinics for preoperative evaluation from a general and an academic hospital in the Netherlands. Nurses held consults with patients who were being seen mainly for general (e.g. vascular, abdominal), orthopaedic, neurological, plastic, or facial surgery. The nursing staff at the outpatient clinic from the academic hospital was made up of bachelor nurses. The nursing staff at the outpatient clinic from the general hospital was made up of bachelor nurses and nursing assistants. These settings were studied during the period between November 2014 and June 2016. The study was ethically approved by Medical Ethical Committee of the Radboud university medical centre in Nijmegen, The Netherlands, number 2014-1353.

Participants of all four studies were requested to provide written informed consent before participation. First, the behavioural and environmental determinants were uncovered through a needs assessment of the context in which the intervention would be performed. The needs assessment was conducted in four consecutive studies. Each study is described below and illustrated in table 2.

Table 2 – Studies conducted to determine the behavioural and environmental determinants (step 1)

Study	Aim	Sampling	Characteristics	N (%)	
Nurses' perspectives	To explore nurses' perspectives towards nutritional care for undernourished surgical patients	Purposive sample of outpatient clinic nurses and nursing assistants (N=10)	Nurses Urology outpatient clinic Anaesthesia outpatient clinic Nursing assistants	1 4 5	(10) (40) (50)
Observation of nutritional care	To observe delivery of nutritional care during nursing consults at outpatient clinics	Consecutive consults (N=341) at the anaesthesia outpatient clinic before a planned surgery in two hospitals	Academic Hospital General Hospital Female Age (mean/SD) MUST† score 0& MUST† score 1 MUST† score 2	48 293 201 55.3 295 24 16	(14) (86) (59) (15) (88) (7) (5)
Survey	To evaluate patients' satisfaction with general and nutritional care received during the outpatient clinic visit	Patients (N=301) at anaesthesia outpatient clinic for preoperative screening	Female Age (mean/SD) MUST† score 0# MUST† score 1 MUST† score 2	156 54 236 14 9	(60) (16) (91) (5) (4)
Patients' perspectives	To explore patients' perspectives towards undernutrition and satisfaction with nutritional care	Patients (N=11) from an academic hospital	Female Age (mean/SD) MUST† score 1 MUST† score 2	7 55.7 8 3	(64) (19.6) (73) (27)

†=Malnutrition Universal Screening Tool; &=nutritional risk screening was performed in 335 (98.2%) of the 341 observed consults. #=surveys were returned by 259 (86%) of the patients.

Study 1: Nurses' perspectives

Semi-structured, face-to-face interviews with the nursing staff from both outpatient clinics were held by two 4th year students of Bachelor of Nursing to explore nurses' perspectives towards nutritional care. The students worked under supervision of a senior researcher who coordinated the study and established the relations with the nursing staff of both outpatient clinics (GHdW). The complete nursing staff consisting of nurses and nursing assistants who evaluated health status before a planned surgery were selected and participated after recruitment by face-to-face contact and email. Interviews were based on the Integrated Change Model (23, 24): a) awareness, b) self-efficacy and skills, c) attitude, and d) current care regarding (risk for) undernutrition (see appendix 1). Interviews were held in separate rooms and were recorded on audio after informed consent was obtained. Audio records were transcribed and analysed using open coding in iterative discussion sessions of the two students and the researcher (GHdW). Then, a coding tree was built and codes were categorised based on determinants of the Integrated Change Model in a thematic analysis approach.

Study 2: Observation of nutritional care

Delivery of nutritional care according to the hospitals' protocol was observed during nursing consults at the outpatient clinic. The protocol included a) screenings for undernutrition with MUST (4), and b) nutritional interventions for patients at risk for or with undernutrition. The MUST is a screening tool, made up of three independent criteria for protein - energy undernutrition and can result in a maximum total score of 6. A score of 0 indicates low risk (well-nourishment), score of 1 indicates medium risk (at risk for undernutrition), and a score of at least 2 indicates high risk (undernutrition). For a patient at risk for or with undernutrition, interventions should be performed. The nutritional interventions included the following: 1) provision of a leaflet with information about protein-rich food; 2) oral information about undernutrition, reasons for weight loss, and advice about protein-rich nutrition; and 3) referral to a dietician in case of MUST-scores ≥2. Protocol activities structured the observation list. Descriptive analyses were used to describe nurses' adherence to the protocol.

Study 3: Survey

The Consumer Quality Index (25) was tailored to suit the outpatient setting in a survey (see appendix 2) designed to evaluate patients' satisfaction with the general and nutritional care received during the outpatient clinic visit. The main topics of the survey included a) the care received from the nursing staff, b) information needs regarding nutrition, and c) perspectives on personal nutritional status and general

health status. Descriptive analyses were performed to describe the sample of patients and the results of the survey.

Study 4: Patients' perspectives

Semi-structured interviews were held with patients of the academic hospital after the consult with the nurse at the outpatient clinic. These patients visited the clinic in preparation for surgery. Nurses contacted the researcher about patients at risk for or with undernutrition. These patients were recruited for the study by telephone . Under supervision of a senior researcher (GHdW), two 4th year students of Bachelor of Nursing students performed the interviews if patients provided informed consent. Based on the Integrated Change Model (23, 24), the topics selected were a) patients' knowledge, attitudes, responsibilities, and motivations regarding undernutrition and nutritional intake, b) patients' needs and expectations regarding nutritional care, and c) patients' experiences with received nutritional care (see appendix 3). The interview guide was pretested. Audio records were made and were transcribed and analysed through open coding and a thematic analysis using the determinants of the Integrated Change Model (23, 24).

Step 1: Logic Model of the Problem - Results

Some clear determinants resulted from the needs assessment. First, nurses did not regularly discuss nutritional risk and did not give advice to undernourished patients. Moreover, nurses did not feel capable of providing nutritional support, and some nurses did not feel that it was their responsibility either. Patients were unaware of their nutritional status. If nutritional status was discussed, patients felt responsible and capable of taking care of their own nutritional intakes. Detailed determinants and results from the four studies follow below.

Study 1: Nurses' perspectives

Ten nurses were interviewed, and five determinants to possibly influence nutritional care were derived from the analysis: current care, attitude, knowledge, skills and self-efficacy, and barriers.

Current care: some nurses complained that nutritional care only included screening of nutritional status. Most of the nurses complained that (under)nutrition was poorly discussed and that advice remained superficial and was provided unsystematically.

*'**I tell patients to 'keep in mind to eat a varied diet', but, I am not a food expert**' (Nurse 4)*

Attitude: Some nurses regarded nutrition as their responsibility. Other respondents argued that dieticians are in leading positions with regard to nutrition on account of their expertise. Nurses themselves should signal nutritional problems, but nutritional advice and sufficient food intake of patients were not considered part of nursing. As such, these elements were not considered to be nurses' responsibilities.

Knowledge, skills, and self-efficacy: Nurses did not uniformly deliver nutritional care, and some nurses did not know how to deliver nutritional care. The reasons cited were due to lack of time during the consults, lack of knowledge concerning undernutrition, and lack of adequate interventions. Nurses felt capable and familiar with screening for nutritional risk using MUST, but did not feel capable of advising undernourished patients about nutrition. All respondents expressed the need to be educated about their roles and (under)nutrition.

*'**I think that it is something that is added to our list, but we do not know what our role should be**' (Nurse 3)*

Barriers: One of the barriers was a lack of privacy during the nursing consults in one of the hospitals because two patients are seen at the same time in one room. Therefore, nurses felt inhibited from discussing nutrition and nutritional status. Another barrier was that nurses were not giving nutrition a high priority, reflected in the fact that they said there is a lack of time. An additional barrier was inadequate weight measurement of patients in wheelchairs or with orthopaedic instruments.

Study 2: Observation of nutritional care

Nutritional status was screened in 98.2% (N=335) of the patients, of whom 7% (n=24) were found to be at increased nutritional risk and 5% (n=16) were undernourished (see table 2). Leaflets were provided to 75% (n=30) of the patients. Only 10% (n=4) of the patients received verbal information from the nurse. Referral to a dietician was arranged for 94% (n=15) of the patients with undernutrition.

Study 3: Survey among patients

The survey was returned by 86% patients (N=259) of which 228 (88%) provided answers on all questions. Risk for undernutrition and undernutrition were found in 5% (n=14) and 4% (n=9) of patients, respectively. The outpatient clinic's overall care was valued at an 8.5 on scale from zero to 10 (0 indicating very poor care and 10 indicating

ideal care). More than half of the patients (54%, n=123) stated that they needed additional information regarding nutrition. Main information needs dealt with the following topics: a) adequate nutrition before surgery (34%, n=77); b) energy and protein-rich food products (15%,n=33); and c) organizing mealtimes during the day (8%,n=19).

Study 4: Patients' perspectives

Eleven patients were interviewed with an mean length of time for each interview of approximately 30 minutes. The analysis resulted in the following determinants: current care, awareness and attitude, knowledge, and skills and self-efficacy.

Current care: Most patients (n=9) did not receive any nutritional advice during the consult at the outpatient clinic and did not have any expectations for outpatient clinic professionals with regard to nutritional care either.

> *'**No, they did not mention anything [how to improve dietary intake]**' (Patient 9)*

Patients who were referred to the dietician claimed that the advice was not applicable to their personal needs.

> *'**The dietician handed me a whole list what I could eat during the day but that was way too much for me, that was not achievable**' (Patient 7)*

Awareness and Attitude: Patients were unaware of their nutritional risk after screening at the outpatient clinic. Patients did not experience undernutrition as a problem for their health and recovery after surgery (see quotations).

> *'**No, I don't know about that, for me it was... yes, I was really surprised to hear that I am undernourished**' (Patient 1)*

> *'**This [being undernourished] sounds like a real problem, for me it is more like ...uh... weighing a little too less**' (Patient 2)*

Adequately informed patients stated that they felt responsible for adequate nutritional intake.

Knowledge, skills, and self-efficacy: Patients did not know what undernutrition could mean for their recovery after surgery. They felt capable of eating a varied diet. Some patients stated that they do know what to do to maintain an adequate weight.

*'**Well, meanwhile I know the way to maintain weight**' (Patient 7)*

Patients who received adequate information and advice stated that they were able to achieve adequate nutritional intake.

Step 2: Program Outcomes and Objectives – Methods

The results of step 1 enabled the project group to define program goals for undernutrition and its behavioural and environmental causes. This was done by discussion panel with stakeholders. The stakeholder panel consisted of two patients, a nurse, a dietician (MvA), an external expert (HK) in clinical undernutrition, and two researchers (GHdW, MH). The discussion started with explaining the gap between the current situation and the ultimate goal that patients are in good nutritional condition before surgery. The current situation was explained by presenting the results of step 1. Then, the stakeholders discussed what should be accomplished to close this gap (program goals). This resulted in program goals and performance objectives. Also, they discussed which determinants needed to be changed. Then, the project group specified the performance objectives and linked these to the changeable determinants (step 1). By linking the performance objectives with the changeable determinants, the project group defined change objectives. Finally, researchers constructed a matrix of program goals, performance objectives, and relevant determinants for both patients and nurses.

Step 2: Program Outcomes and Objectives - Results

To close the gap between the current situation and a good nutritional condition before surgery the stakeholders and project group argued that behaviour change was needed in nurses as well as in patients. The programme goals for patients and nurses were as follows:

- Patients at risk for or with undernutrition and planned for surgery maintain or improve their nutritional status.
- Nursing staff at anaesthesia outpatient clinics support patients in achieving adequate nutritional intake, leading to maintenance or an improvement in patients' nutritional status.

The goal for patients contains 'improve', in order to achieve the good nutritional condition. 'Maintain' was also mentioned in the goal in order to prevent further decline of undernutrition if improvement is too optimistic.

Matrices of both patients' and nurses' performance objectives, determinants, and change objectives were defined and are shown in tables 3 and 4. Based on evidence from step 1, awareness and attitude, knowledge, skills, and self-efficacy were perceived as important and changeable determinants for patients' performance objectives. These determinants are regarded as preconditions for improving nutritional status and were used to define the patients' change objectives (table 3). For nurses, the determinants knowledge, self-efficacy and skills, and attitude were perceived as important for the nurses' performance objectives. By matching these (the determinants and performance objectives), the change objectives were defined (table 4). We illustrate this matching for one performance objective in the next paragraph. One of the performance objectives for nurses state that nurses should inform and advise patients about the causes and consequences of undernutrition, about the need of energy- and protein-rich food, and about eating healthy snacks (see table 4). The determinant knowledge requires nurses to be educated on these topics, and the determinant self-efficacy and skills requires nurses to be able to advise and encourage the patients on these topics. Regarding attitude, nurses need to be convinced of the need for nutritional care for surgical patients and of their important role in supporting patients in having an adequate nutritional status. Then, nurses should expect that the patient know how to improve his or her nutritional status and nutritional intake.

Step 3: Program Design - Methods

This phase of intervention development aims to identify theoretical methods which match with the determinants (step 1) and the program goals (step 2). Theories regarding undernutrition, methods of nutritional support, and behaviour change theories were considered relevant. These theories and methods were studied and discussed by the project group in order to conceptualise the intervention.

Step 3: Program Design - Results

Theories on the following subjects were selected: a) behaviour change (17, 26, 27); b) undernutrition and nutritional care (4, 10, 11, 28, 29); and c) implementation strategies (30, 31). Table 5 displays the methods that were derived from these sources matching with patients' and nurses' determinants (see table 5). These methods were applied in the conceptualisation of the program and taken into account in the program production during step 4 (see table 5).

Table 3 – Patients' performance objectives, determinants and change objectives

Program goal: Outpatients at risk for or with undernutrition and planned for surgery are able to improve or maintain their nutritional status.				
Performance objectives	**Important and changeable determinants and the related change objectives**			
	Knowledge	**Skills and Self-efficacy**	**Awareness and attitude**	**Outcome expectation**
Patients are motivated to improve their nutritional status.	Patients understand their nutritional status. Patients have knowledge of the consequences of undernutrition regarding their health, treatment and recovery.	Patients demontrate to be capable and motivated to improve their nutritional status	Patients acknowledge the risk of undernutrition during their treatment course. Patients acknowledge the need to improve nutritional status to diminish the consequences of undernutrition.	Patients expect to become well-nourished before the planned surgery.
Patients take action regarding the personal cause(s) of undernutrition.	Patients know the cause(s) of undernutrition in their individual situation. Patients know how to diminish the cause's of undernutrition.	Patients apply advices given to the personal cause(s) of undernutrition.	Patients explain causes of undernutrition for their individual situation. Patients are aware of the need to diminish the cause's of undernutrition.	Patients expect to decrease the influence of the personal cause(s) of undernutrition.
Patients eat healthy, energy and protein enriched nutrition.	Patients have knowledge of healthy, energy and protein enriched nutrition.	Patients plan to buy, prepare and eat healthy, energy and protein enriched nutrition.	Patients are aware of the need to eat healthy, energy and protein enriched nutrition.	Patients expect to benefit from eating healthy, energy and protein enriched nutrition.
Patients have an adequate nutritional intake.	Patients have knowledge of their eating pattern. Patients know what they need to change regarding their eating pattern to have an adequate intake.	Patients demonstrate to change their eating pattern and to have an adequate nutritional intake.	Patients are aware of their eating pattern. Patients are aware of the need to change their eating pattern to have an adequate intake.	Patients expect to improve nutritional status by having an adequate nutritional intake.

Table 4 – Nurses' performance objectives, determinants and change objectives.

Program goal: Nursing staff at anaesthesia outpatient clinics support patients in achieving an adequate nutritional intake, leading to an improvement or maintenance in patients' nutritional status.				
Performance objectives	**Important and changeable determinants and the related change objectives**			
	Knowledge	**Self-efficacy and skills**	**Attitude**	**Outcome expectation**
Nurses offer patients the intervention map at the outpatient clinic.	K1.The nurse knows that the intervention map has to be offered to the patient during the outpatient clinic visit.	SE1.The nurse states to be convinced that she is able to offer the intervention map to the patient during the outpatient clinic visit.	A1.The nurse states to be convinced that he/she is able to offer patients the intervention map.	OE1.The nurse expects to improve patients' knowledge and attitude when this intervention map is handed out to every patient.
Nurses actively invite patients to think about possible causes of their undernutrition.	K2.1.The nurse knows why it is important to let the patient think about the cause of undernutrition. K2.2. The nurse knows which factors may lead to undernutrition.	SE2.The nurse is convinced that she is able to actively invite the patient to discuss possible causes of undernutrition. SE2. The nurse is convinced that she is able to discuss possible causes of undernutrition.	A2.The nurse states that it is important to invite the patient to tell what a possible cause might be of undernutrition.	OE2. The nurse expects that the patient understand the personal causes of undernutrition.
Nurses inform and advice about the causes of undernutrition and energy- and protein rich food	K3. The nurse knows the causes and consequences of undernutrition and know the benefit of and what energy- and protein-rich food is.	SE3. The nurse states to be able to advise the patients about how to deal with underlying cause(s) and energy- and protein-rich food.	A3. The nurse is convinced that it is important to support the patient to have an good nutritional intake and status, and that she as a vital role in it.	OE3. The nurse expects that the patient know how to improve nutritional intake and status.
Nurses will instruct the patients to record nutritional intake in a food diary.	K4.1. The nurse knows the content of the food diary. K4.2. The nurse knows the procedure of recording the nutritional intake and how to help the patient with it.	SE4. The nurse states to be able to instruct the patient to record nutritional intake.	A4. The nurse states that it is important to instruct the patient to record nutritional intake.	OE4. The nurse expects the patient to be able to adequalty record his/her nutritional intake for two days.

The program focused on oral nutritional support for patients and training of the nursing staff. Key concepts of the behaviour change theory were applied to achieve the desired behaviour of both nurses and patients. These informed the structure of the support and the training.

Key concepts from the sources on undernutrition and nutritional care were applied to define content of the support and the training. Key concepts from the implementation sources were applied to implement the support in nurses' daily practise and to implement better nutritional behaviour in patients' daily life.

The way we applied the theories in development of the intervention is explained in the following example: In step 1, it turned out that most of the patients were unaware of undernutrition and its consequences. When the researcher informed the patient adequately during the interview, some stated that they felt to be able to maintain their weight. Therefore, we considered awareness, attitude, self-efficacy and skills as important determinants to be changed. According to the program goal for patients (to improve or maintain nutritional status), performance objectives stated that patients need to take action regarding their individual cause(s) of undernutrition and eat healthy, energy and protein enriched nutrition (see table 3). Theories on behaviour change techniques (26, 27) argue that healthy behaviour can be obtained through social support and self-monitoring. Also, components of oral nutritional support included counselling at several points in time (11). Therefore, the project group argued that patients should be encouraged and counselled at several points before hospital admission by both caregivers and healthcare professionals. Encouragement (e.g. social support) and counselling were scheduled two times before surgery, i.e., during the consults at the anaesthesia outpatient clinic and during a follow-up telephone call within a week after the consult. During the consultation, nurses can inform, empower and support the patients and actively involve the caregivers during the consult.

Step 4: Program Production - Methods

The project group synthesised the information from previous steps to determine the program consisting of an Outpatient Nursing Nutritional Intervention and a nursing nutritional training. One researcher (GHdW) prepared all versions of the intervention and presented these for comments to the rest of the project group. After three rounds of feedback, consensus was reached.

The training for the outpatient-clinic nursing staff was developed to help the nurses achieve their change objectives. A researcher (GHdW) and the dietician (MvA)

of the project group developed the training using the methods and applications mentioned in table 5.

Two nurses of the outpatient clinic of the academic hospital tested the ONNI after the training in six consults to evaluate if the ONNI could work (32). Both nurses participated in the interviews of step 1 after written informed consent. Before the training they were unaware of the importance of nutritional status for patients outcomes. The nurses perceived that the nursing role was limited to nutritional screening and did not know how they could provide nutritional care.

The ONNI and the training were evaluated using a short questionnaire and interviews. Topics covered in the semi-structured questionnaire concerned the experiences of nurses with the training and the extent of improvement on the previously identified determinants as a result of the training. The interview based on this semi-structured questionnaire was held in person with a researcher. The six consecutive patients who received the ONNI were interviewed after written informed consent. Objective was to determine the extent to which patients were exposed to different intervention components during the consults, patients' ability to record food intake, and their awareness of nutrition and eating patterns. Patients were also questioned about their preferences regarding two types of food diaries. Notes were made after each interview and analysed through open coding.

Step 4: Program Production - Results

The Outpatient Nursing Nutrition Intervention

The ONNI was developed for use during outpatient preoperative consults and consists of five components (see table 6). First, causes of undernutrition were determined with a checklist. Then, a nutritional care plan aimed to educate the patient with both tailored and general information. In case of a MUST score ≥2, patients were also referred to the dietician (usual care). The third component aimed at providing insight in patient's eating pattern by recording daily intake for two days in a food diary. The fourth component was to counsel and encourage the patient in improving nutritional status during the outpatient clinic visit and a follow-up meeting. The fifth component was support during a telephone follow-up meeting with the patient within one week after the outpatient clinic visit. The ONNI was targeted at patients at risk for or with undernutrition based on MUST scores.

Training

The nursing nutritional training consisted of three plenary meetings. Two of the three meetings were aimed at increasing nurses' knowledge of undernutrition, its causes and consequences, behaviour, and health, along with information about the intervention protocol. Also, to raise awareness the role of nurses in meeting patients' needs including nutritional needs was elaborated during this training through providing an overview of the nurses' role in undernutrition. To increase their skills and self-efficacy, nurses practised the intervention in a role play during the meeting to see examples and make comparisons to their own behaviour. Additionally, to increase their self-efficacy and improve their attitudes towards their nutritional roles, interactive discussions exploring nurses' individual perspectives were held during the training. Nurses discussed how to deal with the patients' points of view using personal experiences. These discussions helped to set a peer group and determine social norms. The third meeting aimed to clarify the intervention protocol and to invite nurses to explain the steps of the intervention to receive feedback from the trainer. Follow-up meetings at the outpatient clinic were scheduled with the trainer and nurses to deal with remarks or queries.

Changing the attitude towards positive awareness of nurses' role in nutritional care was addressed during the training sessions and follow-up meetings. Increasing knowledge, exploring individual and patients' perspectives, several discussion sessions on different time points, and performing the intervention during training sessions and in daily practise will together lead to the desired behaviour. The nursing staff include 10 nurses in total. For the evaluation in step 6, nurses will be randomised to perform the ONNI or usual care. Therefore, attitude of five nurses are to be changed. The researcher is therefore able to coach nurses individually which would lead to optimal attitude and intervention delivery.

Test

The nurses (N=2) stated that the training refreshed and updated their knowledge regarding undernutrition and that information on the intervention was clearly provided. They showed willingness to meet patients' nutritional needs and felt responsible to improve patients' nutritional status. The nurses felt that the intervention was complete and applicable in practice. After completing the intervention for three patients, the nurses stated that they were able to perform the full intervention adequately. They also stated that they were able to carry out the intervention in the time allocated for each patient and that they became more familiar with the ONNI.

Table 5 – Application of methods per patient' and nurse' determinants

Determinant	Methods	Applications	How context and parameters were taken into account
Patients' knowledge	Provide information using different methods about undernutrition and nutrition[6, 7, 9, 10]	General and tailored information during the consults with advice and leaflets	Context: Consult during preoperative evaluation and follow-up Parameters: patients received general information and advice orally by the nurse, received general leaflets. Questions were addressed and discussed.
	Increase memory and understanding[1]	Counselling during the consult and follow-up	
Patients' awareness	Provide information about risks and consequences[1, 6, 7, 9, 10] and encourage on desired behaviour[8]	General and tailored information during the consults with advice and leaflets	Context: Consult during preoperative evaluation and follow-up Parameters: To tailor information, individual causes for undernutrition were determined and related advice was given; evaluation during follow-up to encourage the patient
	Tailor advices to the individual cause(s) of undernutrition[8]	Counselling during the consult and follow-up for encouragement and the nutritional care plan	
	Self-monitor nutritional intake[8]	Evaluation of the intake as recorded in a food diary during follow-up	Context: Consult during preoperative evaluation and follow-up Parameters: by monitoring personal nutritional intake patients become aware
Patients' skills	Instruct how to monitor nutritional intake[1,2,4]	Instruction of recording intake using a food diary during the consult	Context: Consult during preoperative evaluation and follow-up Parameters: a food diary was supplied and patients were instructed to monitor intake.
	Instruct innovation of personal eating pattern[1,5, 6]	Advice during the consult and evaluation during follow-up	
	Plan social support[8]	Follow-up by nurse or dietician	Context: Telephone follow-up Parameters: records of food intake were discussed and questions were addressed

Table 5 *(Continued)*

Determinant	Methods	Applications	How context and parameters were taken into account
Nurses' knowledge	Refresh knowledge[3] and provide information about behaviour-health link[1], about undernutrition, its causes and consequences[6,7], about nutrition during surgery[9,10], and about behaviour change[12]	Training (given by dietician and nursing researcher) in which information is provided	Context: Training in small groups. Parameter: Schematic representations; an overview of current knowledge, adjusted to the knowledge level shown in individual interviews.
	Model or demonstrate the behaviour by modelling [3] Provide instruction by active learning, advance organisers, and cooperative learning[2] Educational meetings by advance organisers, implementation intentions, and persuasive communication[3,4,5]	Training in which information is shown of the several steps of the intervention. Cases are discussed, and nurses did some role playing to exercise. Step-by-step written explanation of how the intervention must be carried out, given to nurses.	Context: Training in small groups. Parameters: a role play of the intervention during the training as an example and comparison with their own behaviour. Schematically displaying the intervention in the step-by-step written information. Discussing the ONNI† during follow up meetings (once a week) to encourage nurses toward the adoption of the intervention.
Nurses' self-efficacy and skills	Provide general encouragement, providing feedback on performance by mobilizing social support, consciousness raising and feedback[1,2,3]	Nurses give feedback to the researcher during role play, and the researcher visits the outpatient clinic to discuss feedback.	Context: the nursing teams at the outpatient clinics included are relatively small and therefore easily approachable, and visiting the outpatient clinic is a low-key approach in talking to the nurses. Parameters: Specific feedback is given, nurses are given the opportunity to talk about the use of the ONNI, and their behaviour, encouraged by the researcher.

Table 5 *(Continued)*

Determinant	Methods	Applications	How context and parameters were taken into account
	Prompt barrier identification and reviewing practice and feedback by planning coping responses and discussion[1]	Individual interviews in which nurses are invited to think about barriers and facilitators around the nursing nutrition intervention, and weekly meetings in which the use of the intervention is discussed.	Context: All nurses of the outpatient clinic were interviewed. Usual care was observed, in both hospitals. Parameters: While designing the intervention, potential barriers, based on observations and interviews, were identified and the expert team discussed on what was needed to overcome these barriers.
	Provide information about colleagues' approval by modelling and information about others' approval[3] Stimulate discussion between nurses by mobilizing social support and guided practice[1, 3]	Follow-up meetings with nurses in the intervention groups (answering questions, discussing experiences)	Context: Weekly follow-up meetings with nurses Parameters: discuss cases, what went well and what could be improved; intervention performance with positive aspects and challenges.
Nurses' attitude	Provide information about patients' perspective by shifting perspective [5] Provide overview of the nursing role in (under) nutrition[1, 8] Validate and empower on desired behaviour[3] Visits to the outpatient clinics by researchers[1, 2, 3, 4]	Training and follow-up meetings in which quotes from patients are discussed.	Context: Training in small groups and weekly follow-up meetings with nurses. Parameters: Quotes from observations of usual care and the nursing nutrition intervention were discussed to encourage nurses to take the perspective of the patient to increase the adoption.

†=Outpatient Nursing Nutritional Intervention; 1= Abraham et al., 2008; 2=Van Achterberg et al., 2011; 3=Grol & Grimshaw, 2003; 4=Grol et al., 2007; 5=Wensing et al., 2010; 6=Daniels et al., 2003; Jensen et al., 2009; www.fightmalnutrition.eu; 7=Weimann et al., 2017; 8=Van Noort et al., 2019; 9=McClave et al., 2013; 10=West et al., 2017

Patients (N=6) stated that they received all the information necessary, were able to use the food diaries, and became aware of their eating patterns by using the diaries. The patients used both the hospital food diary and the Dutch Malnutrition Steering Group food diary. After evaluation, all patients preferred the hospital version of the food diary (see appendix 4).

Table 6 – The five components of the Outpatient Nursing Nutritional Intervention (ONNI)

Component	Content
1) Determine causes of undernutrition	Possible causes of undernutrition were: a) bad appetite, b) decreased intake, c) gastrointestinal problems, d) insufficient physical activity, e) pain, or f) poor oral health
2) Perform a nutritional care plan	A: provide tailored advice related to possible cause(s) B: provide leaflets on 'energy and protein enriched nutrition'# and 'tempting food' C: refer the patient to the dietician in case of MUST score ≥2#
3) Self-monitoring of nutrient intake and eating pattern	A: explain the patient how the food diary works and how to record daily intake within the diary B: instruct the patient to monitor food intake for two days in the dairy
4) Counselling and encouragement	A: counsel the patient on eating patterns and encourage the patient to improve nutrient intake B: advice the patient to inform caregivers and/or involve caregivers during the consult C: plan a telephone follow-up meeting with the patient to be held after approximately one week
5) Follow- up meeting&	A: evaluate how causes of undernutrition did work out B: evaluate the food diary on total intake and the nutrients that were consumed C: counsel and provide tailored advice on energy and protein enrich products and on causes of undernutrition

#=activities of usual care, and was therefore included in the ONNI; &=performed by the nurse of the outpatient clinic or, in case of MUST score ≥2, by the dietician.

Step 5: Program Implementation Plan - Methods

This step involves the adoption and implementation of the ONNI in daily practise. The intention was that the ONNI should be used in the two anaesthesia outpatient clinics to allow for an evaluation of the feasibility and effectiveness of the intervention.

Literature on effective implementation strategies (33, 34) and methods to evaluate complex interventions in health care (30, 31, 35) were used to determine the implementation plan. First, desired behaviours for patients and nurses were derived from the previous steps. Then, barriers to performance of the desired behaviours and

adherence to the program goals (step 3) were identified based on observations in current practices, interviews with nurses and patients (step 1), and questionnaires completed by patients (step 4). Finally, implementation strategies from the literature were matched with these barriers and desired behaviours.

Step 5: Program Implementation Plan - Results

The determinants and barriers identified in previous steps required a multifaceted implementation strategy (30, 31, 35). The project group considered a) lack of awareness of their responsibilities in nutritional care, b) lack of prioritisation during consults, and c) the feeling of being unable to provide nutritional care for undernourished patients as the most important barriers for nurses to adapt and implement the desired behaviour. Lack of knowledge about undernutrition and interventions was also a barrier, however, the training was considered to adequately elevate the nurses' knowledge. For patients, an expected challenge was recording food intake in a food diary. These barriers required a multifaceted implementation strategy and included education, evaluation of the education, feedback during performance for nurses, and evaluation of the types of food diaries for patients (see table 7).

Table 7 – Implementation strategy for adaptation and use of Outpatient Nursing Nutritional Intervention (ONNI)

Implementation strategy	Users	Content	Professionals involved
Education	Nurses	What: Relevant training sessions with regard to disease-related undernutrition and the intervention protocol When: One month before the start of the intervention period How: Two interactive meetings about the basic principles of the intervention protocol	Dietician, researcher, and nurses
Evaluation of the training	Nurses	What: discussion about intervention protocol When: One week after the training How: clarifying by the dietician and researcher, explaining of the ONNI steps by nurses, feedback for nurses about their performance on ONNI	Dietician, researcher, and nurses
Feedback	Nurses	What: Feedback on nurses' performance When: During implementation How: Observation at the outpatient clinic by a researcher	Dietician, researcher, and nurses
Evaluation of type of food diary	Patients	What: Evaluation of patients' preferences for food diary When: During test of the ONNI How: Providing two types of food diaries	Researchers, nurses

The researcher (GHdW) observed the way nurses performed the intervention. Afterwards, the researcher and the nurse discussed the performance and the researcher gave feedback to the nurse. Also, the nurses' experiences with the intervention were discussed with the researcher who visited the outpatient clinic during weekly follow-up meetings in the implementation period. These discussions were meant to increase nurses' skills and improve their attitudes towards nutritional support. Nurses asked the trainer more questions during the first meetings compared to the end of this period. Near the end of the implementation period, nurses started to feel familiar with the intervention.

Step 6: Evaluation Plan

In the final step, the aim is the design of an evaluation study, which required an evaluation of the feasibility and effectiveness of the ONNI. This evaluation is not the focus of this paper and is reported separately (36). The study protocol was registered at the National Institutes of Health (NIH) with the ClinicalTrial.gov Identifier, NCT02440165 (37).

Discussion

This paper describes the methods and end products of the application of the IM approach to develop an ONNI.

Within the MRC framework for complex interventions, IM was used to structure the development phase of the complex nutritional intervention. In step 1, research identified the determinants which contributed to undernutrition or risk for undernutrition before surgery. In this phase of development, we invited patients to share their opinions and experiences. The stakeholders collaborating in the project group all had experience with nursing, undernourished patients, systematic development of interventions, or held a combination of these areas of expertise. Patients were not included in the project group. Involvement of patients was addressed in step 1 by exploring their perspectives, and also during evaluation of the intervention in step 4. Involvement of patients' perspectives is considered as 'consulting' on the ladder of citizen participation (38). Partnership of patients in the design of the study and the intervention would require expert contribution from the patient which appeared difficult according to previous intentions (39). Therefore, we preferred active patient participation in their nutritional prehabilitation rather than their partnership in the design of this study. We argue that we had a strong theoretical framework, recent evidence, and clinical expertise to thoroughly develop an evidence-based intervention.

Additionally, the intervention is tailored to the identified barriers to change and behaviour which is recommended to achieve improvements in professional practice (33).

With regard to the entire process of intervention development, we argue that although IM is time consuming, it results in an examination of the context, an evidence-based, thought-through intervention, as well as training and a set of implementation strategies. At this time, a test confirmed an improvement in nurses' behaviour and patients' knowledge and skills. However, the feasibility and effectiveness of the ONNI are not yet determined. The evaluation plan, step 6 of IM, is meant to determine the feasibility of the ONNI in daily practice and the effectiveness effect based on relevant nutritional outcomes (37). This examination of the ONNI in daily practice will optimize the development phase (40).

Nurses were found to be unaware of their roles and felt incapable of providing nutritional care (step 1). This is in accordance with other studies, which demonstrated that nurses were unaware of their nutritional roles, demonstrated low self-efficacy, and lacked nutritional knowledge (41, 42) and education (43, 44). Since nutrition belongs to the core of basic nursing care (22, 45, 46), nurses need to be educated on their crucial roles regarding nutrition to ensure that patients are properly fed. The training (step 4) has the potential to address this challenge. In our test, we found that nurses' attitude changed as they became aware of their role in nutritional care. As the nursing staff was small, a crucial instrument would be that the researcher can supervise each nurse individually during the implementation at the outpatient clinic.

In the samples of surgical outpatients (step 1), 5-7% of the patients were at risk for undernutrition, and 4-5% of patients were undernourished (see table 2). Despite the fact that these rates are in accordance with other studies in this setting (5, 7), the literature demonstrates higher percentages of patients at risk for or with undernutrition among other populations (4, 47-49). The samples in our study may have been healthier and younger, and patients in our sample were only seen for surgery. The ONNI can be adapted to all types of outpatient clinics, since undernutrition is seen in all types of medical specialties (16, 49). The fact that the ONNI was especially developed for preoperative outpatients must be taken into account. Researchers and policymakers can use several intervention frameworks (17, 50, 51) for further adaption of the ONNI.

Moreover, as a result of the survey during the needs assessment, well-nourished patients stated that they needed additional information regarding nutrition (step1). This may suggest that patients are generally not well informed regarding nutrition and that all patients may benefit from nutritional advise during outpatient preoperative consultation.

The ONNI comprises tailored and general advice, leaflets, counselling on eating patterns based on a food diary, encouragement for sufficient and healthy food intake, and a follow-up meeting. It is intended to be provided in anaesthesia outpatient clinics before patients' admission for surgery. Other oral nutritional interventions include education of caregivers of dependent undernourished patients (52), enhanced recovery protocols during hospital admission (29, 53, 54), and dietetic consultations starting at hospital discharge with fortnightly follow-up meetings for six months (55). This ONNI focuses on nutritional support for the patient but involves caregivers only during the consultation at the outpatient clinic. Further research should address family participation during surgical course. Additionally, further research should address nutritional support during the whole surgical course, i.e. preoperative and postoperative phases. Researchers and health care professionals can adapt the ONNI components and evaluate these during hospital admission and after hospital discharge.

Surgical patients with undernutrition may also have other frailty factors that increase the risk of complications. Levett, Edwards, Grocott, and Mythen (2016) discuss that preoperative prehabilitation of high-risk patients should be based on a multimodal and interdisciplinary approach (56). The health status of patients at risk for or with frailty should be optimized through preoperative physical, nutritional, and psychological optimization. Our intervention contributes to the nutritional prehabilitation, and our study provides the definition of the nurses' role within the inter-professional approach (57).

Conclusions

This application of the IM approach demonstrates that nurses at the outpatient clinics felt incapable and did not feel responsible for delivery of preoperative nutritional support to surgical patients at risk for or with undernutrition. Patients themselves were often unaware of their nutritional status and the increased risks for complications in case of undernutrition. The extensive IM approach resulted in an evidence-based, thoroughly-developed ONNI. The ONNI, including a training for nurses, aims to improve or maintain patients' nutritional status. The test confirmed improved knowledge, skills, and sense of responsibility in nurses. The ONNI enables nurses to empower patients to improve their preadmission nutritional status and ultimately may improve postoperative recovery.

Abbreviations

EN: Enteral Nutrition; IM: Intervention Mapping; MRC: Medical Research Council; MUST: MaInutrition Universal Screening Tool; ONNI: Outpatient Nursing Nutritional Intervention; ONS: Oral Nutritional Supplements; PN: Parenteral Nutrition

Ethics approval and consent to participate

The study was ethically approved by the Medical Ethical Committee of the Radboud university medical centre in Nijmegen, The Netherlands, number 2014-1353. All patients and nurses provided informed consent, and data were processed anonymously.

Consent for publication

Not Applicable

Availability of data and material

The data generated and analysed during the current study are not publicly available but are available from the corresponding author upon reasonable request. The materials used and developed during the study are provided as supplementary materials online. https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-4964-6#Sec26

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Study design: GHdW, MH, RE; Data collection and analysis: MH, MvA, GHdW; Manuscript preparation: HN, MH, MvA, RE, HV, GHdW. The BCR research group contributed in the study design.

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Chapter 4

An outpatient nursing nutritional intervention to prehabilitate undernourished patients planned for surgery: a multicentre, cluster-randomised pilot study

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On the behalf of the Basic Care Revisited research group

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Abstract

Background & Aims: To improve the nutritional status of surgical patients before hospital admission, an Outpatient Nursing Nutritional Intervention (ONNI) was developed. The ONNI comprehends five components: determining causes of undernutrition, performing a nutritional care plan including tailored and general advice, self-monitoring of nutritional intake and eating patterns, counselling and encouragement, and conducting a follow-up telephone call to discuss improvements in nutritional behaviour. Here, we evaluate the feasibility and effectiveness of the ONNI.

Methods: In a multi-centred, cluster-randomised pilot study, nurses from outpatient clinics were randomly allocated to usual care (UC) or the ONNI. Patients planned for elective surgery were included if they were at increased risk for undernutrition based on the Malnutrition Universal Screening Tool (MUST) and hospital admission was not planned within seven days. Feasibility outcomes included participation rate, extent of intervention delivery, and patient satisfaction. Nutritional intake was monitored for two days before admission. Body weight, BMI and MUST scores at hospital admission were compared to measurements from the outpatient clinic visit. Data were analysed on an intention-to-treat basis by researchers who were blinded for patients and caregivers.

Results: Forty-eight patients enrolled the feasibility phase. Participation rate was 72%. Nurses delivered all intervention components adequately in the end of the implementation period. Finally, 152 patients (IG: n=66, 43%) participated in the study. A significant difference in mean energy intake (870kcal/d, 95%CI:630-1109 p<0.000) and mean protein intake (34.1g/d, 95%CI: 25.0-43.2; p<0.000) was observed in favour of the IG. Nutritional energy requirements were achieved in 74% (n=46) of the IG and in 17% (n=13) of the UC group (p<0.000), and protein requirements were achieved in 52% (n=32) of the IG, compared to 8% (n=6) of the UC group (p<0.000). Body weight, BMI and MUST scores did not change in either group.

Conclusions: The ONNI is a feasible and effective intervention tool for nurses at outpatient clinics. Patients in the IG had more nutritional intake and fulfilled nutritional requirements significantly more often than patients receiving UC. Further research is required to determine the optimal preoperative timing of nutritional support and to measure its effect on other patients groups.

Clinical trial registration: The study protocol was registered at the ClinicalTrial.gov website with the following identifier: NCT02440165.

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Keywords

Preoperative Care, Undernutrition, Nutritional support, Essential Care, Nursing Care, Prehabilitation

Introduction

An optimal nutritional preoperative condition is essential for postoperative recovery. Preoperative undernutrition, clinical fasting regimens (1-3) and postoperative nausea and vomiting inhibit recovery from surgery. Undernutrition is a critical condition for patients during recovery from surgery (4-8). Systematic screening during outpatient preoperative evaluation with the Short Nutritional Assessment Questionnaire (SNAQ) or the Malnutrition Universal Screening Tool (MUST) found undernutrition or an increased risk of undernutrition in respectively in 7% and 5% of the preoperative patients (9-11). Nutritional screening upon admission to surgical units demonstrated that up to 17,5% of the patients were undernourished or 45,2% were at risk of developing undernutrition (7). Untreated undernutrition leads to poorer outcomes and more surgical complications, such as infection (12), delayed gastrointestinal motility (13), prolonged length of hospital stay (14), delayed wound healing (15), renal and cardiac impairment (12), symptoms of depression and reduced quality of life (QoL) (16, 17). Therefore, undernourished patients should receive additional nutritional support at an early stage during their surgical treatment so that the clinical course can be adjusted positively.

Patients at risk for or with undernutrition can be treated with extra nutritional support, either orally or through enteral (EN) or parenteral (PN) treatment (18). Oral nutritional support through a regular diet enables patients to self-manage their nutritional intake. Extra support from a dietician or nutritional coach may result in a better nutritional status (19, 20). In our systematic review of the effectiveness of oral nutritional support in undernourished surgical patients, we describe several oral nutritional interventions achieving preserved or better nutritional status and improved QoL (21). The studies in this review were limited in number and lack methodological strength. Surprisingly, all interventions were performed by dieticians, and not by nurses. Nurses are in a pivotal position to facilitate nutritional interventions when outpatient preoperative evaluation is performed (9-11). Needless to say, care for sufficient drinking and eating are among the essentials of nursing (22, 23).

To further expand on and evaluate the role of nursing, we developed an Outpatient Nursing Nutritional Intervention (ONNI) (24). The development of the ONNI followed the guidelines of the Intervention Mapping approach (24, 25). The complex intervention aims to improve patients' nutritional status and consists of five components:

determining the causes of undernutrition; performing a nutritional care plan, including tailored and general advice; self-monitoring nutritional intake and eating patterns; counselling and encouragement; and conducting a follow-up meeting to discuss improvements in nutritional behaviour (see table 1). Our previous article describes the implementation strategies to integrate this intervention into the daily practice of nurses at outpatient clinics (24). In order to follow the Medical Research Council's framework for complex interventions, a newly developed intervention should be evaluated for its feasibility and effectiveness (26). In this study, we evaluate the intervention based on its feasibility in daily practice and effectiveness on nutritional status.

Materials and methods

Design

The ONNI was evaluated in a multi-centred, cluster-randomised clinical pilot study from February 2015 to September 2016. The study was ethically approved by the Medical Ethical Committee of the Radboud university medical centre in Nijmegen, the Netherlands, number 2014-1353. The protocol of this study was registered at the National Institutes of Health (NIH) with the ClinicalTrial.gov Identifier NCT02440165 (27). We used the Consolidated Standards of Reporting Trials CONSORT for adequate and transparent reporting (28, 29).

Participants

The intervention was developed and implemented in the routines of the allocated nurses from anaesthesia outpatient clinics of two Dutch hospitals, one university hospital and one teaching hospital. The nurses were instructed to recruit a convenience sample of at least 150 patients. Pilot studies should include at least 12 patients (30, 31), and cluster-randomized studies need more patients to correct for the clustering (32). To have sufficient power for this pilot study, we intended to include 15 patients per nurse.

Eligible patients visited the outpatient clinic for evaluation of health status before surgery. Types of surgery included orthopaedic, abdominal, vascular, neurological and general surgery. To be included, patients had to be at least 18 years of age, be able to speak, read and write in Dutch, and had to have an increased risk for undernutrition according to the MUST. The MUST is a validated screening tool, made up of three independent criteria for protein – energy undernutrition and can result in a score between 0 and 6. A score of 0 indicates low risk (well-nourishment), a score of 1 indicates medium risk (at risk for undernutrition), and a score of at least 2 indicates high risk

(undernutrition) (33). Patients who were following a specific dietetic regimen or were being treated through tube feeding or oral nutritional supplements were excluded. The intervention period between the outpatient clinic visit and the follow-up call was 7 days. Patients scheduled for surgery within seven days were excluded in order to deliver all intervention components during the intervention period. The mean time between outpatient clinic visit and hospital admission was 42 (32) days (see table 2). Informed consent was obtained before outpatient clinic consultation.

Cluster randomization

Randomisation was performed by independent nursing researchers (MH, EvB) through the use of sealed opaque envelopes. Each envelope contained the name of one of the nurses from the outpatient anaesthesia clinics. In this manner, nurses were randomly allocated to facilitate the intervention or to continue providing usual care. All nurses were informed about the study procedures and facilitated recruitment of the patients. The nurses randomised to the intervention underwent a special training before the start of the study. Details of the training are reported elsewhere. Blinding was not possible for patients and nurses; however, outcome assessors were blinded and did not perform the analysis. Data were derived from medical files by blinded students. Ten percent of the data was audited. Analysis of the data was performed by investigators (HN and GHdW) and a statistician (RA), who were blinded for patients and outcome assessment.

Nutritional support

Outpatient Nursing Nutritional Intervention

The intervention of interest was developed following the steps of Intervention Mapping (25), and the development process is reported in our previous article (24). The ONNI is targeted at patients with increased risk for undernutrition based on MUST scores, and includes the following five components (see table 1). First, causes of undernutrition are determined with a checklist (see supplementary material 1). Then, patients are educated with both tailored and general information in a nutritional care plan. In case of a MUST score equal to or above 2, patients are also referred to a dietician as this is usual care. The third component provides insight in personal eating patterns by recording the daily intake at home for two days in a food diary (see supplementary material 4). Patients were instructed to record food intake at a random mid-week day and a weekend day within the intervention period to enable the fifth component. The fourth component involves counselling and encouraging the patient to improve his or her nutritional status during the outpatient clinic visit and a follow-up meeting.

The fifth component includes support during a follow-up phone call with the patient within seven days after the outpatient clinic visit.

Table 1 – The five components of the Outpatient Nursing Nutritional Intervention (ONNI)

Component	Content
6) Determine causes of undernutrition[@]	Possible causes of undernutrition are: a) bad appetite, b) decreased intake, c) gastrointestinal problems, d) insufficient physical activity, e) pain, or f) poor oral health
7) Perform a nutritional care plan	A: provide tailored advice related to possible cause(s) B: provide leaflets on energy and protein enriched nutrition, and 'tempting food' C: refer the patient to the dietician in case of MUST score ≥2[#]
8) Self-monitoring of nutrient intake and eating pattern	A: explain the patient how the food diary works and how to record daily intake within the diary[@] B: instruct the patient to monitor food intake for two days in the dairy
9) Counselling and encouragement	A: counsel the patient on eating patterns and encourage the patient to improve nutrient intake B: advice the patient to inform caregivers and/or involve caregivers during the consult C: plan a telephone follow-up meeting with the patient to be held after approximately seven days
10) Follow- up meeting[&]	A: evaluate how causes of undernutrition did work out B: evaluate the food diary on total intake and the nutrients that were consumed C: counsel and provide tailored advice on energy and protein enrich products and on causes of undernutrition

[@]= see supplementary material 1 and 2; #=referral to the dietician in case of MUST score ≥2 is usual care, and was therefore included in the ONNI; &=performed by the nurse of the outpatient clinic or, in case of MUST score ≥2, by the dietician.

Usual Care

Usual nutritional nursing care (UC) was performed according to the hospital's protocol. The protocol included a) screenings for undernutrition with MUST (33) and b) nutritional interventions for patients at risk for or with undernutrition. The interventions include the following: 1) provision of a leaflet with information about protein-rich food; 2) verbal information about undernutrition, reasons for weight loss, and advice about protein-rich nutrition; and 3) referral to a dietician in case of MUST-scores equal to or above 2. Observations during the development of the ONNI demonstrated that all of these activities were performed except for verbal advising (24). Thus, complete UC was not provided. The ONNI differed from UC in components 1, 2A, 4, and 5 (see table 1). The leaflet 'Tempting food' (component 2B) was only provided to ONNI patients, while the leaflet on energy and protein-enriched nutrition was provided to both groups. Instruction to monitor food intake (component 2 of the ONNI) was also performed

during UC for evaluation of nutritional intake as a study outcome. However, nurses performing UC did not use the food diary to discuss nutritional health and motivate and empower patients as the nurses of the intervention group (IG) did.

Feasibility outcomes

The feasibility of the ONNI was determined based on the work of Sorenson and Steckler (34) and of Bowen et al. (35). The outcomes of the process evaluation were 1) the percentage of the patient population who would participate, 2) the extent of delivery of the ONNI components, and 3) patients' satisfaction with both nutritional and general nursing care. The ONNI was implemented between April and June 2015, which was also the period dedicated to evaluation of the feasibility. During implementation of the intervention, nurses received feedback on intervention performance and discussed their experiences during weekly meetings with a researcher (GH-dW). Non-participative observations were performed at the university hospital in order to determine feasibility outcomes 1 and 2. Data were gathered through a structured observation questionnaire (see supplementary material 3). Patients' satisfaction was measured with an adapted version of the Consumer Quality questionnaire (36) (see supplementary material 4). The questionnaire contained questions regarding the outpatient clinic, general nursing care and nutritional care. All participating patients were asked to complete this survey between the outpatient clinic visit and hospital admission.

Effectiveness outcome

The primary outcome of the study was the nutritional status of the patients. Nutritional status was evaluated based on nutritional intake, weight, nutritional risk based on MUST scores (33) and Body Mass Index (BMI). Nutritional intake was recorded in the food diary for two days between the outpatient clinic visit and hospital admission as part of the ONNI. The researcher who analysed the data (GHdW) called patients when food diaries were not clear. Weight, height, and MUST scores were measured during outpatient visits (t=0), at hospital admission (t=1), and at discharge or the last measure during hospital stay(t=2). Patients' body weight was measured with their clothes and shoes on at the outpatient clinic or at admission in the hospital. Patients' BMIs were calculated as weight, (kg)/height (m)2, and classified according to the criteria of the World Health Organisation (37).

Statistical methods

Descriptive analyses were used to describe patients' characteristics and outcomes. Depending on the distribution of the variables, percentages or mean and standard

deviation were shown. Additionally, depending on the distribution, Pearson's Chi-square or the independent sample t-test was used to validate the study groups.
A multivariate linear regression analysis was performed to evaluate the differences in nutritional intake, weight and BMI for both groups. The mean nutritional intake was calculated for each patient based on the two days of food documentation. There was no pre-intervention information of nutrient intake of all patients. Differences in nutrient intake were analysed between the UG and IG. Also, difference between the two days of monitoring were calculated. Intake was compared with recommended nutrient requirements. Protein requirements were estimated based on 1.5 gram/kg per day (18, 38). For estimation of the resting energy expenditure (REE), the FAO/WHO/UNU equation was used for patients with a BMI ≤ 30 kg/m^2. The Harris and Benedict equation was used for patients with a BMI > 30 kg/m^2 (39, 40). For determination of energy requirements, 30% to was added to the REE for each patient. A multivariate logistic regression analysis was performed to evaluate the differences in intake fulfilment. Changes in nutritional risk MUST scores and weight were analysed with Pearson's Chi-Square. Weight, MUST scores and BMI during hospitalisation (T=1) and discharge (T=2) were compared with baseline scores (T=0). Age, gender, BMI, weight and MUST scores at T=0 were considered potential confounders and were included in the model during the regression analysis. The clustering of data was corrected by using hospital site and surgical treatments as confounders within each model.
Study results were analysed on an intention-to-treat basis. Missing values were not imputed because of the explorative character of the study. Potential selective dropout in follow-up measurements was determined by evaluation of patient characteristics. A p-value less than 0.05 was considered statistically significant based on two-sided tests. All analyses were carried out with IBM SPSS statistics 25.0.

Results

Participants

The nursing staff of the two outpatient clinics included a total of ten nurses. Five of them were randomly allocated to provide the intervention. All ten nurses recruited patients a total 158 patients of whom 152 patients fulfilled the inclusion criteria. Sixty-seven (43%) patients received the ONNI (figure 1). Reasons for exclusion or withdrawal from the study and incomplete data are displayed in figure 1. Most patients were females (n=106, 70%) and were on average 50 (SD 17,8) years of age. Fifty-three percent of the patients (n=81) underwent orthopaedic surgery. A MUST

score of two (indicating a high nutritional risk) was found in 55 (37%) patients (see table 2 for detailed information).

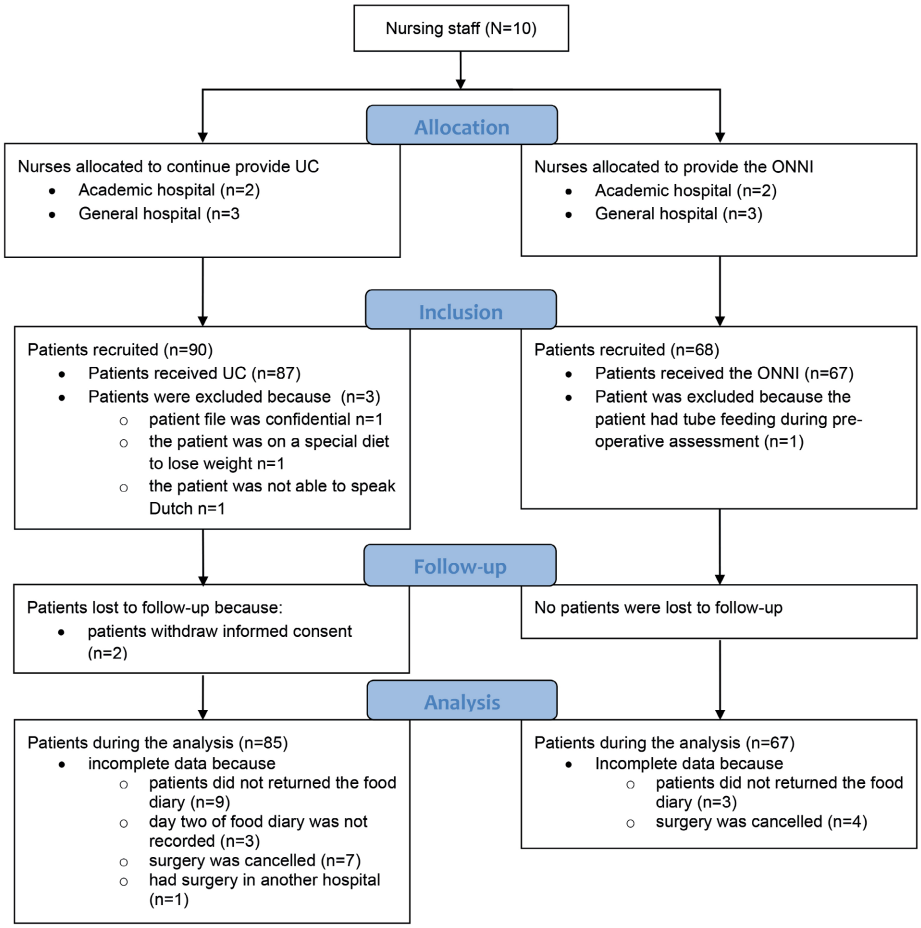

Figure 1 – Allocation of nurses, patient and data flow during the study

Table 2 – Patients characteristics

	Study population N=152 (100%)	ONNI group n=67 (44%)	UC group n=85 (56%)	p-value
Gender (female) [a]	106 (70)	41 (61)	65 (77)	0.042‡,**
Age (years) [b]	49.8 (17.8)	49.7 (17.3)	49.9 (18.2)	0,871*
Hospital [a]	80 (53)	35 (52)	37 (44)	0.286‡
General	72 (47)	32 (48)	48 (56)	
Academic				
Surgical treatment [a]	37 (24)	15 (22)	22 (26)	0.501‡
General#	81 (53)	40 (60)	41 (48)	
Orthopaedic	34 (22)	12 (18)	22 (26)	
Other$				
Time to hospital admission [b] (days)	42 (32)	38 (29)	44 (34)	0.177*
Length of hospital stay [b] (days)	4.9 (7.4)	4.8 (5.6)	4.9 (8.7)	0.708*
Nutritional parameters	65.75 (16.3)	66.2 (17.3)	64.7 (15.1)	0,653*
Weight @,b(kg)	22.48 (4.7)	22.48 (4.8)	22.43 (4.60)	0.849*
BMI @,b				0.108‡
MUST €,a	92 (62.6)	36 (55.4)	56 (68.3)	
Score 1	55 (37.4)	29 (44.6)	26 (31.7)	
Score ≥2				
Nutrient requirements [b]	1875 (295)	1910 (331)	1848 (263)	0.653*
Energy (kcal/day)	98.4 (24.3)	99.6 (25.9)	97.4 (23.0)	0.653*
Protein (grams/day)				

ONNI=Outpatient Nursing Nutritional Intervention; UC= Usual Care; BMI= Body Mass Index; MUST: Malnutrition Universal Screening Tool

#=abdominal, traumathologic and vascular surgery; $= thoracic, facial, plastic, neurosurgery; @= data of 149 (98%) patients were available of whom 66 (44%) were in the intervention group; ‡= data of 135 (89%) were available of whom 59 (44%) were in the intervention group; ‡= Pearson Chi-square; * =independent sample t-test; **=significant at p=<0.05

a: results are expressed as number of patients per group (percentages);

b: results are expressed as mean ± SD.

Feasibility outcomes

For determination of the participation rate and intervention delivery, 66 consultations of nurses were observed at the academic outpatient clinic. The participation rate was 72%, resulting in 19 (40%) patients in the IG and 29 (60%) in the UC group (see table 3). These 48 patients covered 32% of the final sample. Patients were excluded if they were going to have surgery within one week (n=5, 8%), unable to speak or read Dutch (n=3, 5%), or if they did not provide informed consent (n=8, 12%).

Delivery of the different intervention components is displayed in table 3. Determination of the possible causes of undernutrition was conducted in 74% of the patients, resulting in the provision of tailored advice to only 68% of the patients. The leaflet 'energy and protein enriched nutrition' was handed to eight (42%) patients of the IG and six (21%) of the UC group. Other leaflets as part of the ONNI were suf-

ficiently provided. Referral to a dietician in case of a MUST score of or above 2 was conducted for 100% of the IG and 13% of the UC group. Planned follow-up was not completed for two patients due to hospital admission for surgery before the phone call. Overall, most of the components were sufficiently delivered to all patients, either by the nurse or the dietician. The discussion session with nurses from the IG demonstrated that, at the end of the feasibility period, nurses were familiar with how to perform the intervention and performed all components.

Table 3 – Delivery of the Outpatient Nursing Nutritional Intervention and Usual Care

		ONNI (n=19)	UC (n=29)
Patient characteristics			
Gender (female) [a]		10 (53)	15 (52)
Age (years) [b]		52.4 (20.7)	52.8 (19.1)
Surgical treatment [a]		11 (58)	13 (45)
General [#,a]		2 (11)	3 (10)
Orthopaedic		6 (32)	13 (45)
Other [$,a]			
MUST scores [#,a]		11 (58)	21 (72)
Score 1		8 (42)	8 (38)
Score ≥2			
Delivery of the components of the ONNI and UC [a]			
1	Determine causes of undernutrition	14 (74)	n/a
2	Perform a nutritional care plan	13 (68)	n/a
	a) tailored advice related to possible cause(s)		
	b) provide leaflets:	8 (42)	6 (21)[@]
	'energy and protein enriched nutrition'[#] ,	19 (100)	n/a
	'Tempting food'	8 (100)	1 (13)[@]
	c) refer to the dietician in case of MUST score ≥2[#]		
3	Self- monitoring of nutrient intake and eating pattern[#]	19 (100)	29 (100)[@]
4	Counselling and encouragement	11 (100)	n/a
5	Follow-up meeting[&]	9 (82)	n/a
	a) discussion of the food diary:	4 (44)	
	b) tailored advice regarding protein rich products	3 (33)	
	c) evaluation of determined causes of undernutrition	1 (5)	
	d) other questions	4 (26)	

ONNI=outpatient nursing nutritional intervention; UC= usual care; MUST: Malnutrition Universal Screening Tool; #=abdominal, traumathologic and vascular surgery; $= thoracic, facial, plastic, neurosurgery; @= components which were provided during both UC and ONNI; &=phone calls performed by dieticians were not observed.

a: results are expressed as number of patients per group (percentages);

b: results are expressed as mean ± SD.

Questionnaires on satisfaction were returned by 103 (67.8%) of the patients (UC= 55 (53.4%); IG=48 (46.6%)). The outpatient clinic, nursing care and nutritional nursing care were well rated (8.2, 8.2 and 7.8 respectively) by all patients, with no differences between the study groups (see table 4).

Effectiveness of the ONNI

Nutritional intake

Mean energy intake was 2417 (793) kcal per day, and mean protein intake was 94.8 (26.1) grams per day for patients in the IG (see table 4). The intake per day of patients in the UC group was significantly lower, with a mean difference of 870 (95%CI 630-1109) kcal of energy ($p<0.000$) and 34.1 (95%CI 25.0-43.2) grams of protein ($p<0.000$). The UC group had a higher, but not significantly higher, energy intake on the second day of monitoring compared with the first day (delta mean difference 80kcal (95%CI -6,805-168,15; paired t-test p=0,070).

Energy requirements were reached more often than protein requirements (43% (n=59) versus 28% (n=38) of all patients) (see table 4). Energy was adequately consumed by 74% (n=46) of the IG versus only 17% (n=13) of the UC group ($p<0.000$). Fifty-two percent (n=32) of the IG fulfilled the protein requirements versus only 8% (n=6) of the UC group.

Weight and BMI

Data on change in weight and BMI were available for 97 (64%; IG: n=49; UC group: n=48) patients at t=1 and for 23 (15%) patients at t=2. Data on body weight of all other patients were missing. No differences were found in body weight and BMI between outpatient clinic visit and hospital admission, and between the two study groups (see table 4). Twenty-four (49%) patients in the IG gained some weight (2.1(1.8)kg) compared to 21 (44%) patients in the UC group (1.9 (1.7)kg). However, further weight loss appeared more frequently in the IG (n=14, 29%; -1.3 (1.0) kg) compared to the UC group (n=12, 25%; -1.9 (1.8) kg). The lack of data hampered clear analysis of change in weight between t=0 and t=2.

MUST

Screening for nutritional risk with the MUST was performed in 57 (38%) patients at t=1. Twenty-seven (48%) of these patients improved nutritional risk resulting in lower or no nutritional risk (see table 4) of whom 15 patients who received the intervention. No change in MUST scores was observed in 27 (47%) of the patients. Change in MUST scores was not different for the ONNI and UC group (p=0.717).

Table 4 – Effect on nutritional intake, nutritional parameters and patient satisfaction

		Study population N=152 (100%)	ONNI group n=67 (44%)	UC group n=85 (56%)	Mean difference (95%CI)	p-value
Nutritional Intake						
Energy (kcal)[a]	Day 1	2000 (870)	2402 (801)	1384 (542)	926 (689-1162)	<0.000‡
	Day 2	2064 (907)	2432 (870)	1473 (651)	803 (529-1077)	<0.000‡
	Average per day	2032 (856)	2417 (793)	1423 (569)	870 (630-1109)	<0.000‡
Protein (grams)[a]	Day 1	78.0 (31.4)	93.7 (25.9)	54.5 (25.3)	34.1 (25.2-43.0)	<0.000‡
	Day 2	79.0 (35.3)	95.9 (31.0)	56.0 (28.7)	33.6 (22.8-44.4)	<0.000‡
	Average per day	78.5 (31.9)	94.8 (26.1)	55.2 (25.4)	34.1 (25.0-43.2)	<0.000‡
Consumption of nutritional requirements						
Energy [b,]	Not achieved	78 (56.9)	16 (25.8)	62 (82.7)	n/a	<0.000¤
	Achieved	59 (43.1)	46 (74.2)	13 (17.3)	n/a	
Protein [b,]	Not achieved	99 (72.3)	30 (48.4)	69 (92)	n/a	<0.000¤
	Achieved	38 (27.7)	32 (51.6)	6 (8)	n/a	
Change in nutritional parameters						
Weight at T=1 (kg)[a]		66.5 (15.5)	67,26 (16.70)	65.20 (14.83)	0.652 (-4.4-5.7)	0.800‡
Weight change between T=0 and T=1 (kg)[a]		0.52 (2.05)	0.66 (2.01)	0.38 (2.10)	0.334 (0.5-1.2)	0.425‡
	Weight loss (kg) [a]	-1.57 (1.39)	-1.3 (0.97)	-1.87 (1.76)	0.76 (-0.913-2.43)	0.353‡
	Weight gain (kg) [a]	2.03 (1.73)	2.11 (1.77)	1.94 (1.72)	-0.134 (-1.352-1.085)	0.825‡
	Maintained [b]	26 (27)	11 (22)	15 (31)	n/a	0.634†
	Weight loss[b]	26 (27)	14 (29)	12 (25)	n/a	
	Weight gain [b]	45 (46)	24 (49)	21 (43.8)	n/a	
BMI at T=1[a]		22.71 (4.63)	22.94 (4.99)	22.49 (4.54)	0.45 (-1.32-2.23)	0.613‡

Table 4 *(Continued)*

		Study population N=152 (100%)	ONNI group n=67 (44%)	UC group n=85 (56%)	Mean difference (95%CI)	p-value
MUST-scores T=1[b]						
	Score 0	19 (34)	11 (39)	8 (29)	n/a	0.776[†]
	Score 1	26 (46)	12 (43)	14 (50)	n/a	
	Score ≥2	11 (20)	5 (18)	6 (21)	n/a	
	Maintained	27 (48)	12 (43)	15 (54)	n/a	0.790[†]
	Deteriorated	2 (4)	1 (4)	1 (4)	n/a	
	Improved	27 (48)	15 (54)	12 (43)	n/a	
Patient satisfaction [a]						
	Outpatient clinic	8.2 (0.75)	8.36 (0.76)	8.13 (0.74)	0.191 (-0.136-0.519)	0.248[‡]
	Nursing care	8.3 (0.95)	8.38 (1.1)	8.15 (0.83)	0.143 (-0.249-0.535)	0.472[‡]
	Nutritional nursing care	7.8 (1.3)	7.92 (1.5)	7.60 (1.1)	0.261 (-0.280-0.802)	0.340[‡]

ONNI=Outpatient Nursing Nutritional Intervention; UC=Usual Care; ‡= Multivariate linear regression analysis; ¤= Multivariate logistic regression analysis; [†]=Pearson Chi-Square;

a: results are expressed as mean ± SD;

b: results are expressed as number of patients per group (percentages).

Discussion

The newly developed nursing nutritional intervention appeared to be feasible in daily practice and improved nutrition intake of undernourished patients before surgery compared to usual care. No effects were found on nutritional risk, weight or BMI.

Feasibility

At the beginning of the study, nurses were not yet completely familiar with the ONNI too. As a result, some patients did not receive all intervention components. At the end of the feasibility phase, nurses were better trained able to deliver all components. Our observations and discussions with the nurses throughout the implementation period ensured us that from feasibility phase on patients did received all intervention components.

One of the components in the nutritional care plan during the ONNI and UC was the provision leaflets. The delivery of leaflets alone, as was done in our UC group, did not change the nutritional behaviour of patients. The systematic review of leaflets by Susteric et al (41) demonstrated that a combination of verbal and written information together with tailored support may lead to better adherence, as was done in our nursing intervention. Therefore, in our study we only investigated the effectiveness of the combinations of components (see table 1).

Nutritional counselling has been described previously in patients at risk for cardiovascular diseases (42) and with cancer (43). In these studies, nutritional counselling is described that includes the following components: 1) goal-setting; 2) self-monitoring practices (use of food diaries); 3) motivational interviewing; 4) providing tailored instruction based on stage of change; and 5) addressing patients' barriers to making and maintaining diet changes (42). Only components 1 to 4 were included in our study because component 5 was not applicable in the nutritional prehabilitation phase before surgery.

Effectiveness

No differences were found in nutritional status, e.g., weight, nutritional risk and BMI. The aim of the ONNI was to improve nutritional status, which we did not achieve according to these parameters. This could be the result of the high percentage of missing values at both hospital admission and hospital discharge. It seems that nurses do not routinely evaluate weight and nutritional risk upon both admission and discharge. Furthermore, there was great variation in the period between the outpatient clinic visit and the hospital admission as is shown in table 2. This wide range may be the result of different preoperative routes and waiting lists for a planned surgery. Some patients were operated within a short period of time. It is possible that

the time between intervention and surgery was exceedingly short and the power of the patient group was exceedingly small to demonstrate a clinical effect on these parameters. Further research should therefore focus on the ideal timing of nutritional prehabilitation in order to define the optimal timing of surgery.

Nutritional intake was significantly higher in the IG compared to the UC group in terms of mean total energy and protein intake and percentages of achievements of individual nutritional requirements (see table 4). We think that nutritional awareness is an important determinant for this intake improvement, as awareness appeared to be one of the identified barriers in our needs assessment (24). Patients in the IG were extensively informed during the consultation. As a result, patients were self-assured regarding their eating patterns and were willing to improve. Moreover, the use of a food diary by the patients in the UC group may have increased self-awareness of eating habits that, unintentionally, influenced eating behaviours. They subsequently demonstrated better intake results on the second day. However, this statement should be handled with caution, and further research should investigate the mechanism behind intake improvement in outpatients to confirm that awareness improves food intake.

We used accurate equations (39, 40) and a recommended standard (18) to evaluate whether patients also managed to consume their calculated nutrient requirements. Based on these formulas, most of our undernourished patients did not meet the nutrient intake requirements. This is in contrast to the fact that the majority of patients in the IG consumed sufficient amounts of daily energy and protein. Therefore, we concluded that our ONNI is a new promising tool improving preoperative nutritional intake. In order for it to be used to prehabilitate all undernourished surgical patients, further research is required to identify the more vulnerable patients who did not achieve nutrient requirements even in the IG. Moreover, further research must validate the estimation of individual nutrient requirements as the GRADE recommendation for protein requirements are low and there is a lack of evidence base for energy recommendations for clinical nutrition in surgery (18).

A weak point in our study was that the nurses, randomly allocated to either UC or ONNI, were all part of the same team. As a result, the knowledge of the ONNI protocol may also have been acquainted by the nurses in the UC group and they may have consequently improved their nutritional care. Patients in the UC group may have gained the advantage of this exchange, perhaps receiving more nutritional care than they may have received before the start of the study. This could be one of the reasons that we did not find a difference in patients' satisfaction regarding nutritional care.

Another limitation is that we performed a correction on the clustering of the patients by using multivariate regression analysis. Correction on clustering in trials is recommended because inappropriate analysis in cluster-randomised trials may

lead to incorrect conclusions (32). Patients within one cluster may be more likely to respond in a similar way and, consequently, may not act independently. This leads to a loss of power, and the intracluster correlation coefficient (ICC) may achieve the equivalent power of a trial randomised at the patient level. In order to calculate the ICC, the average cluster size is needed. In our study, we were unable to determine the average cluster size because we lacked information regarding which nurse included each patient. This information may have been lost between the inclusion of the patients and data collection. However, we argue that the results are sufficient because we included all relevant and potential confounders during our multivariate regression analysis.

In conclusion, the ONNI is feasible in daily practice and improves the fulfilment of energy and protein requirements through more intake in undernourished patients. We speculate that the ONNI could also be used in other patient groups exhibiting a high incidence of undernutrition. Further research must be performed on optimal preoperative timing for the nutritional intervention to improve its effect on nutritional status. Research is also needed to further improve the fulfilment of nutritional requirements.

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Statement of Authorship

HN analysed the data and drafted the manuscript. BW and HV critically reviewed the manuscript. GHdW designed and performed the study, analysed the data and critically reviewed the manuscript. All authors approved the final version of the manuscript and declare no conflict of interests.

Conflict of Interest Statement and Funding sources

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Supplementary materials

Supplementary materials are available online; only material 1 is provided in this thesis.

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Supplementary material 1 – CHECKLIST for Causes of Undernutrition

Component 1 of the Outpatient Nursing Nutritional Intervention

1. **Impaired or bad appetite**

How does the patient estimate his appetite on a Visual Analogue Scale in the last week?

2. **Impaired intake**

Did the patient ate at least three mealtimes and at least three snacks a day? Yes/ No

3. **Intestinal problems**

Had the patients obstipation or bowel obstruction within the last weeks? Yes/No

4. **Insufficient physical activities**

Does the patient have physical activity during each day of at least 30 minutes? Yes/ No

5. **Pain**

How does the patient estimate pain on a Visual Analogue Scale in the last week?

6. **Impaired oral health**

Does the patient regularly perform oral care? Yes/No

How does the patient rate his oral health?

Chapter 5

Fasting habits over a 10-year period: Observational study on adherence to preoperative fasting and postoperative restoration of oral intake in two Dutch hospitals

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Abstract

Background: Since 1999, international guidelines recommend fasting from solid foods up to six hours and clear liquids up to two hours before surgery. Early recovery after surgery programs recommend restoration of oral intake as soon as possible. This study determines adherence to these guidelines up to 20 years after its introduction.
Methods: A two-centre observational study with a 10-year interval was performed in the Netherlands. In period I (2009), preoperative fasting time was observed as primary outcome. In period II (2019), preoperative fasting and postoperative restoration of oral intake were observed. Fasting times were collected using an interview-assisted questionnaire.
Results: During both periods, 311 patients were included from vascular, trauma, orthopaedic, urological, oncological, gastro-intestinal, and ear-nose-throat and maxillary surgery units.
Duration of preoperative fasting was prolonged in 290 (90.3%) patients for solid foods and in 208 (67.8%) patients for clear liquids. Median duration of preoperative fasting from solid foods and clear liquids was respectively 2.5 and 3 times the recommended six and two hours, with no improvements from one period to another. Postoperative food intake was resumed within four hours in 30.7% of the patients. Median duration of perioperative fasting was 23:46hrs (IQR 20:00–30:30hrs) for solid foods and 11:00hrs (IQR 7:53–16:00hrs) for clear liquids.
Conclusion: Old habits die hard. Despite 20 years of fasting guidelines, surgical patients are still erroneously exposed to prolonged fasting in two hospitals. Patients should be encouraged to eat and drink until six and two hours before surgery and to restart eating after surgery.

Keywords

Preoperative fasting, guidelines, surgery, fasting regimens, guideline adherence, postoperative intake

Introduction

Nutrition in the perioperative period is important for optimal metabolic response and successful recovery (1). Many perioperative programs and guidelines therefore incorporate optimisation of preoperative nutritional status. During the preoperative period, the nutritional focus in prehabilitation programmes (2-5) is to provide nutritional support for undernourished patients to meet individual nutrient requirements. Preoperative fasting from solids and liquids is mandatory to prevent gastric content causing pulmonary aspiration during anaesthesia (6-8). Sufficient preoperative fasting behaviour is defined as abstaining from solid foods for six hours and from clear liquids for two hours (8, 9). As such, in the direct preoperative phase, there is a competing interest between preventing aspiration and optimising the metabolic condition.

After surgery, oral nutritional intake should be restored as soon as possible. Enhanced recovery after surgery (ERAS) programs incorporate nutritional recommendations and ensure improved recovery with less complications, shorter hospital stay, and lower hospital costs (10). These recommendations include early restoration of oral intake (1), preferably within four hours (11).

Adherence to these perioperative recommendations is difficult for both patients and health care professionals. Studies have demonstrated that fasting periods are unnecessarily prolonged in American, German, and South African hospitals (12-14). A common reason for this delay is that healthcare professionals still prescribed to start fasting from midnight. Other barriers for adherence to the guidelines are 'low flexibility in operation room management' and 'increased risk of aspiration'(13). Culture change, poor communication and collaboration, and patient characteristics also hinder the implementation of and optimal compliance to ERAS programs (15). In practice, it may take years to successfully embed an optimal and sustainable perioperative nutritional program (15, 16).

This paper determines adherence to perioperative fasting guidelines from solid foods and clear liquids and ERAS guidelines regarding resumption of oral intake in two Dutch hospitals. Measurements were conducted twice, with a decade in between.

Methods

Data from two prospective observation periods were analysed to describe adherence to nutritional perioperative recommendations and to investigate the effect of time on adherence. We used the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement for transparent reporting (17).

Setting

Adherence to perioperative fasting guidelines was evaluated in one university hospital (site A; five surgical wards) and one university-affiliated teaching hospital (site B; three surgical wards) in the Netherlands. Patients were preoperatively informed about the upcoming surgery, including recommendations about fasting. This information was provided both in spoken form (e.g. from the nurse, surgeon, and anaesthesiologist) and in written form (e.g. leaflets). Data were collected in two separate time periods with a 10-year interval (i.e. period 1: between 2009 and 2011 and period II: between 2018 and 2019; see Figure 1).

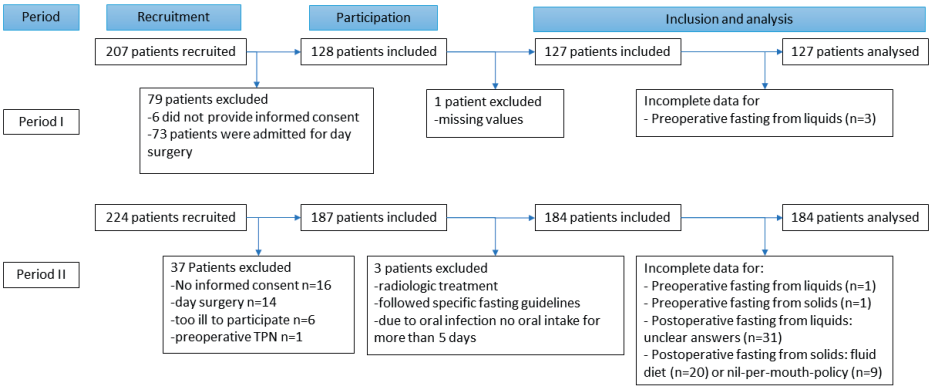

Figure 1 – Flow of patients during recruitment, participation, inclusion, and analysis during both periods

Participants

Patients undergoing surgery were invited for participation if they were at least 18 years old, able to communicate in Dutch or English, and admitted to the vascular, trauma, orthopaedic, urological, oncological, gastro-intestinal and ear-nose-throat and maxillary surgical units. Both elective and acute patients were recruited. Patients with a hospital stay of less than 24 hours were excluded. During period I at site B, only patients who were scheduled for elective surgery were included.

Variables and data sources

Primary outcomes were (1) adherence to the guidelines on preoperative fasting, (2) restoration of oral intake, and (3) total perioperative fasting time.

Adherence to preoperative fasting

Duration of preoperative fasting, adequate adherence, any delay of the scheduled starting time of the procedure, and patients' awareness of the guidelines were measured to determine adherence to the preoperative fasting guideline.

During period I, data on duration of preoperative fasting were gathered as part of evidence-based quality improvement projects in both hospitals. Data collection periods covered three consecutive weeks. During period II, data on pre-, post-, and perioperative fasting time, delay of the scheduled starting time of the procedure, and patient's awareness of the guidelines were collected in both hospitals. Data collection covered four consecutive weeks.

Duration of preoperative fasting was defined as the time interval between consumption of the last meal or drink before surgery and the introduction of anaesthesia. The time of the last consumption of solid foods and clear liquids was provided by the patients themselves, in the holding 10-30 minutes before surgery (n=72, 23%; period I Site B) or on the first day after surgery (n=239, 77%).

During the data collection in period II, the delay of the scheduled starting time of the procedure and patients' awareness of the guidelines were also measured. To determine delay in operation time, the scheduled operation time communicated with the patient was confirmed by the starting time of the procedure. Patients' awareness of the fasting guidelines was determined using a structured questionnaire (see Supplementary File 1).

Adherence to restore oral intake

Adherence to the guideline regarding restoration of oral intake was measured by the duration of postoperative fasting and was recorded during period II. Duration of postoperative fasting was estimated by the time interval between the end of the surgical procedure according to the patients' records and the patients' first consumption of solid foods and clear liquids after surgery. Abstaining four hours for solid foods (18) and two hours for clear liquids was defined as adequate for postoperative resumption of oral intake.

Perioperative fasting

Duration of perioperative fasting was defined as the time between the last consumptions before surgery and the first consumptions after surgery.

Baseline characteristics

The following patient characteristics were collected from the patients' digital records: gender, age, American Society of Anaesthesiologists Physical Status Classification

(ASA PS Classification) (19), surgical treatment, urgency of surgery (i.e. elective or acute), time of surgery (i.e. morning or afternoon), and duration of surgical procedure.

Ethical considerations

Informed consent was obtained from all patients. In period I, patients provided verbal informed consent for participation and anonymous collection of data. In period II, privacy requirements were changed. Ethical approval was obtained from the local ethics review committees of both hospitals (site A reference number W19-177 and site B reference number 1804-074). Patients in both hospital sites were eligible for participation if they provided verbal and written informed consents.

Statistical methods

Descriptive statistics were used to describe patients' characteristics and fasting times. For continuous data with a normal distribution, means were presented with their standard deviations (SDs). Medians with their interquartile ranges (IQRs; i.e. 25th and 75th percentiles) were presented when data were not normally distributed. The Kolmogorov-Smirnov test was performed to assess normality of data (20). Consecutively, summary estimates were calculated. For continuous outcome measurements with a normal distribution, mean differences (MDs) were calculated with a 95% confidence interval (95% CI). If data were not normally distributed, we used the Mann-Whitney test to analyse significant differences between study groups. For dichotomous outcome measurements, the absolute differences were determined with a 95% CI. Fasting duration was described in hours and minutes (i.e. XX:XX hrs). In our analysis, eight hours for solid foods and three hours for clear liquids were defined as adequate adherence to preoperative fasting guidelines. This is longer than the recommended six hours and two hours to correct for possible measurement errors. We also opted for this because ensuring exactly six hours and two hours may not be feasible due to clinical activities in daily practice. Adherence was reported as numbers and percentages and was categorised into adequate (i.e. category A) or inadequate fasting times (i.e. categories B, C, and D). All analyses were performed using IBM SPSS v. 25.0 (IBM Corp, Armonk, NY).

Results

Participants

A total of 410 patients were recruited from both hospitals in both time periods. Of these patients, 99 were excluded, mostly because of an expected hospital stay less

than 24 hours (*n* = 87; 21%) or no informed consent (*n* = 6; 1.5%) (see Figure 1). Of the remaining 311 patients, 127 (40.9%) underwent surgery in period I, while 184 (59.1%) underwent surgery in period II. The total sample had a mean age of 58 years (*SD* 18), and 161 (51.9%) patients were female. Most patients underwent gastro-intestinal (*n* = 72; 23.2%) or orthopaedic surgery (*n* = 60; 19.3%) (see table 1). Patients included during period II were 7.2 years older than patients in period I (95% CI; 3–11 yrs.). Furthermore, the duration of surgical procedures increased, with 1:22 hrs between both periods (95% CI; 1:06–1:38 hrs) (see table 1). Delay of operation time, as observed during period II, occurred in 41 cases (22%).

Table 1 – Patient characteristics

	Total N=311	Period I n=127	Period II n=184
Female [a]	161 (51.9)	67 (53.2)	94 (51.1)
Age [b]	58 (18)	54 (20)	61 (17)**
Urgency of surgery [a]	258 (83.2)	119 (94.4)	139 (75.5)*
Elective	52 (16.8)	7 (5.6)	45 (24.5)
Emergency			
Surgical treatment [a,@]	41 (13.2)	8 (6.3)	33 (17.9)
Vascular	34 (10.9)	6 (4.7)	28 (15.2)
Trauma	21 (6.8)	8 (6.3)	13 (7.1)
Gynaecologic	20 (6.4)		20 (10.9)
Oncologic	72 (23.2)	29 (22.8)	43 (23.4)
Gastroenterology	60 (19.3)	34 (26.8)	26 (14.1)
Orthopaedic	16 (5.1)	12 (9.4)	4 (2.2)
ENT & Maxillary	31 (10.0)	16 (12.6)	15 (8.2)
Urology	16 (5.1)	14 (11.0)	2 (1.1)
Plastic surgery			
ASA PS Classification [a,#]	60 (24.0)	29 (42.6)	31 (17.0)
ASA 1	110 (44.0)	32 (47.1)	78 (42.9)
ASA 2	69 (27.6)	7 (10.3)	62 (34.1)
ASA 3	11 (4.4)	-	11 (6.0)
ASA 4			
Duration of surgical procedure (min)[b]	117 (95)	57 (28)	139 (101)**

a: results are expressed as numbers of patients per group (percentages);

b: results are expressed as means ± SD.

[@]= some patients underwent surgical treatment for more than 1 option;

ENT= Ear-Nose-Throat

[#]= data was not gathered in hospital A during period I

*=p-value <0.05; **=p-value <0.001

Adherence to preoperative fasting

Fasting from solid foods

Duration of fasting from solid foods was prolonged in 280 (90.3%) patients. The median duration for fasting from solid foods was 15:19 hrs (IQR 13:00–18:19 hrs), which is about 2.5 times longer than the recommended six hours (see table 2). As noted in Figure 2, one out of four patients fasted for more than 18 hours (category D; *n* = 81, 26.1%).

Table 2 - Time of preoperative fasting from clear liquids and solid foods

	Fasting from clear liquids				Fasting from solid foods			
	N	IQR$			N	IQR$		
		25th	Median	75th		25th	Median	75th
Study population@	307	2:25	05:15	11:26	310	13:00	15:19	18:19
Period I	124	2:10	05:00*	11:30	127	13:15	16:00**	18:20
Urgency of surgery								
Elective	116	2:10	4:23	10:55	119	13:15	15:75	18:20
Emergency	7	3:00	11:45	16:00	7	11:45	16:00	16:45
Time of surgery#								
Morning	41	1:50	3:10	10:08	42	15:19	16:00	18:32
Afternoon	29	1:53	2:40	4:45	30	6:24	16:33	19:23
Period II	183	2:29	05:23*	11:21	183	12:50	14:51**	18:18
Urgency of surgery								
Elective	138	2:07	05:25	10:40	138	12:45	14:30	16:58
Emergency	45	3:18	05:07	13:41	45	13:10	16:39	29:23
Time of surgery								
Morning	97	2:09	07:12	11:29	97	12:54	14:25	16:30
Afternoon	74	2:52	05:06	10:40	74	13:05	16:19	19:00
Evening-night	11	3:55	04:56	08:31	11	11:50	13:56	18:18
Start of surgery								
8.00-9.00 AM	61	1:59	3:25***	10:26	61	12:37	13:55****	14:33
9.00-8.00 AM	123	3:16	5:35	12:00	122	13:02	16:04	18:59

IQR=Interquartile range; $=HH:MM are hours and minutes; #= data of one hospital (B) was available; @=data of 4 patients were missing for fasting from clear liquids and of 1 patient for fasting from solid foods; *=Mann-Whitney test: p=0.741; **=Mann-Whitney test: p=0.410; ***= Mann-Whitney test: p=0.046; ****= Mann-Whitney test: p>0.000

Period I versus period II

No improvement was observed in adequate adherence for period II compared to period I (period I *n* = 18 out of 127, 14.2%; period II *n* = 12 out of 183, 6.5%). Moreover, adequate adherence to fasting from solid foods was 7.6% lower in period II (95% CI 6.9–8.3%) (see Figure 2). Median duration of fasting from solid foods was 16:00 hrs (IQR 13:15–18:20 hrs) during period I and 14:51 hrs (IQR 12:50–18:18

hrs) during period II. This difference was not statistically significant based on the Mann-Whitney test (p = 0.41).

During period II, it was found that patients who were scheduled between 8.00-9.00AM fasted significantly shorter compared to patients who underwent surgery after 9.00AM (table 2). No significant differences were found between morning, afternoon or evening/night surgery.

Fasting from clear liquids

Duration of fasting from clear liquids was prolonged in 208 (67.8%) patients and was adequate in 99 (32.2%) patients. The median duration for preoperative fasting from clear liquids was 5:15 hrs (95% CI 4:30–6:17 hrs; IQR 2:25–11:26 hrs), which is about 2.5 times longer than the recommended two hours (see table 2). One out of five patients from both periods (n = 64, 20.8%) fasted longer than 12 hours from clear liquids (see figure 2). Detailed fasting times and adherence per surgical specialty are illustrated in supplementary file 2.

Period I versus period II

Adequate fasting from clear liquids did not improve from period I (n = 45, 36.3%) to period II (n = 55, 30.1%), with difference at 6.2% (95% CI -4.5–16.9%). Median of fasting time from liquids was 5:00 hrs (IQR 2:10–11:30 hrs) in period I and 5:23 hrs (IQR 2:29–11:21 hrs) in period II. This difference was not statistically different based on the Mann-Whitney test (p = 0.74).

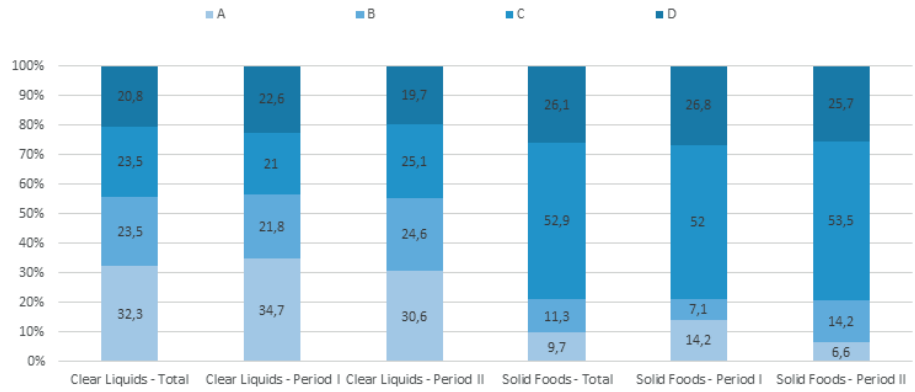

Figure 2 – Adherence to preoperative fasting from clear liquids and solid foods per period

Duration of fasting from clear liquids: A= <3hrs; B = 3-6hrs; C = 6-12hrs ; D = >12hrs. Duration of fasting from solid foods: A = <8hrs; B = 8-12hrs; C = 12-18hrs; D= >18hrs. A indicate adequate duration of fasting; B, C and D indicate inadequate duration of fasting.

Guideline awareness

Data were available from 153 (83%) patients about their awareness of the fasting guidelines. Many of them (*n* = 131; 86%) stated to had been informed about the fasting guidelines by nurses, surgeons, anaesthesiologists, or all of them. Only 44 (29%) patients were aware of the six hours of fasting from solids, and 51 (33%) patients were aware of the two hours of fasting from clear liquids. About half of the patients thought that they had to fast from solids (*n* = 82; 54%) and liquids (*n* = 70; 40%) from midnight onward.

Duration to restore oral intake and perioperative fasting

Time to restore oral intake was observed among 184 patients during period II (see figure 1). Some patients were excluded because 31 (16.8%) patients provided unclear answers regarding exact time, 20 (10.9%) patients were on a prescribed liquid diet after surgery, of whom 17 had undergone oncological or gastroenterological surgery, and nine (4.9%) patients had a nil-per-mouth policy during their postoperative course.

Table 3 –Duration of postoperative and perioperative fasting during period II

	Duration of postoperative fasting#				Duration of perioperative fasting #			
	N	25th	Median	75th	N	25th	Median	75th
Fasting from clear fluids	144	01:38	02:56	04:13	135	07:53	11:00	16:00
Urgency of surgery								
Elective	111	01:36	03:03	04:27	104	08:16	11:48	15:30
Emergency	33	02:02	02:30	03:58	31	07:00	10:00	16:30
Time of surgery								
Morning	80	01:51	03:13	03:57	73	07:30	12:15	17:38
Afternoon	57	01:15	02:29	03:58	56	07:52	10:30	14:00
Evening-night	6	02:45	03:35	06:55	5	09:49	11:00	15:25
Fasting from solid foods	153	03:32	05:35	14:53	146	20:00	23:46	30:30
Urgency of surgery								
Elective	117	03:42	05:46	15:35	113	17:11	23:30	34:00
Emergency	36	03:17	04:53	12:23	33	14:36	24:00	29:15
Time of surgery								
Morning	83	04:06	06:15	17:14	78	20:09	23:30	31:00
Afternoon	62	03:20	08:39	11:58	61	20:27	24:00	30:30
Evening-night	7	03:02	09:35	12:49	6	17:17	21:03	27:38

#=25th, median, and 75th percentiles are presented in hours and minutes.

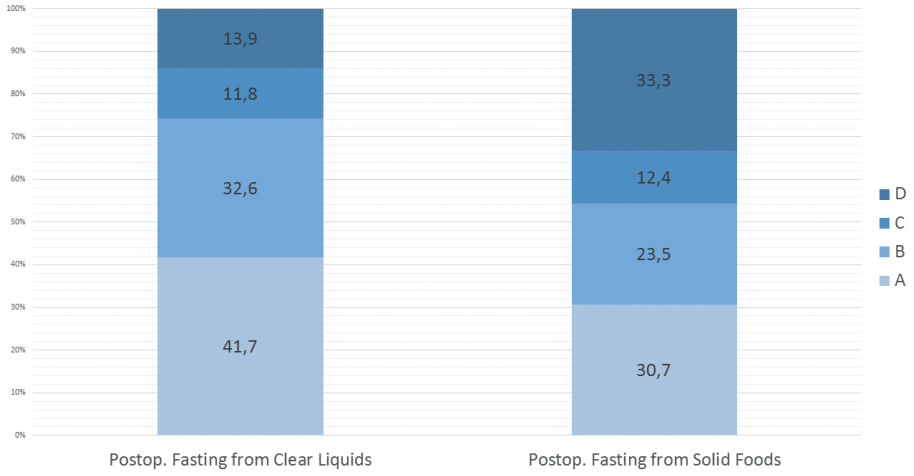

Figure 3 – Duration of postoperative fasting form clear liquids and solids foods

Duration of postoperative fasting for clear liquids: A= <2hrs; B = 2-4hrs; C = 4-6hrs ; D = >6hrs. Duration of postoperative fasting for solid foods: A = <4hrs; B = 4-6hrs; C = 6-8hrs; D= >8hrs.

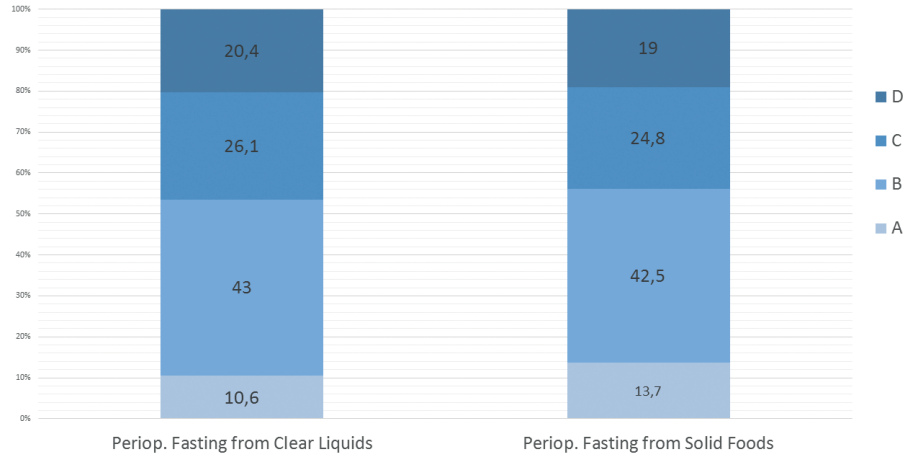

Figure 4 – Duration of perioperative fasting from clear liquids and solids foods

Duration of perioperative fasting for clear liquids: A= <6hrs; B = 6-12hrs; C = 12-18hrs ; D = >18hrs. Duration of perioperative fasting for solid foods: A = <18hrs; B = 18-24hrs; C = 24-36hrs; D= >36hrs.

Food intake

Time to restore food intake was adequate in 46 patients (30.7%). It took at least eight hours to resume intake of solid foods in 51 patients (33.3%) (see Figure 3). The median time to resume food intake was 5:35 hrs (IQR 03:32–14:53 hrs) (see Table 3). Median time to restore food intake was three times longer in patients undergoing oncologic or gastroenterological surgery compared to other surgical specialties (see Supplementary File 2). The median duration of perioperative fasting from solid foods was 23:46 hrs (IQR 20:00–30:30 hrs) (see table 3). Almost half of the patients (*n* = 67, 43.8%) abstained from food for more than 24 hours. Perioperative fasting was less than 18 hours in 21 patients (13.7%) (see figure 4).

Fluid intake

Time to restore fluid intake was adequate in 60 patients (41.7%) (see figure 3). One hundred twenty-four patients (86.1%) had a drink within six hours after surgery. Median time to restore fluid intake was 2:56 hrs (IQR 1:38–4:13 hrs) (see table 3). For perioperative fasting from clear liquids, the median duration was 11:00 hrs (IQR 7:53–16:00 hrs). A small majority (*n* = 76; 53.6%) abstained from clear liquids for less than 12 hours (see figure 4).

Discussion

Despite the 20-year existence of registered preoperative fasting guidelines, our results demonstrate prolonged preoperative fasting times in an academic and a general Dutch hospital. Current adherence to preoperative fasting recommendations for solid foods appeared to be even suboptimal compared to the period 10 years ago. Duration of preoperative fasting was 2.5 times longer than the recommended six hours for solid foods and three times longer the recommended two hours for clear liquids. Fasting behaviour was severely inadequate (i.e., more than 18 hours from solid foods or 12 hours from clear liquids) in each fourth or fifth patient, respectively. Notably, half of the patients stopped eating and drinking before midnight. Median duration of the time of preoperative fasting and the time to resume intake after surgery was almost 24 hours.

Prolonged fasting can be caused by several factors. First, the opportunity to have breakfast is hindered by early morning scheduled surgery because that is within six hours before surgery). However, drinking is allowed up to two hours before surgery, yet such is still not common practice. Secondly, surgeries scheduled in the afternoon did, unexpectedly, not lead to shortened duration of fasting as our findings illustrate. Low awareness among preoperative patients regarding correct fasting guidelines despite being informed beforehand is another factor since half of the patients in our

study thought they had to stop eating and drinking before midnight (21). Although our study did not evaluate the way instructions were provided, an increased awareness of correct preoperative fasting is needed for both patients and health care providers. Another factor may be operation schedules with delayed or undetermined starting times (13, 22, 23). The most important factor from our study appears to be that patients are still instructed to fast from midnight. The European Society of Anaesthesiology (ESA) guidelines explicitly suggest that patients should be encouraged to keep drinking until two hours before surgery (6). This study clearly demonstrated that this recommendation is not well implemented in clinical practice. This gap between the official guidelines and clinical practice seems difficult to overcome, which has been demonstrated before, (24, 25). The above factors affirm that patients erroneously stop eating and drinking too soon, and this can be addressed through further research and implementation of the guideline.

Prolonged fasting can have physical and emotional consequences (26). Physical consequences include increased thirst and hunger and metabolic impairment (26-28). The metabolic effect of prolonged fasting is decreased insulin sensitivity (29), which is associated with increased risk of major postoperative complications, such as mortality and infection (30). Furthermore, prolonged fasting may be associated with cardiac stress and hypothermia (31). Emotional consequences include patients' feeling loss of control as they are not allowed to have food or drinks. Patients are aware that they have to fast, but they sometimes do not understand what fasting or nil-per-mouth means and why it is recommended (26). Health care professionals may consider fasting as an easy task; however, when patients have to be encouraged to consume nutritional products until a certain time point, as the guidelines explicitly recommend, fasting may be more complex (32). Therefore, it may be wise to shift health care professionals' discourse from instructing patients what not to do (i.e. eating and drinking), to educating them about prevention strategies they can use to avoid unnecessarily long fasting times (e.g. they should eat and drink as long as allowed) to reduce the risk of postoperative complications. To reduce the time of postoperative fasting, postoperative intake should be stimulated as soon as possible. Several interventions may help, such as providing room service or improving meal conditions (33, 34).

Our findings have clinical implications for surgeons, anaesthesiologists, nurses, and dieticians. There is a growing body of evidence suggesting that preoperative consumption of carbohydrate beverages is safe (35), reduces postoperative insulin resistance (35-37), positively influences well-being (e.g. malaise thirst, hunger, and weakness (38), nausea and vomiting (39), and shortens length of hospital stay up to one day (36, 40, 41). Moreover, preoperative consumption of carbohydrate beverages

has been used in several fields of surgery. Therefore, patients' instructions should not only emphasise when they should stop eating and drinking but also should encourage them to keep eating and drinking until six hours and two hours, respectively, before surgery (6). This approach has been studied and has shown decreased fasting duration and decreased sensation of thirst (42, 43).

To prevent another decade passing without any improvement in guideline adherence, health care professionals, researchers, and staff members should change the fasting paradigm into planned eating and drinking before and after surgical procedures. Nurses and other health care workers should adjust their behaviour and encourage patients to eat and drink as long as possible, within the limits of the applicable guidelines (6). Although evidence shows that preoperative consumption of oral carbohydrate beverages is safe (35) and ERAS protocols include eating recommendations (44), suggestions for translating this knowledge to daily practice are lacking (24). Knowledge translation may be difficult in this case because patients are primarily instructed to eat sufficiently within prehabilitation programs (2-5). This is complemented by fasting instructions during the direct preoperative period. Implementing concrete instructions about what and when to eat and then to do not eat and drink may be complex for both patients and health care professionals. After surgery, patients have to continue eating while sleepy from narcosis, in pain, or feeling nauseous. Behavioural change techniques or knowledge translation models are needed to achieve optimal fasting regimens in surgical patients (24, 45, 46). Future studies on perioperative eating and drinking should focus on awareness and translation of knowledge into daily practice. Furthermore, in these future studies can incorporate lessons learned from other studies about how to de-implement old habits (47, 48).

This study has some limitations. Estimation of the duration of fasting may have been imprecise. First, time intervals of eating and drinking were estimated by the patients themselves, and these estimations may be imprecise. Notably, routine preoperative assessments of the duration of fasting before surgery are usually based on the patients' responses as well; therefore, we argue that our findings are still valid. Moreover, the duration of the surgical procedure (e.g. start and end time) recorded in the patients' records may not be accurate. These errors may occur on both sides of the true interval, so we believe our conclusions are still valid.

A second limitation concerns the consumption of popsicles during the patients' stay at the Post Anaesthesia Care Unit (PACU) (49). During the direct postoperative period in the PACU, popsicles may be provided to some patients during both study periods. Unfortunately, these consumptions were not recorded because the patients did not remember it, as it happened shortly after narcosis. As such, the actual time of abstinence from fluids may be shorter than our results suggest for patients who

consumed ice pops at the PACU. However, these popsicles contain a limited amount of fluid that hardly contributes to postoperative metabolic recovery and therefore have not been taken into account.

A third concern include the fact that we used data from two Dutch hospitals from two study periods. Procedures of data collection within these periods may lack consistency, for instance, patients were asked about the time of the last meal during the first day after surgery (period I, sites A, and period II, both sites) or preoperatively at the holding (period I, site B). Hospital routines may have also changed. Moreover, patients included in period II were older, and the duration of the surgery they underwent was longer compared to period I. Nevertheless, this should not influence preoperative fasting times. Undergoing major surgery can increase post-surgical symptoms, which may hinder nutritional intake (e.g. lack of appetite, nausea, full stomach, food tastes differently, difficulty chewing or swallowing). However, we were not able to determine whether this explains the postoperative fasting times or not because we did not observe postoperative fasting in period I.

Finally, our findings are funded on data from samples of an academic and general hospital taken during the years 2009 and 2019. We have several arguments for that our findings are representative and relevant. First of all, prolonged preoperative fasting was a consistent finding over both the years with a decade in between. Secondly, a search through the websites of 25 larger (i.e. at least 600 beds) Dutch hospitals showed that hospitals commonly advise to fast from solid food and fluids for six and two hours, respectively, before admission time, including on the website of one of the hospitals that participated in our study. Thirdly, prolonged fasting was found in other countries with comparable sample sizes such as Iceland (21), Turkey (31, 50), Brazil (51, 52), South Africa (14), and Oman (53), including low awareness of hospital staff in Germany (13) and Egypt (54). Therefore, despite representing only two settings, we are convinced that our findings are relevant and indicate throughout revision of current fasting guidelines and practices.

In conclusion, patients stop eating and drinking too soon before surgery in two Dutch hospitals, despite the introduction of the per-operative nutritional guidelines 20 years ago. Duration of fasting from solid foods and clear liquids is, respectively, 2.5 and 3 times longer than the recommended six and two hours. Recommendations to keep eating until six hours and drinking until two hours before surgery are not applied in daily practice. Taking the total perioperative course into account, almost half of the patients abstain at least 24 hours from solid foods and at least 12 hours from clear liquids. For this reason, it is urgent that all health care professionals ensure that their patients understand that they can eat up to six hours and drink up to two hours before surgery and restart nutrition postoperatively according to the ERAS protocol.

Conflict of interest/Disclosure

The authors have no conflict of interests to declare.

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Supplementary materials

Supplementary materials are available online; only supplementary file 2 is presented in this thesis. https://www.sciencedirect.com/science/article/pii/S0039606021000751?via%3Dihub#appsec1

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Supplementary file –Perioperative fasting times, time of surgical procedures and adherence per surgical specialty

Table 4 – Preoperative, postoperative and perioperative fasting times and time of surgical procedures

	Preoperative fasting							Time of surgical procedure		
	Clear Liquids			Solid foods				Clear Liquids		
Surgical specialty	N (%) *	25th IQR	median	75th IQR	25th IQR	median	75th IQR	25th IQR	median	75th IQR
Vascular	41 (13)	4:33	7:30	13:24	12:25	14:49	16:41	1:01	1:36	2:39
Trauma	34 (11)	3:30	8:30	12:28	12:25	16:00	18:53	0:38	1:04	1:21
Gynaecologic	20 (6)	3:20	8:58	10:32	9:42	11:44	14:32	0:45	1:02	1:48
Oncologic	20 (6)	2:42	4:34	9:55	12:54	14:36	24:24	1:04	2:26	4:48
Gastroenterology	72 (23)	2:23	5:03	9:59	11:47	14:56	18:13	1:00	1:30	4:03
Orthopaedic	60 (19)	1:55	4:17	7:30	12:56	15:14	18:17	0:59	1:30	2:19
ENT & Maxillary	16 (5)	0:54	5:44	10:36	12:26	14:21	16:18	0:20	1:30	2:42
Urology	31 (10)	1:05	1:48	10:04	13:53	15:35	16:48	0:33	1:26	3:14
Plastic surgery	16 (5)	6:48	9:25	-	13:30	14:24	-	1:00	1:30	1:30
Total	311	2:25	05:15	11:26	13:00	15:19	18:19	0:52	1:30	2:32

ENT= Ear-Nose-Throat; *= some patients underwent surgical treatment for more than 1 option IQR=Interquartile range; $=HH:MM are hours and

Table 5 – Adequate and inadequate adherence to fasting from en resumption of oral intake per surgical specialty

	Preoperative fasting								
	Clear Liquids				Solid foods				
Surgical specialty	N (%) *	A	B	C	D	A	B	C	D
Vascular	41 (13)	8	9	8	16	6	3	25	7
Trauma	34 (11)	2	12	7	13	2	5	17	10
Gynaecologic	20 (6)	8	5	8	0	2	6	7	5
Oncologic	20 (6)	8	5	4	3	2	2	8	8
Gastroenterology	72 (23)	30	16	14	11	7	9	34	22
Orthopaedic	60 (19)	23	14	12	9	4	5	34	17
ENT & Maxillary	16 (5)	8	2	3	2	2	1	9	4
Urology	31 (10)	10	5	6	10	1	3	21	6
Plastic surgery	16 (5)	3	2	8	3	4	1	9	2
Total	311	100	70	70	67	30	35	164	81

ENT= Ear-Nose-Throat; *= some patients underwent surgical treatment for more than 1 option;

Preoperative fasting

- clear liquids: A= <3hrs; B = 3-6hrs; C = 6-12hrs ; D = >12hrs.
- solid foods: A = <8hrs; B = 8-12hrs; C = 12-18hrs; D= >18hrs.

Postoperative fasting

- clear liquids: A= <2hrs; B = 2-4hrs; C = 4-6hrs ; D = >6hrs.
- solid foods: A = <4hrs; B = 4-6hrs; C = 6-8hrs; D= >8hrs.

Perioperative fasting

- clear liquids: A= <6hrs; B = 6-12hrs; C = 12-18hrs ; D = >18hrs.
- solid foods: A = <18hrs; B = 18-24hrs; C = 24-36hrs; D= >36hrs.

A indicate adequate duration of fasting; B, C and D indicate inadequate duration of fasting.

Postoperative resumption						Total time of absence of oral intake					
Solid foods			Clear Liquids			Solid foods					
25th IQR	median	75th IQR	25th IQR	median	75th IQR	25th IQR	median	75th IQR	25th IQR	median	75th IQR
1:08	2:20	4:58	2:23	4:10	6:14	9:08	11:07	19:55	18:11	21:00	23:51
1:32	2:29	3:14	2:50	4:25	5:41	7:39	12:15	17:00	18:30	21:30	26:25
2:18	2:55	3:35	3:16	4:43	12:29	7:57	12:00	14:30	16:14	20:12	24:23
1:53	3:27	4:21	4:15	12:40	22:53	8:20	10:00	20:15	19:32	39:00	44:30
1:27	3:38	6:19	4:52	14:02	19:01	9:02	13:15	17:22	22:45	30:15	37:45
1:08	2:32	3:47	3:11	4:34	8:37	6:38	10:30	15:45	20:15	24:00	26:15
2:20	4:08	6:10	4:47	5:48	14:44	8:12	13:30	18:49	22:07	23:22	33:04
1:48	3:30	4:36	3:56	4:50	7:20	5:30	10:00	17:46	21:00	24:30	29:30
3:02	3:50	-	3:17	4:57	-	11:00	15:23	-	19:45	21:30	-
01:38	02:56	04:13	03:32	05:35	14:53	07:53	11:00	16:00	20:00	23:46	30:30

minutes.

		Postoperative resumption							Total time of abcense of oral intake								
n	n	Clear Liquids			Solid foods				Clear Liquids					Solid foods			
food	liquids	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
25	21	11	4	3	3	10	6	3	6	1	10	4	6	5	12	5	3
21	21	10	9	1	1	8	8	3	2	1	9	7	4	5	8	7	1
9	9	1	8	-	-	3	3	1	2	1	4	4	-	3	5	2	-
18	15	5	6	2	2	2	3	2	11	1	8	2	4	2	5	1	9
33	32	13	6	4	9	5	5	3	20	2	12	11	6	2	9	12	10
26	25	14	6	3	2	13	4	3	6	5	11	4	4	3	16	4	3
4	4	1	1	1	1	-	2	1	1	-	2	1	1	-	2	2	-
15	15	5	5	3	2	5	5	2	3	4	4	4	3	1	6	5	3
2	2	-	2	-	-	1	-	1	-	-	1	-	1	-	2	-	-
153	144	60	47	17	20	47	36	19	51	15	61	37	29	21	65	38	29

Chapter 6

Patient education regarding fasting recommendations to shorten fasting times in patients undergoing esophago-gastro-duodenoscopy (EGD): a controlled pilot study

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Abstract

This study evaluated the applicability and efficacy of patient education regarding fasting recommendations to shorten fasting times in patients undergoing esophagogastroduodenoscopy (EGD). A prospective nonrandomized controlled pilot study was performed. The intervention group (IG) was educated by nurses to eat until 6 hours and drink until 2 hours before EGD. The control group (CG) received usual care. Outcomes were applicability as perceived by patients, adherence to fasting recommendations, gastric visibility, and patients' comfort. A total of 109 patients were included of whom 42 were IG patients (37%). Patients' perspectives on fasting, their experienced discomfort, professional support, and circadian rhythm influenced application of fasting recommendations. Adherence to length of fasting from foods improved with 3:14 hours ($p < .001$) and from liquids with 5:22 hours ($p < .001$) in the IG compared with the CG. Gastric visibility during EGD was better in the IG than in the CG. The IG patients experienced significant less thirst, hunger, headache, and anxiety. To successfully reduce fasting times, fasting education should include positive, individual instructions, which help patients apply the fasting recommendations within their biorhythm. Positive, concrete instructions by nurses shortened fasting times before EGD, which improved gastric visibility and reduced patient discomfort

Keywords: Education, Fasting, Esophagogastroduodenoscopy, Adults, Guidelines.

Introduction

Prolonged fasting times appear to be common practice and lead to discomfort in patients. Preprocedural fasting is required for esophago-gastro-duodenoscopy (EGD) and surgery to reduce the risk of aspiration (1-3). The ASA guidelines state that patients should fast at least 2 hours after ingestions of clear liquids and 6 hours after ingestion of light meals before sedation is administered. Recommendations are sometimes poorly implemented, which result in prolonged fasting (4-6). Numerous studies report median preoperative fasting times from solid foods ranging from 12 to 16 hours, and from clear liquids from 5 to 15 hours (7-17).

Prolonged fasting decreases insulin sensitivity (18) and increases discomfort including thirst, hunger, and headache (10, 19). Fasting before EGD reduces the risk of aspiration during insertion of the scope or administration of anesthetics (1, 3, 6). An empty stomach as a result of fasting facilitates a clear view on the upper gastrointestinal mucosa. In an EGD the upper gastrointestinal (GI) mucosa should be free from debris and gastric residue to optimize the diagnostic yield and the treatment of benign and malignant conditions. Successful patient preparation for EGD requires the patient's thorough understanding of pre-procedural fasting instructions. Previous studies demonstrated how patient-centered instructions contribute to shortened fasting times before surgery (20-23). Patient compliance was improved by saying "drink up to" instead of "allowed to drink" (22). Available brochures and educational materials should be carefully reviewed with the patient and/or family to ensure adequate preparation (24-26). In this study, we studied the applicability and efficacy of patient education on fasting recommendations among patients undergoing EGD to shorten fasting times.

Methods

Study design

A prospective, nonrandomized, controlled pilot study was performed at the outpatient clinic of a general hospital in The Netherlands. Data were collected between November 2019 and July 2020. The study examined adherence to fasting recommendations. We educated an intervention group (IG) with concrete, evidence-based fasting instructions and used Strengthening the Reporting of Observational studies in Epidemiology statement for transparent reporting (27).

Study population

The patients undergoing an EGD procedure were informed about the study by telephone. Further information was provided via a letter or email if interested. The patients were considered eligible when they were at least 18 years old, on a regular diet, and understood the Dutch language. The patients were excluded when they had undergone bariatric surgery, had diabetes mellitus, had a proven gastroparesis, or had no swallow reflex. The patients provided written and verbal informed consent at the hospital site in a quiet and private room. This study was approved by the Medical Ethical Committee of Wageningen University, Wageningen, The Netherlands, (CMO number 20/09). This study was conducted in accordance with the Declaration of Helsinki (28).

Sample size calculation

We calculated the required number of patients for the IG based on findings in the control group (CG). The aim was to achieve a decrease in mean fasting time of at least 3 hours. Previous educational approaches decreased fasting time with 1.5-8.2 hours (21, 22) for liquids and 7.9 hours for solids (21). Using $\alpha = .05$ and $\beta = .9$ in the equation for continuous variables (29), 35 patients should be included. To account for possible dropouts, we aimed to include at least 40 patients in the IG.

Fasting instructions

Intervention group

Within the routines to prepare for EGD, we introduced concrete, evidence-based fasting instructions. Education included the why, how, and what of the recommendations. Specifically, 'to fast from solids and liquids for 6 and 2 hours' and 'to eat and drink as long as possible'. The focus of the instructions was changed to a positive, stimulating approach (20-22). Nurses informed patients about the rationale of preprocedural fasting, the consequences of prolonged fasting, and the benefits of eating and drinking as long as possible. The patients received a timetable that contained the date and time of the EGD and the times that patients could consume their last meal and drink. Consumption suggestions were given including meals and drinks that fitted within the Dutch eating habits like two slices of bread with a topping of cheese, a slice of chicken filet, or jam; or low-fat yoghurt with muesli. The drinks included 200ml of apple juice, lemonade, or tea. Patients received all information in a leaflet and an infographic.

Control group (CG)

Routine care for patients undergoing EGD included information about the planned EGD via telephone and an information leaflet. This leaflet included instructions to fast for 6 hours from solid foods and 2 hours from clear liquids together with information about the procedure. The patients who were scheduled for an EGD in the morning were instructed to fast from midnight. The patients were allowed to have a light breakfast (i.e., sandwich or cracker) and a cup of tea before 9 a.m. if the EGD was scheduled in the afternoon. No instructions on type of meals and drinks were given.

Data collection

Data were collected on patient characteristics, that is, gender, age, American Society of Anesthesiologists Physical Status Classification (ASA PS Classification) (30), history of gastric problems, indication for EGD, and length of the procedure.

Outcomes of interest were applicability of the instructions as perceived by IG patients (31), and efficacy of the education on adherence to fasting recommendations, gastric visibility, and patients' comfort.

Applicability

Applicability was measured with patients' satisfaction with preprocedural care and patients' perceptions towards the applicability of the instructions.

Satisfaction

The Consumer Quality Index (CQ-Index) (32) was adapted for our setting to determine the satisfaction of patients from both groups (see Supplemental Digital Content Appendix, available at: http://links.lww.com/GNJ/A78). The patients were requested to complete the questionnaire within 6 hours after the EGD, either in the outpatient clinic or at home. Patients who did not return the questionnaire were reminded by telephone.

Patients' perceptions

Perceptions of IG patients towards the applicability of the instructions were investigated in a structured face-to-face interview 15 minutes before the EGD (see Supplemental Digital Content Appendix, available at: http://links.lww.com/GNJ/A79). Using open ended questions, we investigated how patients perceived the instructions, and how they experienced it to apply them. Barriers and facilitators for adherence to the fasting recommendations were identified.

Efficacy

Adherence to fasting instructions

Adherence to the fasting instructions was determined by (1) the duration of fasting, (2) adequate fasting behavior, and (3) the type of last meal and drink. Duration of fasting was the time interval between the last meal or drink and start of the EGD. The times of these consumptions were based on the patients' recall within 15 minutes before the EGD. In this study, adequate fasting behavior was defined as a maximum fasting time of 8 hours for solid foods and 4 hours for clear liquids. This longer period was chosen to be able to correct for possible measurement errors, and to take clinical activities into account. In both groups, type of last meal and drink were chosen by the patients themselves. Last meals included sandwiches, yoghurt, fruit, and warm meals; last drinks included lemonade, apple juice, water, tea, and coffee.

Gastric visibility

Gastric visibility was assessed by endoscopic flush volume, gastric residual volume, the Mucosal Visibility Score (MVS), and judge ability of the mucosa. Flush volume was recorded to estimate the gastric residual volume (total suctioned volume subtracted by flush volume).

MVS measures mucosal visibility in the lower esophagus, upper body greater curve, antrum, and fundus (33, 34). After the procedure, the endoscopist rated the visibility of each area on a 4-level scale based on pictures of each area made during introduction of the scope before flushing: 1) No adherent mucus and clear view of the mucosa; 2) A thin coating of mucus that did not obscure view of the mucosa; 3) Some mucus/bubbles partially obscuring view of the mucosa (a small mucosal lesion might be missed without flushing); 4) Heavy mucus/bubbles obscuring view of the mucosa (a small mucosal lesion could easily be missed without flushing). The MVS resulted in a total score (TMVS) between 4 and 16. The MVS has been used in other studies (33-37), and reliability of the TMVS was previously determined with Spearman's ρ (ρ =0.79–0.83) (33) and the weighted κ (0.901) (36).

Judge ability was defined as the extent to which the endoscopist was able to assess the mucosa. Judge ability of each area was rated by the endoscopist on a Numeric Rating Scale (NRS) from zero (indicating worst judge ability) to ten (indicating perfect judge ability).

Patients' comfort

The presence of symptoms of prolonged fasting, including nausea, vomiting, thirst, hunger, anxiety, weakness, and headache, was assessed (37-42). The patients

scored these symptoms on a 4-point Likert scale 15 minutes before the procedure. They could also add other complaints or experiences.

Data analysis

Descriptive analysis were used for patients' characteristics and outcomes. Numbers and percentages are presented for nominal and ordinal variables. Means and standard deviations or medians with interquartile ranges are presented for continuous variables depending on normality. Differences in outcomes between study groups were evaluated using the Pearson's $\chi 2$ test, the Mann- Whitney U test, and the independent t test for nominal, ordinal, and continuous variables, respectively.

The patients' perceptions towards the instructions were analyzed using the conventional content analysis approach including open coding, categorizing, and synthesizing by defining themes (43). Open answers were first coded and afterwards discussed by two researchers. Then, codes were clustered during discussions to define categories. Themes were consequently defined based on the synthesis of the codes and categories. In each step, consensus was obtained during the discussions.

Study results were analyzed on an intention-to-treat basis. Missing values were not inputed because of the explorative character of the study. A p-value less than 0.05 was considered significant based on two-sided tests. Statistical analyses were carried out with IBM SPSS, version 25.0 (IBM Corp, Armonk, NY).

Results

Study sample

Of 130 invited patients, 18 patients (14%) were excluded: no informed consent (n=7, 5.4%), a history of gastric surgery (n=5, 3.8%), a colonoscopy (with oral bowel preparation) during the same procedure (n=4, 3.1%), or not understanding the Dutch language (n=2, 1.5%). Data of 3 patients (2.3%) were incomplete. Finally, 109 patients (84%) participated in the study, of whom 42 patients (37%) in the IG (Figure 1). The groups were comparable in terms of age and gender distribution (Table 1). Most of the EGD procedures were performed during morning sessions (n=91, 84%).

Table 1 – Patients' characteristics

	Control group (CG) (n=67)	Intervention group (IG) (n=42)
Female	42 (63)	19 (45)
Age (years)	59.6 ± 15.3	58.7 ± 18.6
ASA PS Classification [1]		
I	13 (20)	6 (15)
II	48 (73)	32 (78)
III	5 (7)	3 (7)
Session		
Morning	59 (87)	33 (79)
Afternoon	9 (13)	9 (21)
Indication for endoscopy		
Dysphagia	23 (34)	14 (33)
Nausea	12 (18)	3 (7)
Reflux or pyrosis	13 (19)	9 (21)
Dyspepsia	29 (43)	11 (26)
Follow-up endoscopy	9 (13)	3 (7)
Other	13 (19)	12 (29)
Duration of endoscopy (minutes)	5.8 ± 2.3	5.8 ± 2.3
Type of last meal		
Sandwich	21 (31)	17 (41)
Yoghurt	5 (8)	12 (29)
Warm meal	28 (42)	5 (12)
Fruit	2 (3)	3 (7)
Other	11 (16)	5 (12)
Type of last drink		
Water	35 (52)	23 (55)
Tea	11 (16)	11 (26)
Apple juice	1 (2)	0 (0)
Lemonade	3 (5)	2 (5)
Coffee	10 (15)	2 (5)
Other	7 (10)	4 (10)

Continuous data are presented as mean ± SD. Categorical data are presented as n (%).

Abbreviation: ASA= American Society of Anaesthesiologists Physical Status Classification (ASA PS Classification);

[1] data was missing for two patients.

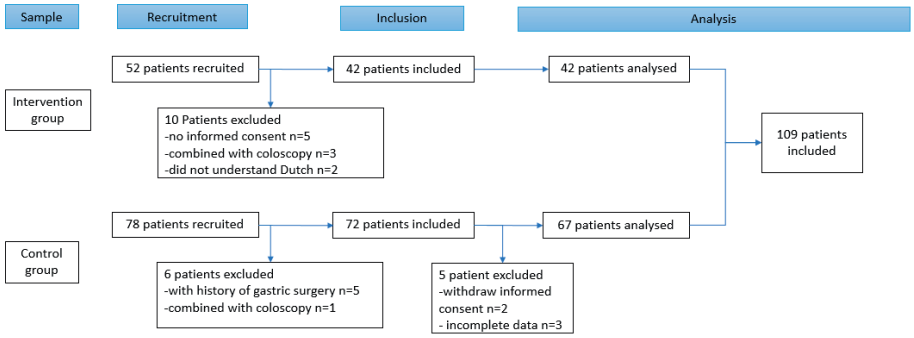

Figure 1 – Selection of patients

Applicability

Patients' satisfaction

Questionnaires on patients' satisfaction were returned by 45 patients (67%) from the CG and 26 patients (62%) from the IG. The majority of patients were very satisfied with mean scores of at least 8.2. IG patients were less satisfied with the care to prepare for the EGD than CG patients. On a scale from 0-10, they rated this 0.56 points lower (p=.017).

Patients' perceptions towards the applicability

Perceptions towards the applicability were evaluated among IG patients. The applicability of fasting education was influenced by five themes derived from the conventional content analysis: motivation, perceptions, discomfort, circadian rhythm of eating and sleeping, and professional support (Table 2).

Table 2 – Impact of different fasting instructions on patients' satisfaction, fasting times, gastric visibility, and patients' comfort

Patients' satisfaction	CG (n=67)	IG (n=42)	mean difference (95%CI)	p-value
care to prepare for endoscopy	8.7 ± 1.0	8.2 ± 1.2	0.56 (0.103-1.030)	**0.017**
outpatient clinic	8.7 ± 0.9	8.8 ± 0.9	0.05 (-0.481-0.378)	0.811
Overall	8.6 ± 0.9	8.8 ± 0.9	0.06 (-0.468-0.356)	0.786
Fasting times (hh:mm)	12:56 ± 3:09	9:31 ± 3:01	3:14 (2:05-4:24)	**<0.000**
from solid foods	13:18 ± 2:08	9:48 ± 2:39	3:20 (2:19-4:20)	**<0.000**
morning session	10:34 ± 6:30	7:43 ± 3:39	2:51 (-2:32-8:14)	0.274
afternoon session				

Table 2 *(Continued)*

Patients' satisfaction	CG (n=67)	IG (n=42)	mean difference (95%CI)	p-value
from clear liquids	10:26 ± 3:26	5:03 ± 3:46	5:22 (3:57-6:46)	**<0.000**
morning session	10:35 ± 3:03	4:57 ± 3:42	5:38 (4:06-7:09)	**<0.000**
afternoon session	9:29 ± 5:29	5:25 ± 4:12	244 (-0:50-8:57)	0.096
Mucosal Visibility Score (MVS)*				
Lower esophagus	2.2 ± 1.0	1.9 ± 0.9	0.304 (-0.085 – 0.694)	0.125
Corpus	2.6 ± 1.1	2.0 ± 0.8	0.573 (0.222 – 0.925)	**0.002**
Antrum	2.0 ± 1.0	1.5 ± 0.7	0.563 (0.198 – 0. 927)	**0.003**
Fundus	1.9 ± 1.0	1.4 ± 0.7	0.527 (0.171 – 0.883)	**0.004**
Total MVS	8.7 ± 3.4	6.8 ± 2.4	1.92 (0.831 – 3.013)	**0.001**
Judge-ability				
Lower esophagus	7.0 ± 2.3	8.4 ± 1.3	-1.3 (-2.2- -0.6)	**<0.000**
Corpus	6.4 ± 2.6	8.2 ± 1.2	-1.7 (-2.5 - -0.9)	**<0.000**
Antrum	7.5 ± 2.1	8.8 ± 1.4	-1.5 (-2.2- -0.8)	**<0.000**
Fundus	7.4 ± 2.4	9.1 ± 0.9	-1.2 (-1.9 - -0.5)	**0.001**
Presence of gastric residue	63 (96)	35 (85)	10.1 (-1.9 – 22.1)	0.070
Gastric residual volume (ml)	58 ± 50	31 ± 26	27.0 (9.1-45.0)	**0.003**
Need to flush	42 (64)	15 (37)	27.0 (8.4 – 45.6)	**0.006**
Flushing volume (ml)	72 ± 44	48 ± 23	24.7 (0.9-48.5)	**0.042**
Symptoms of discomfort				
nausea	18 (27)	10 (24)	n/a	0.320
vomiting	3 (5)	0 (0)	n/a	**0.033**
thirst	43 (64)	25 (59)	n/a	**0.001**
hunger	35 (52)	19 (45)	n/a	**0.004**
headache	19 (28)	6 (14)	n/a	**0.004**
weakness	16 (24)	7 (17)	n/a	0.077
anxiety	28 (42)	13 (31)	n/a	**0.008**

Continuous data are presented as mean ± SD. Categorical data are presented as n (%). Bold values are significant.
*MVS scores ranges from 1-4: 1) No adherent mucus and clear view of the mucosa; 2) A thin coating of mucus that did not obscure view of the mucosa; 3) Some mucus/bubbles partially obscuring view of the mucosa (a small mucosal lesion might be missed without flushing); 4) Heavy mucus/bubbles obscuring view of the mucosa (a small mucosal lesion could easily be missed without flushing). Total MVS (TMVS) are sum scores ranging from 4 to 16

The theme motivation included patients' motivation to be loyal to appointments and the value to contribute to science. The patients appeared to be willing to follow rules and to be loyal to instructions. They were willing to fulfill requirements that healthcare professionals suggested them to do. Some patients were also motivated to apply the instructions because that would contribute to science. For them, this was also a reason to participate in the study. Patients may have felt the importance of applying the instructions.

The theme perceptions included patients' perceptions toward "fasting" and the recommendation "to keep eating and drinking" until 6 and 2 hours. Some patients

perceived fasting as part of the instructions they were already familiar with. Fasting for was not a problem for some patients, as they could eat and drink right after the EGD. Others also believed that a longer fasting period would enhance the chance that the EGD would have good visual results, and they would not vomit afterward. Some patients mentioned that the recommendations were easy to follow. This helped provide reassurance to patients who were anxious related to fasting.

Within the theme discomfort, the patients indicated that symptoms of discomfort helped them adhere to the recommendations, for instance due to thirst. Physical complaints could either hamper or enable patients to keep eating and drinking until bedtime, such as experiencing abdominal discomfort, or always having appetite or being thirsty.

A major theme occurring from the analysis was the circadian rhythm of eating and sleeping. The patients had to fit the recommendations into their individual eating behavior during the day. This could include eating before bedtime, eating during the night, or having a late breakfast. Most patients were willing to put effort in applying the recommendations, for instance, to wake up early to eat or drink, to postpone sleeping time for a late evening snack or meal, or to prepare the meal to be eaten during the night. Some patients mentioned that they ate during the night as a result of awakening due to sleep disturbances. Other patients mentioned that the time of eating or drinking, or the time of fasting optimally fitted in their eat or sleep rhythm, which meant that both actions did not burden them. Few patients planned to eat or drink but forgot it eventually due to other activities.

Professional support was another major theme. The conversation with a nurse about the recommendations increased the urgency to apply them. For some patients, it was helpful that instructions included examples and that it was provided both on paper and by telephone. Patients became aware of the possibility to eat and drink longer. Also, support from relatives and family helped some patients comply to the instructions Efficacy.

Efficacy adherence to fasting instructions

Duration of fasting from solid foods was 12:56 hours ± 3:09 hours for CG patients and 9:31 hours ± 3:01 hours for IG patients ($p < .001$, Table 3). Length of fasting was three times more adequate (i.e., less than 8 hours) in the IG than in the CG (n = 12 [29%] vs. n = 5 [8%], $p = .003$). Moreover, less patients fasted more than 12 hours in the IG compared with the CG (n = 7 [17%] vs. n = 47 [63%], $p < .001$) (Figure 2).

Table 3 – Themes, codes and citations of patients' perceptions towards the applicability of the instructions

Theme	Codes	Citations
Motivation	Contribute to science	(110085) 'I would like to support you (i.e., nurse from the study)'
		(110107) 'I did it because of the study, without the study I would not do it'
	Loyal to appointments	(110088) 'I like to stick to the rules'
		(110095) 'For me, a deal is a deal'
Perceptions	Perception towards fasting	(110086) 'For me, prolonged fasting is not a big problem, now the night was in between so it was easy'
		(110090) 'It is clear, I had to do it before, it is obvious. Fasting belongs to these procedures'
	Perceptions towards the recommendations	(110110) 'it gave rest to be allowed to eat something. Because I always suffer from thirst due to Sjogren, it was reassuring that I could still have something'
		(110096) 'The task was very easy, just follow two rules'
Discomfort	Symptoms of discomfort	(110089) 'I was hungry, and the advice was to eat some'
		(110113) 'Being not allowed to drink would be difficult because the feeling of thirsty, but now it was allowed to drink something'
	Physical complaints	(110101) 'I suffer a lot from burping, Belching, feeling nausea. Then eating during the evening is not pleasant'
Circadian rhythm of eating and sleeping	Eating routines	(110085) 'I usually eat something like toast or sausage before I go to sleep, now it was yoghurt with muesli as you advised'
		(110096) 'I never eat during the evening'
	Effort to fit it in eating routines	(110102) 'I use to have breakfast late in the morning, so the endoscopy fits optimal'
		(110094) 'I never eat during the evening, but the advice convinced me to eat a cracker during the evening'
	Was not awake	(110114) 'I was still a sleep at 7.00AM, so when I woke up it was too late to drink'
	Effort to fit it in sleep routines	(110100) 'I went to bed a bit later than normal to eat a bit later than I usually do'
		(110093) 'I could have set an alarm, but I do not want to do that; eating late in the evening is not a problem, though'
	Feeling tired/sleepy	(110083) 'I intended to eat at midnight, but I was tired, so I ate at 11.00PM'
		(110115) 'I awakened spontaneously, and then I decided to drink something'
	Sleep disturbances	(110107) 'I wake up frequently during the night, so now I went out to eat something'
		(110103) 'I slept not good; I was awake each hour due to the procedure that was awaiting'
Professional support	Professional support	(110103) 'I had spoken with a nurse about it'
	Advice and instruction	(110104) 'information about the rationale of fasting did give me more awareness; otherwise, I would not have eaten during the evening'
		(110098) 'the clear information with examples of meals helped me'
	Clear instructions	(110113) 'The instructions made me more aware and made me eat something before bedtime; the advice were helpful'
		(110094) 'husband had prepared a cup of tea'
	Social support	

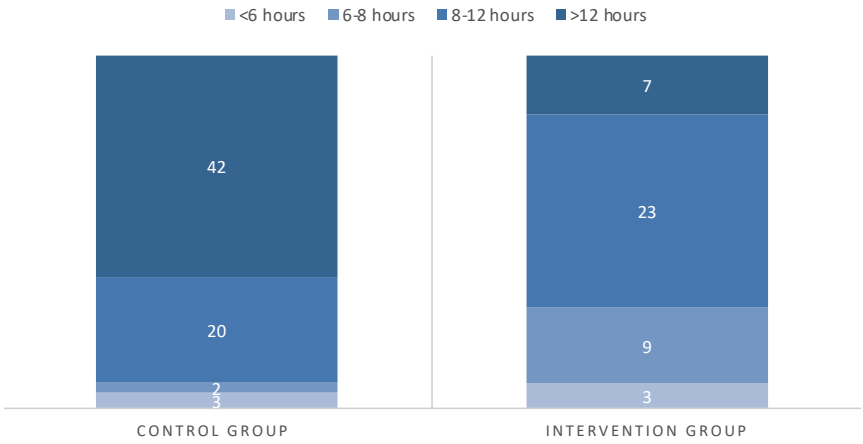

Figure 2 – Adherence to fasting recommendations for solid foods

Number of patients per study group that fasted for maximum 6 hours, 6-8 hours, 8-12 hours, or more than 12 hours from solid foods.

Last consumptions that IG patients ate were less frequently warm meals (n = 5 [12%] vs. n = 28 [42%], p = .001) and more frequently the meal suggestions (i.e., sandwiches or yoghurt) compared with CG patients (n = 29 [70%] vs. n = 26 [38%]), p = .001).
Fasting From Clear Liquids

Duration of fasting from clear liquids was 10:26 hours ± 3:26 hours for CG patients and 5:03 hours ± 3:46 hours for IG patients (p < .001, Table 3). Length of fasting from clear liquids was 10 times more adequate (i.e., < .001) (Figure 3). There were no differences in type of last drink between the groups (Table 1).

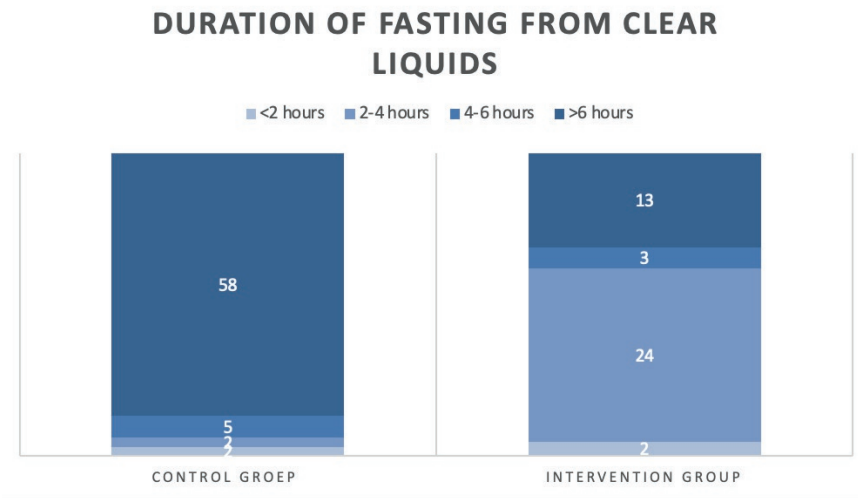

Figure 3 – Adherence to fasting recommendations for clear liquids

Number of patients per study group that fasted for maximum 2 hours, 2-4 hours, 4-6 hours, or more than 6 hours from clear liquids foods.

Gastric visibility

Gastric residual volume was 27.0 ml higher in CG patients than in IG patients (p = .003). Flushing during EGD occurred more often and with 24.7 ml more in CG patients than in IG patients (p = .006; p = .042; Table 3). The TMVS was 1.92 points lower in the IG than in the CG (p = .001) (Table 3). Judge ability of each area was higher in the IG than in the CG (p = .001).

Patients' Comfort

The IG patients reported significantly less (symptoms of) discomfort (Table 3), except for nausea and weakness, which were reported equally in both groups. In general, the patients most frequently reported thirst (CG: n = 43 [64%]; IG: n = 25 [59%], p = .001) and hunger (CG: n = 35 [52%]; IG: n = 19 [45%], p = .004). Vomiting before EGD happened only in three CG patients (5%, p = .033). Sixteen CG patients (24%) and seven IG patients (17%) felt weak before the EGD (p = .077) (Table 3).

Discussion

Education including the why, how, and what of fasting recommendations led to shorter fasting times in patients undergoing EGD. Applicability of the instructions was influenced by patients' motivation, their perceptions toward fasting, and the instruc-

tions, patients' discomfort, circadian rhythm of eating and sleeping, and professional support. Adequate fasting routines were applied more often for clear liquids than for solid foods. Shortened fasting times reduced discomfort and maintained gastric visibility with lower gastric residual volume and better mucosal visibility in well-informed patients.

Fasting guidelines state that patients should be encouraged to keep eating and drinking as long as permissible (3). The current study demonstrated how this endorsement can be carried out in daily practice by outpatients undergoing EGD. Patients' motivation and perceptions toward both recommendations (i.e., fasting and eating and drinking as long as possible) contributed to the extent to which they were willing to apply these recommendations. Some patients in our study argued that (prolonged) fasting did not burden them, because they were used to having a late breakfast. Others endorsed the importance of fasting, or they did not see why shortened fasting times would benefit them. Patients argued that the ingestion of the last pre-EGD meal and drink should preferably fit within their individual circadian rhythm. Professional support is important to provide clear instructions on the latest time to eat and drink and examples of possible consumptions. The current study demonstrated that educating patients can prevent prolonged fasting.

Patient education belongs to fundamental nursing care enabling patients to manage their health and to make treatment decisions themselves (24, 45, 46). However, it appears to be in the top three nursing activities that remains undone (24-26). In our study, nurses educated patients on optimal eating and drinking behavior when fasting was required. Limited evidence is available to conduct optimal education strategies regarding eating and drinking behavior (7, 20-23). In our study, Dutch-speaking patients were educated by telephone and written information. This way of education does not reach patients who are illiterate or nonnative speakers. Furthermore, information videos arise as new instruments to educate patients (47-49). Therefore, future studies on education strategies should address fasting combined with multimedia approaches in all languages. Furthermore, education empowers patients to participate in the care of their individual health (45). Our findings confirm that active involvement of patients prevents prolonged fasting. Moreover, it indicates that patient involvement can improve adherence to guidelines. In the future, partnership of patients in preprocedural care can be achieved by addressing their individual level of knowledge and skills to apply fasting behavior (50).

To eat and drink exactly until 6 or 2 hours before the procedure may affect the sleep rhythm, especially for morning EGD sessions. Patients in this study demonstrated that drinking 2 hours before fits sufficiently in their rhythm, and a late-night snack before or during bedtime is feasible as well. It was already known that a fasting

period of 6 and 2 hours before procedures is safe. This study adds the latest time that patients will likely eat and drink before procedures when they are well informed. Sleep rhythm must be taken into account when determining the final eating and drinking time for procedures that require fasting.

Our study provides knowledge on how patient-related barriers can be addressed and how patients could be instructed to acquire optimal fasting behavior. Other factors complementary to patient-related factors should be addressed as well (51), including organizational and healthcare staff-related factors (52). Organizational barriers that affect prolonged fasting are inflexible procedure programs, planning of procedures, and organizational culture like sticking to old habits. Healthcare staff-related barriers are a lack of guideline knowhow (4, 17), and lack of awareness about the impact of prolonged fasting on patients' comfort (52, 53). Especially, nurses have an important role in the communication of fasting instructions to patients, because they are closest to the patient (53). Moreover, keeping patients informed, comfortable, well nourished and hydrated belong to the fundamentals of nursing care (46, 54, 55).

Strengths and limitations

This study lacks randomization of patients. Randomization would have supported the effectiveness interpretation of the instructions. However, our study demonstrated efficacy meaning whether education can change fasting behavior. This feasibility approach mainly addresses how something can work, not whether it is effective. Effectiveness should be addressed in future randomized studies to determine how fasting education affects other relevant outcomes. Secondly, our patients consumed different products that might have influenced gastric visibility. Moreover, we did not correct for prokinetic medication use among the patients. The stomach empties faster from liquids compared to solids (56). Moreover, fatty and fried foods have a longer gastric emptying time compared to light meals (3). Therefore, it might have been better to standardize the consumption of food products and use of prokinetics. However, our purpose was to investigate how personal fasting instructions can be applied in real life while maintaining endoscopic quality.

Our study strengthened the growing awareness that reducing fasting times requires modern, multifaceted approaches (9, 23, 52). We explored how fasting recommendations can be carried out by patients in daily practice after being educated by nurses with verbal and written instructions. In our study, we intended to mediate as natural as possible enabling patients to adhere to guidelines in a suitable manner while continuing their preferences. This realistic approach strengthens the value of our study. Another strength of our study is that we evaluated the impact of shortened fasting times on gastric visibility. This outcome is relevant for endoscopic purposes.

Finally, we established an adequate sample size providing sufficient power for our purposes.

Conclusion

Positive, concrete instructions on fasting and to eat and drink as long as permissible are applicable for patients undergoing EGD. Instructed patients had shorter fasting times while gastric visibility was maintained, and their physical comfort was better. Instructed patients ate and drank as long as possible by fitting it in their daily rhythm of eating and sleeping. The encouragement to keep drinking was easier to apply for most patients than to keep eating. Participation of patients is a precondition to prevent prolonged fasting and to achieve healthy fasting behavior.

Practical implications

Patients should be involved in reducing length of fasting. Positive, concrete instructions on how patients must apply fasting before EGD will lead to more optimal fasting behavior, maintain gastric visibility and lead to improved patient comfort. Future research should validate the identified factors that influence adherence to fasting recommendations and address organizational and healthcare staff barriers to reduce prolonged fasting. Research should provide further information on the type of nutritional products that can be consumed by patients before preprocedural fasting.

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Supplementary materials

Supplementary materials are available online.
https://journals.lww.com/gastroenterologynursing/Fulltext/2022/09000/Patient_Education_Regarding_Fasting.7.aspx

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Chapter 7

General discussion

General discussion

Nutritional support for patients undergoing surgery is one of the fundamentals of nursing care. This thesis demonstrates a personalized approach by nurses to improve nutrient intake of patients before (surgical) procedures. Nurses educated patients at outpatient clinic consultations regarding (under)nutrition with general and tailored information and with special emphasis on fasting. Its implications for preoperative nutritional nursing care and considerations regarding the theoretical and methodological choices are discussed in this chapter.

Preoperative nutritional support

Optimization of nutritional status

Optimization of patients' health status before surgery is hot. (Inter)national literature appoints that prehabilitation, i.e., preoperative improvement of health status, facilitates the recovery after surgery (1-7). Part of this movement is the optimisation of nutritional status (3). The new developed outpatient nursing nutritional intervention including five steps especially focused on this part of prehabilitation and is valuable for several reasons.

Firstly, the body of knowledge in preoperative nutritional support did not shed light on the significant contribution of nurses. Our systematic review revealed that no nurses were involved in preoperative nutritional supportive interventions (8). Other reviews on nutritional nursing care also did not find studies in outpatient preoperative care settings (9-11). Although nutritional preoperative care by nurses has been described in one paper, this study was excluded in our review because its effect was not described (12). This thesis demonstrates the significant impact of nurses in nutritional prehabilitation to overcome this gap (13-15). Nurses must therefore be involved in prehabilitation programs.

Secondly, the five steps of the intervention addresses contributing factors of undernutrition and patient-related determinants (13). By addressing the contributing factors (i.e., bad appetite, decreased nutrient intake, gastrointestinal problems, impaired physical activity, pain, or poor oral health), the intervention focuses on personal components of general health as well. For instance, pain negatively affects appetite, and can decrease physical activity and mental wellbeing which both affects patient's nutritional status. Furthermore, behavioural elements such as impaired knowledge, skills, and awareness to improve or maintain nutritional status were addressed which

resulted in empowered patients. Therefore, the personalized contribution of nurses to nutritional prehabilitation must be acknowledged in prehabilitation programs.
Another valuable aspect of the nursing intervention concerns the use of oral diets for improvement of patients' nutritional status. Oral nutritional support compromises regular or therapeutic diets and, if indicated, oral nutritional supplements with dietary advice and nutritional counselling (16). This formula is especially relevant because this could particularly be delivered by nurses and may be less expensive than enteral or parenteral nutritional prehabilitation. A recent review revealed that many prehabilitation studies did not monitor the intervention nor any nutritional outcomes (17). Therefore, the components of our intervention can be complementary for prehabilitation programs and longitudinal studies

Future studies can continue to evaluate the effectiveness of the nurses' contribution and implement the involvement nurses at outpatient clinics to contribute to the inter professional approach of prehabilitation. Moreover, when nurses address the factors that contribute to undernutrition, patients will not only improved their preoperative nutrient intake, but they also may have an enhanced recovery after surgery, and they may even have learned how to apply an healthy nutritional lifestyle. However, to date, evidence that nutritional prehabilitation leads to lower complications and mortality rates, and reduced hospital stay remains low to very low (18). Future longitudinal studies must address the effect of nutritional prehabilitation on these outcomes.

Consumption of food products

In our intervention, patients were advised to consume energy-rich and protein-rich products (14). Patients arranged the food products themselves, and consumed food products of their own preferences. Other studies focused on the delivery of preselected food products to the patient, either at home or within the hospital (19-21). The approach of nutritional support in these studies stick to the formula of consuming 'regular diets' but differentiates from the counselling- and personalized approach in our intervention study. For instance, patients were offered a home-delivered meal service before a planned surgery, which resulted in an increased preoperative nutrient intake (21). Other meal services also demonstrated that increased attention on frequency and diversity of meals did increase nutrient intake (22). Although we demonstrated an increased nutritional intake as a result our counselling approach, individual nutrient requirements were not always fulfilled. By adding the effect of the home-delivered meal service (21), we may overcome this gap. However, a meal delivery program requires logistical and financial resources along with a vision on how patients, or citizens, must participate in their nutritional health. Nowadays, we expect patients to demonstrate self-management and demand them more and more

to make healthy choices(23). Deliver healthy food at home relieve patients from this duty, while the personalized approach of nurses enables patients to demonstrate the desired behaviour. Therefore, to improve or maintain independency of patients from the health care system, nutritional support through education by nurses will be a more future-proof solution.

Tailoring of recommendations

Patients' individual care needs were especially addressed in the outpatient nursing nutritional intervention (13), which is acknowledged as fundamental care (24, 25). Individual causes of undernutrition were addressed along with individual barriers to improve nutrition intake during the consultation sessions. Subsequently, tailored measures were applied. A recent study confirms that patients require support on their level of individual expertise and desired level of engagement (26). A recent umbrella review demonstrated that nutritional interventions ranged from delivery of general advice to personalised supplementation (18). However, tailored nutritional support appears not to be a standardized element of these nutritional prehabilitation programs (18). Tailoring of care towards individual care needs enables the delivery of holistic care which is especially the expertise of nurses (27). Tailoring has its benefits especially for vulnerable patients with impaired health literacy (28), complex nutritional problems (29), and different food preferences (30). Therefore, future prehabilitation programs should include personalized approaches which is especially the expertise of nurses.

Digital nutritional support

In our intervention, information was provided to patients verbally and with leaflets, and nutrient intake was recorded by a paper diary (14). Patients in our study valued the physical contact with nurses and having the physical diaries at the table as a reminder. This old-school approach may not be future proof in the time of digital health. Even more, it becomes standard care that patients enter hospital services through digital applications. Digital nutritional support can therefore be initiated for information delivery, for tailoring advice to patients, and to monitor food intake. Informative applications on smartphones and tablets can improve knowledge of participants, adherence to instructions, and even effectiveness in terms of prevention (31-34). The number of informative apps for patients undergoing surgery (35-39) are rising and promising (31). A benefit of using smartphone and tablets applications to inform patients is the timing of information delivery (31). Another benefit of digital nutritional support includes individually tailored recommendations. Based on scientific formula's and individually based physical characteristics and patients' individual

information, such an application can suggest the patient what and when he must eat, and can provide the required informational content (40). Also, monitoring food intake can be done with a digital dietary intake monitoring system (41). However, although future initiatives can integrate such applications, the nurses' personalized approach of verbal information delivery must still be part of the information delivery especially for vulnerable patient groups.

When digital nutritional support is developed and appears to be feasible, its effectiveness on nutritional status, fasting habits, and postoperative recovery can be investigated. Furthermore, such an app can be incorporated within a prehabilitation program as literature demonstrate that stand-alone apps are less effective (32). Although moving from physical consultations towards digital nutritional support sounds innovative and future-proof, this approach may not be suitable for vulnerable patients without sufficient digital skills, with language problems, or illiterate people. Furthermore, retention and engagement of patients and adherence to behaviour change remain challenges for digital behaviour change interventions (42). Therefore, future studies must explore how applications can be used by nurses as supportive instrument to nutritional care.

Perioperative fasting

Fasting before administration of anaesthetics is mandatory to prevent aspiration of gastric content into the lungs. Current preprocedural fasting times are much longer than guideline recommendations (43-45). In this thesis it was found that patients had no nutrient intake for about 15 hours before surgery (43). While researchers already in 2005 claimed that preoperative fasting was outdated (46), no significant improvements were observed in 2009 and 2019 in Dutch hospitals (43). Fasting from midnight is an old habit that became standard care in the 1960s, thus this will not be changed easily (47, 48). The consequences of prolonged fasting for patients, mentioned in multiple sections of this thesis, are the main reasons we must ensure adequate fasting habits from our patients. To prevent the society to keep fasting from midnight for another 60 years, it is time for a next step towards pre-procedural modern fasting. To do so, one must acknowledge a competing interest of guidelines before surgery. On the one hand, the stomach must be empty to prevent aspiration-related pulmonary complications which is achieved by fasting for six and two hours for solids and liquids, respectively. On the other hand, patients must be encouraged to keep eating and drinking for as long as possible, to prevent insulin resistance and increase wellbeing. Both fasting aspects must be acknowledged when health care staff and patients take a next step towards modern fasting habits.

Education

A first step is to improve the knowledge of patients regarding fasting. Patients in chapter 5 were unaware of the six and two hours of prescribed fasting illustrating the gap of knowledge (43). Patients' knowledge and interpretation of fasting are crucial to adapt to the guidelines (15, 49), as fasting instructions may be complex for patients (49). Chapter 6 describes a first effort to shorten fasting times through the education of patients the rationale of fasting, the consequences of prolonged fasting, and what and when they have to eat and drink at the latest possible time (15). The pilot study showed that patients are willing to apply to the fasting recommendations when they perceive fasting as a burden or expect discomfort when fasting longer than required. Furthermore, the extent of professional support that patients receive, and whether it can fit in their circadian rhythm are also important factors to take into account (15). Future studies must continue to evaluate optimal strategies of patient education to achieve adequate fasting behaviour.

Eat and drink

Secondly, consumption of carbohydrate beverages up to two hours before surgery must be implemented in daily care for all patients (50, 51). Evidence on the benefits of preoperative consumption of oral carbohydrate beverage 2-4 hours before surgery is clear. It reduces postoperative insulin resistance (50, 52-59), while prolonged fasting decreases insulin sensitivity (60-63) having a subsequent effect on postoperative complications (64). A carbohydrate beverage as a glucose bolus until two hours before the operation is safe (50), has a positive effect on postoperative wellbeing (e.g. less malaise, thirst, hunger and weakness (65), nausea and vomiting (66) and is even associated with shortened length of hospital stay compared to placebo or fasting (57, 67, 68). The time of waiting until surgery can be filled with the management of discomfort, for instance with the consumption of popsicles (69). Eating six hours before surgery can be complicated as this can be during the night when surgery is in the morning. Therefore, patients scheduled in morning sessions must be encouraged to eat before bedtime for an optimal fit within the patients' circadian rhythm. Patients can be instructed in individual counselling sessions with their nurse, via leaflets and informational video's that they receive within the care pathway. Reminders on their smartphone may also be a solution (70).

Interprofessional collaboration

A third step is that all health care staff, especially nurses, must do their part. Surveys demonstrated that health care staff including nurses are not sufficiently aware of the guidelines and of the negative consequences of prolonged fasting (71-73). For

patients to apply to guidelines, nurses must educate them with up to date knowledge (74). Involvement of health care staff requires three steps. First, healthcare staff must be aware of the main goals regarding fasting, i.e., to keep eating and drinking until six and two hours before surgery instead of fast from midnight. Even more, they must achieve inter professional consensus to what extent of 'adequate fasting habits' can be achieved. Of course, consensus on how long patients must fast from solids and liquids is already achieved decades ago. However, we also need agreement on the maximum time that patients 'may' be abstained from solids and liquids. For instance, some studies now have demonstrated that education on fasting will lead to shortened but still prolonged fasting times for clear liquids (15, 51, 70), while fasting times from solid foods remained prolonged. Furthermore, interprofessional consensus is a contributing factor to the implementation of preoperative carbohydrates (75). Therefore, consensus among health care staff on what length of fasting (longer than 6 and 2 hours) is acceptable, and how we can get there is required. A second step is to involve particularly anaesthesiologists and nurses. Anaesthesiologists are the first who should take action: they are the one who ask patients to fast; they should lead the change by appropriately informing all administrators of preoperative fasting instructions (76). As the pilot study in this theses demonstrated, nurses can inform patients on fasting demonstrating the significant contribution of nurses (15). A third step should be an update of curricula of educational programs for both nurses and physicians regarding fasting and nutrition before surgery. This must be addressed both during and after graduation.

Facilitating interventions

Fourthly, we must facilitate optimal fasting behaviour. This can be achieved with stable operation room planning, nudging of oral intake in preparation for surgery, and ensuring safety by assessment of gastric residual volume. *Operation room planning* is a complex, somewhat unpredictable and inflexible system that affects the timing of the start of fasting (48). Changes in start times occur because procedures are extended or abbreviated, or because patients with urgent problems show up. Especially the emergency theatre list has a high level of unpredictability. Twenty-two percent (n=41) of the surgeries started later than intended and fasting from solids was two hours longer in emergency surgeries compared to elective surgeries (43). It was also interesting that fasting was shorter (Mann-Whitney test P= 0.046 and >0.000 for liquids and solids) when surgery started between 8.00 and 9.00 AM (first on the list) compared to starting times on a later moment (43). Therefore, stable starting times of surgeries will lead to better fasting times. Regarding the actual oral intake, *nudging* could be an approach that may facilitate hospitalized patients to eat and

drink until the defined hours. Foods and drinks must be present in the surroundings of the patients and hospital staff under responsibility of nurses must actively provide the required foods and drinks. Next, an empty stomach at administration of anaesthetics will prevent pulmonary aspiration leading increasing patient safety. As we demonstrated in chapter 6, gastric residual volume was lower in patients who fastened shorter before EDG (15). For patients with risk factors of delayed gastric emptying, gastric residual volume can be screened before anaesthesia. Although this is not commonly in daily practice, in several studies the amount of gastric volume is determined via ultrasound assessments (77-82). Therefore, implementation of drinking and eating as long as possible can be investigated together with an exploration of bed side ultrasound assessment of gastric residual volume to facilitate safe anaesthetic procedures.

Postoperative restoration of nutritional intake

In one of the ERAS programs, it was suggested that oral nutritional intake should be restored within 4 hours (59). In chapter 5, we demonstrated that it took 5:35 hours for patients to restart eating after surgery. The first liquid was consumed after approximately 3 hours (43). Nurses at Post Anaesthesia Care Units and general surgical wards are therefore in leading positions to facilitate postoperative eating and drinking as early as possible. Chapter 5 slightly addressed the period after surgery, in which oral intake was not always allowed due nil-per-mouth policies. Because nutrient requirements are hardly met during the days after surgery (83, 84) restoration of nutritional intake after surgery with emphasis on recovery is of interest for future studies. Interventions to shorten the time to restart eating and increase nutrient intake include optimal nudging with for instance protein-enriched popsicle (85), participation of family (86), and informing patients about postoperative recovery when they prepare for surgery.

Theoretical and methodological issues

Following the MRC framework

Chapter 2, 3, and 4 followed the Medical Research Council (MRC) Framework as a basis for building evidence on fundamental nutritional care. This framework enabled the development of an evidence-based outpatient nursing intervention (25, 87). Since nursing care is characterized by complex interventions (88, 89), the MRC framework can guide its development and evaluation (90). Following this framework provided

several insights. First, it showed what patients and nurses need for the desired behaviour. This input enabled tailoring of the intervention components and adaptation of the intervention later in the process (89). Moreover, the impact on nutrient intake in the intervention group can be acknowledged from the contribution of patients and professionals from scratch. Second, within the development phase we integrated the Intervention Mapping approach to further design the nursing intervention. Using Intervention Mapping was reasoned since this method was used in previous nursing (91, 92) and nutrition (93, 94) programs. This 'health promotion' method has the advantage of step-wise building a program for improvement of health (95). The benefit of the IM approach may lay in the design of activities targeting at behavioural factors. Other methods could have led to same intervention components since these also address the context. The main lesson is that systematic design of interventions remains important to understand the underlying mechanisms.

Although the first phases of the MRC framework were followed, this thesis did not continue with in-dept evaluation of the (cost) effectiveness as well as the implementation phase of the MRC framework. Several considerations have been made on that. First, effects on patient's recovery after surgery should be evaluated in homogenous patient groups. Secondly, nutritional prehabilitation should be delivered together with other prehabilitation aspects such as physical training and psychological interventions. Both these remarks can be addressed by nurses who participate in interdisciplinary prehabilitation programs. Furthermore, a third consideration is that components of the interventions may need adaptation before it can be implemented to other settings as is suggested by the updated framework (96). For instance, nurses hold in-person consultations and can communicate with each other with digital innovations as well (97). Considering the rising opportunities with video consultations, future initiatives by nurses must address the opportunity to have online consultations with patients (97). All these considerations require systematic cooperation of a project group before it can be further implemented into care pathways.

Basic Care Revisited – a ZonMw program

The first part of this thesis belongs to the ZonMw-funded project Basic Care Revisited which attempted to build on scientific evidence for essential elements of nursing care (25, 87). Keeping patients informed, coping, and involved are elements of the psychosocial domain of the fundamentals of care framework (98). This thesis provide knowledge on how patients can take a role to improve their nutritional status before surgery. Patients were instructed to take action to address the causes of undernutrition and to monitor personal nutrient intake. Furthermore, this thesis provide insight in the role of nursing care within the multidisciplinary prehabilitation team, which

now has evidence on its feasibility and effectiveness (13, 14). The contribution of nursing care is complementary to other formulas to optimize nutritional status before surgery. The knowledge build during this project can be used in future studies and daily practices.

Within Basic Care Revisited program, three universities systematically collaborated (87) while for this thesis, also the Gelderse Vallei Hospital provided financial co-support. In this manner, expertise on scientific methodology, nursing science, and nutrition was easily shared and an infrastructure for performing scientific research in nursing was built with success. During this project, multiple students in nursing have participated on all levels. For future programs on the scientific evidence of nursing care, it can be recommended to have structural collaboration between nursing staff from academic and general hospitals and with topic-related research groups. An initiative for collaboration is the Dutch Science in Surgical Nursing group, which is led by nursing researchers and supervised by professors in nursing and surgery. Such an initiative must be facilitated by the hospitals but also may require funding for projects and individual leadership programs. Leaders in nursing and healthcare, for instance professors, funding institutes, and nursing directors, must stimulate such collaborations in nursing research to stimulate academic nursing and ensure methodological expertise. The collaboration and funding organized for this project did lead to this thesis.

Other considerations

Also, more detailed considerations must be argued for studies in this thesis. Our systematic review in chapter 2 included only six papers representing five interventions. Although six papers may be few, it was already argued that the search strategy was solid (8), and that other systematic reviews did come to similar findings (11, 99). Other reviews on nutritional care by nurses focused especially on older people (9) or clinical care settings (10). Although the methodology was solid, our review does not provide strong, new evidence. However, evidence on oral nutritional support before surgery has now been supplemented with our cluster-randomized controlled trial (14).

In chapter 4, nurses were randomized to deliver the intervention or usual care. Although they work in a team, the nurses at outpatient clinic worked independent from each other as well on different days. That made it possible to randomize within a team of nurses. For studies on nursing care at inpatient care units, this will not be possible, and one must use other methods such as before-after or stepped-wedge designs.

In chapter 6, we tested how fasting instructions could be applied to shorten fasting times (15). Several remarks can be made on this study. First, it remains unclear

whether patient education is effective because the education was not systematically designed, and because we only conducted a pilot study. Furthermore, to conclude on the impact of eating and drinking until six and two hours before endoscopy on gastric visibility, a full-scale randomized trial design must be performed. Thirdly, we included patients undergoing a gastroduodenoscopy instead of surgical patients as we did in chapter 5. It is obvious that these patient groups differ from each other in terms of procedure and extend of physical challenge. We included this group in our pilot study because of several reasons. First, fasting instructions are applied before any procedure that requires anaesthetics. As chapter 5 demonstrated inadequate fasting behaviour before surgery, chapter 6 confirmed that patients fasted too long before endoscopic procedures as well. Second, most patients start fasting at home because they come in the hospital at the morning of the surgery, just as outpatients undergoing gastroduodenoscopy do. Therefore, both patient groups can be studied to understand how fasting recommendations can be carried out.

Implications

This thesis has implications for clinical practice, research and education. In daily practices, nurses can take their role in prehabilitation programs. It is of course an interprofessional approach which lacked the contribution of nurses. Within clinical pathways, nurses can take their role as well based on the findings of this thesis. To do so, nurses should be trained as we did in our study. Also, nursing directors should endorse the contribution of nursing in prehabilitation and they can proceed on building a scientific base for clinical nursing care using this project as an example. They are in key positions to guide policies in organisations and can build infrastructures for research on fundamental nursing care. Physicians such as anaesthesiologists and dieticians, can learn from this thesis the complementary role of nurses for optimal patient conditions during perioperative care.

Furthermore, this thesis impacts science with evidence on nutritional nursing care en suggestions for future research. Further studies must investigate how patients can change their nutritional habits over time when receiving personal nutritional support before surgery, and how nurses can address personal nutritional care after surgery as well. Also, research is required on the interprofessional perspective to achieve optimal fasting behaviour. Studies on this topic must address patient-related and organisational aspects, the integration of informational applications, and the use of ultrasound for gastric volume assessments.

Finally, this thesis also has implications for education of nurses. First, this thesis did impact the knowledge of clinical nurses and students in nursing who had any role

during the several projects. Furthermore, it can be a source for nutritional programs in nursing curricula to develop nurses' skills in delivery of nutritional support as previous research demonstrated that nursing students do not yet receive theoretical education about nutrition (100). Also, this thesis can be used as an example for how to research nursing and how to apply the MRC framework.

Conclusions

To optimize perioperative nutritional status of patients, preoperative nutritional support using regular diets was sufficiently delivered by applying a set of activities. An outpatient nursing nutritional intervention was systematically developed, which appeared feasible and effective in daily practice. It resulted in an improved nutrient intake among undernourished surgical patients. This formula of nutritional support for undernourished patients before surgery does have potential to prehabilitate and optimize nutritional status. Furthermore, preprocedural fasting recommendations are still poorly implemented in daily practise resulting in prolonged fasting in majority of patients. To shorten fasting times, fasting recommendations should be complete and include concrete instructions on the exact time that patients can consume a particular product. This approach appeared especially feasible for liquids. To prevent prolonged fasting from solid foods before morning procedures, one must be recommended to eat before bedtime. Future studies should address other factors for optimal fasting behaviour. Clinical leaders can impact their patients' comfort by implementing concrete fasting instructions for patients within the clinical pathways. Future research on perioperative nutritional support should be interprofessional, focussing on education, type and timing of foods, and technology for information delivery and nutritional and gastric assessment.

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Chapter 8

Summary

Nederlandse samenvatting

Data management plan

Curriculum vitae

List of publications

PhD portfolio

Dankwoord

Summary

Undergoing surgery requires an optimal nutritional status to support physical, cognitive and relational recovery. Patients with (risk for) undernutrition require nutritional support. Nurses are in key positions at outpatient clinics and at in-hospital surgical departments to address the nutritional status of the patients and to deliver evidence-based nutritional care tailored to individual needs. Despite the pivotal role of nurses in nutritional care, evidence is lacking on how nurses should deliver nutritional care for these patients. Adequate delivery of nutritional care by nurses will empower patients to take their own role and improve patients' nutritional intake and nutritional status. In the direct preoperative period, patients are recommended to fast from solid foods and clear liquids to prevent aspiration-related pulmonary complications. This guideline is used worldwide in perioperative care. Since the 1960's, fasting from midnight is implemented as practical recommendation in daily care for patients undergoing surgery. Therefore, this thesis first developed and evaluated nutritional nursing interventions for patients undergoing surgery. Secondly, adherence to and applicability of fasting recommendations are determined. This summary describes the main research findings, and the main messages from the discussion for nutritional care for surgical patients.

Preoperative nutritional support

The phases of the MRC Framework for development and evaluation of complex interventions were followed to generate evidence on delivery of preoperative nutritional support for undernourished surgical patients in nurse-led outpatient clinics (43). Per phase of this framework studies were performed on an outpatient nursing nutritional intervention for undernourished surgical patients. An overview of these studies are shown in figure 1.

In chapter 2, a systematic literature review was done to evaluate the effectiveness of nutritional support using regular diets as first step in the development phase of the MRC framework (136). Six articles describing five interventions were summarized. These interventions aimed to fulfil nutrient requirements, and mainly included counselling and advice, follow-up meetings and encouragements, and subscribing oral nutritional supplements (ONS). All interventions were delivered by dieticians, and there was no involvement of nurses, despite their primary role in outpatient clinic settings. Patients who received this type of nutritional support had significant improvements in nutritional status, nutrient intake and quality of life. Patients who

had dietary counselling had better improvements compared to patients who only received ONS. The components of nutritional support derived from the systematic review study formed the basis of a nursing nutritional intervention to be delivered at outpatient clinics for undernourished patients planned for surgery. `

In chapter 3 we developed an outpatient nursing nutritional intervention within the MRC framework. Intervention Mapping (IM) was used to develop the proposed intervention (137). A research panel followed the six steps of IM (259). During the need assessment in the first step, nutritional care needs and current nutritional care delivery were determined from both nurses and undernourished patients' perspectives. It appeared that both patients and nurses were unaware of the consequences of undernutrition, and nurses were unaware of their role in nutritional support.

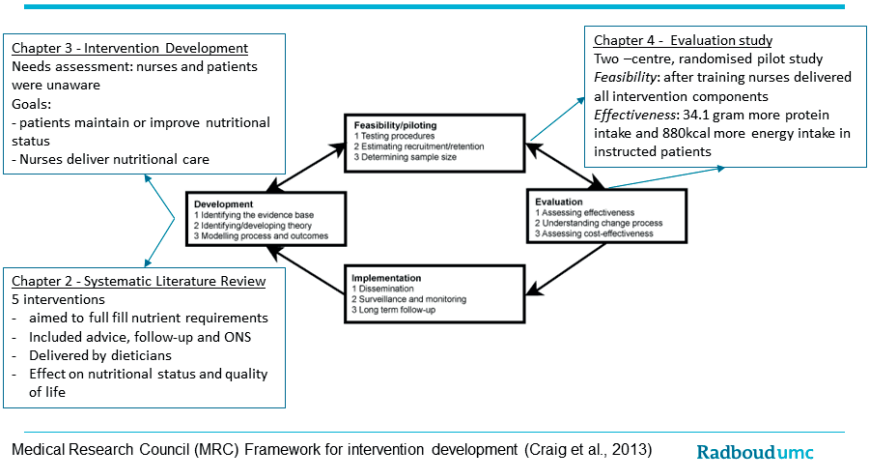

Figure 1 – Overview of results per phase of the MRC Framework for nutritional nursing care

These insights were addressed in the second step of intervention development. The goals of the intervention were 1) outpatients with risk for or with undernutrition planned for surgery to maintain or improve nutritional status and 2) for nurses to deliver nutritional support. To reach these goals, an outpatient nursing nutritional intervention and a training program for nurses were developed during the third and fourth step. The outpatient nursing nutritional intervention included five components. First, causes of undernutrition were identified. Then, a nutritional care plan was delivered including general and tailored advice. Thirdly, patients were instructed to monitor their nutrient intake for two days. The fourth activity included counselling and encouragement to address potential barriers to improve nutrient intake. Evaluation

of the personal recommendations was done as fifth activity in a telephone follow-up call a week after the outpatient clinic visit. This newly developed outpatient nursing nutritional intervention including five nursing activities was pretested in fifth step of IM. Finally, the intervention was prepared in a study protocol for the sixth step (154).

To continue following the phases of development and evaluation of complex interventions in chapter 4, the evaluation phase of the outpatient nursing nutritional intervention is described. During the evaluation, the feasibility and effectiveness of the newly developed intervention are determined in a two-centre cluster-randomized pilot study (153). Nurses of two outpatient clinics were randomized to intervention delivery for which they completed the training or to continue usual care delivery. They delivered the intervention in participating patients while completing the final part of the training to demonstrate the desired behaviour. Forty-eight patients (31.6%) participated in the feasibility phase. At the end of the feasibility phase, nurses delivered all intervention components. In total, 152 patients completed the study of whom 67 (43%) patients received the intervention. Patients in the intervention group had more protein and energy intake and fulfilled nutrient requirements more often compared to patients who received usual care.

In conclusion, the first three studies in this thesis demonstrated that preoperative nutritional support using regular diets could sufficiently be delivered by nurses as applying a set of activities. An outpatient nursing nutritional intervention was systematically developed, which appeared feasible and effective in daily practice. The evidence-based nursing intervention led to an improved nutrient intake in surgical patients with (risk for) undernutrition.

Fasting from solids and liquids

Short before surgery, it is mandatory for patients to fast to prevent pulmonary aspiration during anaesthesia (78, 85, 192). Fasting recommendations indicate to stop eating six hours and drinking two hours before a procedure. After surgery, enhanced recovery after surgery (ERAS) guidelines recommends to restore oral intake as soon as possible (46, 72, 193). In chapter 5, adherence to the anaesthesiologic and ERAS guidelines was observed in two Dutch hospitals (229). This was done in two observational periods with 10 years in between, i.e., 2009 and 2019. A total of 311 patients were included of whom 127 (40.9%) patients in 2009. Preoperative fasting from solid foods and clear liquids was prolonged in 280 (90.3%) and 208 (67.8%) of the patients over both periods. Median preoperative fasting times were 15:19hrs (IQR 13:00 - 18:19 hours) from solid foods and 5:15hrs (IQR 2:25-11:26 hours) from clear liquids. No differences in fasting times and adequate fasting behaviour were found between 2009 and 2019. After surgery, patients resume oral intake of

solid foods within a median of 5:35hrs (IQR 03:32 - 14:52 hours) and of clear liquids within a median of 2:56hrs (IQR 1:38 – 4:13 hours). Total absence of oral intake was 23:46hrs (IQR 20:00 – 30:30 hours) for solid foods and 11:00hrs (IQR 7:53 – 16:00 hours) from clear liquids. Patients appeared to be instructed to fast from midnight. Moreover, half of the patients were not aware of the interval time they were allowed to eat and drink. It was concluded that patients still stop eating and drinking too soon leading to erroneously prolonged fasting periods and subsequent consequences. Furthermore, the anaesthetic recommendation 'to keep eating and drinking until six and two hours before surgery time' was still poorly implemented.

Chapter 6 describes how this preprocedural fasting recommendation could be implemented in patients' habits to prevent prolonged fasting (260). According to chapter 5 and other studies, patient education on fasting can be a factor that can prevent the unnecessary prolonged fasting times (18, 215, 216, 229). Therefore, a prospective single-centre, controlled pilot study was undertaken to evaluate applicability and efficacy of fasting education among outpatients undergoing esophago-gastro-duodenoscopy (EGD). Outcomes were the applicability as perceived by patients, adherence to the recommendations, gastric visibility, and patients' comfort. After observation of usual fasting behaviour among 67 (61%) patients, an intervention group of forty-two patients (39%) was educated by a nurse on the why, how, and what of fasting. As a results, patients fasted shorter compared to the control group. Adequate length of fasting from solids occurred three times and fasting from liquids occurred ten times more often in educated patients compared to patients receiving usual care. The encouragement to keep drinking was easier to apply for most educated patients than to keep eating. Patients' application of the fasting instructions was influenced by their perspectives on fasting, their experienced discomfort, professional support, and biological rhythm. Patients' perspectives towards fasting and eat/drink instructions and their motivation influenced how they were willing to apply these instructions. Professional support appeared to be important for patients to optimally plan their last meal and drink before a procedure in their biological rhythm. In the educated patient group, gastric visibility was maintained, and they experienced significant less thirst, hunger, headache, and anxiety.

In conclusion, fasting habits in daily practices remain erroneously longer than recommended in guidelines. Despite updates of the guidelines and improvements in surgery, too much patients are not aware of the current fasting instructions. Too prevent patients from prolonged fasting, nurses should inform their patients with adequately before anaesthetic procedures. Nurses should provide them with concrete instructions on the exact time that patients should consume a particular product. This approach of patients education appeared especially feasible for adequate fasting

from liquids. For adequate fasting from solid foods, it's recommended to eat until 6 hours before the procedure or before bedtime for patients who are scheduled for a procedure in the morning. Patients who are scheduled in the afternoon can eat early in the morning. Future studies should address other barriers in order to achieve optimal fasting behaviour.

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Samenvatting

Een operatie ondergaan vraagt een goede conditie en goede voedingsstatus omdat hiermee herstel na de operatie vlotter zal verlopen. Patiënten met (risico op) ondervoeding hebben ondersteunende voedingszorg nodig. Verpleegkundigen kunnen tijdens het preoperatieve spreekuur voedingszorg initiëren en patiënten voorlichten over wat goed eten vóór een operatie inhoud. Echter ontbreekt wetenschappelijk bewijs voor deze essentiële verpleegkundige zorg en worden patiënten vaak niet goed voorgelicht. Dit proefschrift beschrijft daarom de ontwikkeling en evaluatie van verpleegkundige voedingszorg voor ondervoede patiënten die een operatie ondergaan. Ook wordt de naleving en de haalbaarheid van de het nuchterbeleid onderzocht. De belangrijkste bevindingen worden hieronder weergegeven.

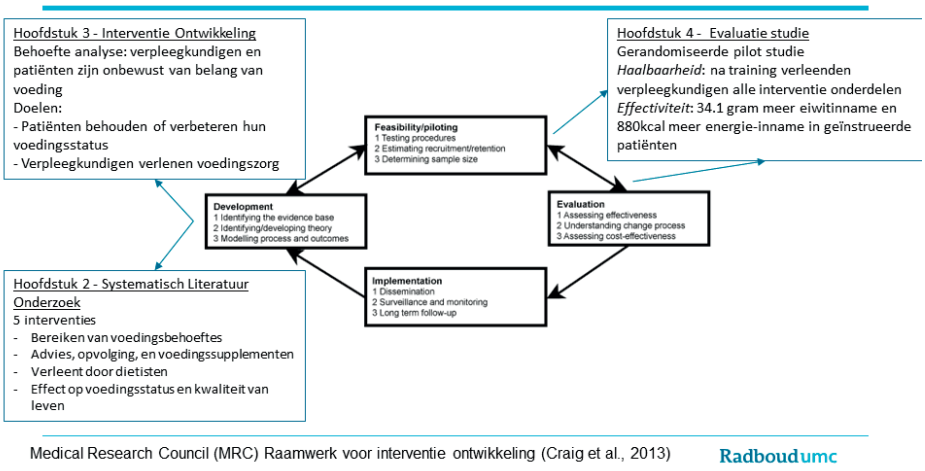
Preoperatieve voedingszorg

In deel 1 van dit proefschrift gaat over de ontwikkeling van een verpleegkundige voedingsinterventie voor patiënten met ondervoeding. Hiervoor worden de fases van het MRC raamwerk gevolgd. Dit raamwerk ondersteunde de ontwikkeling en evaluatie van een complexe interventie voor ondervoede chirurgische patiënten (figuur 1).

De eerste stap hierin is beschreven in hoofdstuk 2. Een literatuuronderzoek werd gedaan om de componenten van voedingszorg waarbij patiënten reguliere voedingsproducten eten in kaart te brengen. Er werden zes artikelen in de literatuurstudie meegenomen die gezamenlijk 5 interventies beschreven. Deze interventies richtten zich op het behalen van voedingsbehoefte, en bestonden uit begeleiding en informeren, herhaalafspraken, aanmoedigingen, en voedingssupplementen. Deze componenten werden door diëtisten uitgevoerd, er waren geen studies waarin verpleegkundigen hierin het voortouw hadden. Patiënten die deze voedingszorg ontvingen hadden een verbetering van hun voedingsstatus, voedingsinname en kwaliteit van leven. Patiënten die begeleiding rondom voeding kregen hadden betere uitkomsten dan patiënten die alleen voedingssupplementen kregen. De componenten van voedingszorg vormden de basis van een nieuw-ontwikkelde verpleegkundige voedingsinterventie aan patiënten met ondervoeding die geopereerd gaan worden.

In hoofdstuk 3 wordt de ontwikkeling van deze interventie beschreven. De ontwikkeling werd gestructureerd door *Intervention Mapping* (IM) te gebruiken. Een onderzoeksgroep volgde de zes stappen van IM. De eerste stap was het inventariseren van behoeftes van verpleegkundigen rondom verlenen van voedingszorg, en van patiënten rondom het verbeteren van hun voedingstoestand. Het bleek dat zowel verpleegkundigen en patiënten onbewust waren van de consequenties van

ondervoeding, en dat verpleegkundigen onbewust waren van hun rol in het verlenen van voedingszorg. Dit inzicht werden meegenomen in de interventieontwikkeling.



Figuur 1- Overzicht van resultaten per fase van het MRC raamwerk voor verpleegkundige voedingszorg

Doelen van de verpleegkundige voedingsinterventie waren de voedingsstatus van patiënten te verbeteren en voor verpleegkundigen het verlenen van voedingszorg. Hiervoor werd de voedingsinterventie met een training voor verpleegkundigen ontwikkeld. De verpleegkundige voedingsinterventie bestaat uit vijf verschillende componenten, en bestaat uit het achterhalen van oorzaken van ondervoeding, het informeren over voeding rondom op de operatie en over acties om de oorzaken van ondervoeding te verminderen, het bijhouden van eigen voedingsinname, het achterhalen van mogelijke barrières en aanmoedigen om voedingsinname te verbeteren. In een telefonisch consult na een week vindt evaluatie van de doelen plaats. Vervolgens is de verpleegkundige interventie in een gerandomiseerde studie geëvalueerd op haalbaarheid en effectiviteit.

Hoofdstuk 4 beschrijft de volgende fase in het MRC raamwerk: de evaluatie van de haalbaarheid en effectiviteit van de verpleegkundige voedingsinterventie. Verpleegkundigen van twee poliklinieken werden gerandomiseerd tot het verlenen van standaardzorg of de interventie waarvoor ze eerst de training volgden. Vervolgens werd de voedingsinterventie verleend terwijl de training werd afgerond. Achtenveertig patiënten namen deel tijdens deze haalbaarheidsfase. Aan het einde van de haalbaarheidsfase verleenden de verpleegkundigen alle interventiecomponenten. Voor de effectevaluatie werden in totaal 152 patiënten geïncludeerd van wie 67 (43%)

de interventie ontvingen. Patiënten in de interventie groep had meer eiwit en energie-inname en behaalden vaker de voedingsbehoeftes vergeleken met de patiënten die standaardzorg ontvingen.

Samenvattend, de eerste drie studies in dit proefschrift laten zien dat preoperatieve voedingszorg middels reguliere voedingsproducten goed verleend kan worden door een set van interventiecomponenten. Een verpleegkundige voedingsinterventie werd ontwikkeld, en bleek haalbaar bleek in de praktijk. De wetenschappelijke ontwikkelde verpleegkundige voedingsinterventie leidde tot betere voedingsinname door ondervoede patiënten die een operatie ondergaan.

Nuchter blijven

Het tweede deel van dit proefschrift omschrijft de naleving van richtlijnen omtrent het nuchter houden vóór een operatie en snelle hervatten van orale voedingsinname na een operatie. Kort voor de operatie is het verplicht voor patiënten om nuchter te blijven ter preventie van aspiratie van maaginhoud in de longen. Nuchter blijven betekent niet eten gedurende 6 uur voor de operatie en niet drinken gedurende 2 uur voor de operatie. Na de operatie raden de richtlijnen voor verbeterd herstel na een operatie (ERAS) aan om de orale inname zo snel mogelijk te herstellen. In hoofdstuk 5 werd de naleving van de anesthesiologische en ERAS-richtlijnen onderzocht in twee Nederlandse ziekenhuizen (13). Dit werd gedaan in twee observatieperiodes met een tussenperiode van 10 jaar, namelijk 2009 en 2019. In totaal werden 311 patiënten geïncludeerd, van wie 127 (40,9%) patiënten in 2009. Preoperatief vasten van vast voedsel en heldere vloeistoffen was verlengd in 280 (90,3%) en 208 (67,8%) van de patiënten over beide perioden. Mediane preoperatieve duur van nuchter zijn 15:19 uur (IQR 13:00 - 18:19 uur) voor vast voedsel en 5:15 uur (IQR 2:25-11:26 uur) voor heldere vloeistoffen. Tussen 2009 en 2019 werden geen verschillen in duur van nuchter zijn en adequaat nuchter blijven gevonden. Na de operatie hervatten patiënten de orale inname van vast voedsel binnen een mediaan van 5:35 uur (IQR 03:32 - 14:52 uur) en van heldere vloeistoffen binnen een mediaan van 2:56 uur (IQR 1:38 – 4:13 uur). Totale afwezigheid van orale inname was 23:46 uur (IQR 20:00 – 30:30 uur) voor vast voedsel en 11:00 uur (IQR 7:53 – 16:00 uur) voor heldere vloeistoffen. Patiënten bleken te zijn geïnstrueerd om vanaf middernacht nuchter te blijven. Bovendien was de helft van de patiënten niet op de hoogte van het interval dat ze niet mochten eten en drinken. Er werd geconcludeerd dat patiënten nog steeds te vroeg stoppen met eten en drinken, wat leidt tot onnodig lange nuchtere perioden. Verder werd de aanbeveling om ‘tot zes en twee uur voor de operatie blijven eten en drinken’ nog steeds slecht uitgevoerd.

Hoofdstuk 6 beschrijft hoe deze aanbeveling voor nuchter blijven kan worden toegepast door patiënten om langdurig vasten te voorkomen. Volgens hoofdstuk 5 en andere onderzoeken kan voorlichting aan de patiënt over het nuchter blijven onnodig lange nuchtere periodes voorkomen. Daarom werd een prospectieve, gecontroleerde pilotstudie uitgevoerd in één ziekenhuis om de toepasbaarheid en de effectiviteit van voorlichting over het nuchter beleid te evalueren bij poliklinische patiënten die gastroduodenoscopie ondergaan. Uitkomsten waren de toepasbaarheid volgens het perspectief van patiënten, de daadwerkelijke naleving van de aanbevelingen, maagzichtbaarheid en comfort van de patiënt. Na observatie van de nuchterduur bij 67 (61%) patiënten tijdens de standaard zorgverlening, werd een interventiegroep van tweeënveertig patiënten (39%) door een verpleegkundige voorgelicht over het waarom, hoe en wat van nuchter blijven. Hierdoor hadden deze patiënten een kortere nuchtere periode in vergelijking met de controlegroep. De duur dat geen vaste voeding werd gegeten was drie keer vaker adequaat, en de duur dat geen heldere dranken werden gedronken was tien keer vaker adequaat bij de geïnstrueerde patiënten in vergelijking met patiënten die de gebruikelijke zorg kregen. De aanmoediging om te blijven drinken was voor de meeste geïnstrueerde patiënten gemakkelijker toe te passen dan om te blijven eten. De toepassing van het nuchterbeleid door patiënten werd beïnvloed door hun perspectieven op nuchter blijven, hun ervaren ongemak, professionele ondersteuning, en biologisch ritme. De perspectieven van patiënten op het nuchter blijven, en op de eet- en drinkinstructies en hun motivatie waren van invloed op hoe zij bereid waren deze instructies toe te passen. Professionele ondersteuning bleek belangrijk te zijn voor patiënten om hun laatste maaltijd en drankje voor een ingreep optimaal in hun biologische ritme te plannen. De voorgelichte patiënten hadden een goede zichtbaarheid van de maag en ze ervoeren significant minder dorst, honger, hoofdpijn en angst.

De implementatie van het nuchterbeleid moet concrete instructies bevatten over het exacte tijdstip waarop patiënten nog een bepaald product kunnen consumeren. Deze benadering bleek vooral geschikt voor het nuchter blijven voor heldere dranken. Om onnodig lange nuchter periodes voor vast voedsel te voorkomen, wordt aanbevolen om te eten tot 6 uur voor de procedure en in ieder geval voor het slapengaan voor patiënten die ‘s ochtends een procedure moeten ondergaan. Patiënten die ‘s middags worden ingepland, kunnen ‘s ochtends vroeg eten. Toekomstige studies moeten de andere barrières aanpakken om het optimale nuchtere gedrag te bereiken.

Data management plan

This thesis is based on the results of human studies which were conducted in accordance with the principles of the declaration of Helsinki. The medical and ethical review boards of the participating hospitals reviewed all studies in this thesis. The Committee Research Involving Human Subjects Region Arnhem Nijmegen, Nijmegen, the Netherlands has given approval to conduct the study on preoperative nutritional nursing support at two outpatient clinics. The fourth study (chapter 5) was approved by the committees of Gelderse Vallei and Amsterdam UMC. The fifth study (chapter 6) was approved by the Medical Ethical Committee of Wageningen University & Research, Wageningen, The Netherlands.

The protocol, the data, and, output of all studies are stored on the server of Radboudumc, department IQ healthcare: I:\Sectie3_NAHC\Basic Care Revisited\BCR_Eating\Polikliniek studies. For the fourth study which took place in 2019, the forms in paper used in the Gelderse Vallei are stored in the research archive of the Gelderse Vallei Hospital, Ede. Paper data were entered into Castor EDC. The non-anonymous data of the Amsterdam UMC are stored under supervision of Dr. Anne Eskes, while other data were directly collected and managed with Castor EDC. Anonymous data of 2009 were shared by Prof. Dr. Dirk Ubbink, AUMC, and Prof. Dr. Ben Witteman, and are secondary stored at the server of the department of IQ. For the fifth study (chapter 6), paper forms are stored in the research unit of the Gelderse Vallei Hospital, Ede. All data were entered in Castor EDC. Privacy of patients who participated in one of each of the four studies was encrypted and did receive a unique participant number. These codes were stored separately from study data as is according to the norms of data storage. All the quantitative data were analysed in SPSS after conversion from Castor EDC.

Funding

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Storing and sharing

The data will be saved for 15 years after termination of the study (July 1, 2036). The datasets analysed during these studies are available from the corresponding author on reasonable request.

Curriculum Vitae

Harm van Noort (11 augustus 1989, Lienden) behaalde zijn VWO diploma aan het Ichthus College te Veenendaal in 2007. Daarna studeerde hij HBO-Verpleegkunde aan Christelijke Hogeschool Ede (CHE) te Ede. Na zijn diplomering in 2010 startte hij in Ziekenhuis Gelderse Vallei (ZGV) direct met de opleiding tot Medium Care verpleegkundige. Om meer klinische ervaring op te doen werkte hij vervolgens op de verpleegafdeling abdominale chirurgie, vaat&trauma chirurgie, en op de nefrologie/ interne geneeskunde. In 2012 werd hij lid van de Verpleegkundige Advies Raad, waar hij ook enige tijd vicevoorzitter van was. In 2015 rondde hij de master verpleegingswetenschappen af aan de Universiteit Utrecht.

Vervolgens werkte hij als verpleegkundig wetenschapper in ZGV en startte hij parttime als docent bij de opleiding Verpleegkunde aan de CHE. Als docent Verpleegkunde was Harm betrokken bij EBP onderwijs en afstudeerbegeleider voor zowel voltijd al deeltijd studenten, en was hij examinator in jaar 4. Hij rondde hiertoe de basiskwalificaties examinering en afstudeerbegeleiding af. Als verpleegkundig wetenschapper in ZGV deed Harm een onderzoek naar dorst op de afdeling nefrologie.

In september 2016 startte Harm als junior onderzoeker in het project Basic Care Revisited. Dit project om wetenschap te generen voor Essentiele Zorg werd uitgevoerd door o.a. IQ healthcare van het Radboudumc. Vanuit ZGV werkte hij in dit project mee aan de ontwikkeling van verpleegkundige voedingszorg. Gedurende 4,5 jaar was hij zowel docent Verpleegkunde als verpleegkundig wetenschapper in ZGV én buitenpromovendus bij IQ healthcare. Dit leverde in maart 2020 de Young Professional Award op die tijdens het Voeding NL congres in Utrecht werd uitgereikt. In de 1e COVID golf in 2020 werkte hij mee op de COVID-afdeling in ZGV. In juni 2020 maakte Harm een overstap naar het Radboudumc als verpleegkundig wetenschapper op de verpleegafdeling Chirurgische oncologie, MDL, en High Flow Unit. Als fulltime verpleegkundig wetenschapper combineert hij 2 dagen patiëntenzorg met zijn taken als onderzoeker. Om onderzoek voor de chirurgische patiënt te verbeteren was hij mede-initiator van het netwerk de Dutch Science in Surgical Nursing Group.

Harm is getrouwd met Krijnie van Noort-Maliepaard. Samen hebben zij drie kinderen, Tessa (2013), Jasmijn (2015) en Julius (2022).

List of publications

This thesis

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Harm van Noort, Esther Cruijsen, Roos de Pie, Nancy Janssen, Elbrich Postma. Smaakveranderingen bij chemotherapie gemeten. NED TIJDSCHR VOOR VOEDING & DIËTETIEK. 2020;75(5):28-9.
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Awards, grants and nomination

2019 Grant for study to educate patients regarding fasting before undergoing gastro-duodenoscopy. Granted by the Research Fund of the Ziekenhuis Gelderse Vallei, Ede
2020 Award for Young Professional with vision for nutrition and health in nursing as part of the application ‘nutritional nursing care during surgical procedures’. The ‘Young professional Award’ was granted by VoedingNL.
2020 Nomination for the 22nd Anna Reynvaan Wetenschapsprijs with the paper ‘An outpatient nursing nutritional intervention to prehabilitate undernourished patients planned for surgery: A multcentre, cluster-randomised pilot study’.

2021 Award for best abstract during the 14th Nationale Voedingscongres with the paper 'Fasting habits over a 10-year period: observational study on adherence to preoperative fasting and postoperative restoration of oral intake in 2 Dutch hospitals'.

Research profiles
LinkedIn www.linkedin.com/in/harmvannoort
ORCiD 0000-0001-9467-8434
ResearchGate www.researchgate.net/profile/Harm-Noort-2

PhD Portfolio

Name PhD candidate:
Harm H.J. van Noort
Department:
Department of Surgery
IQ healthcare
Graduate School:
Radboud Institute for Health Sciences

PhD period:
23-12-2016 t/m 1-4-2022
Promotors:
Prof. Dr. H. Vermeulen
Prof. Dr. B.J.M. Witteman (Wageningen University & Research)
Co-promotor:
Dr dr. G. Huisman – de Waal

	Year(s)	ECTS
TRAINING ACTIVITIES		
a) ***Courses & Workshops***	2016	0.1
- PubMed Workshop	2016	0.1
- Endnote workshop	2017-2022	3
- PhD meetings Nursing Science	2016-2017	0.8
- BCR-nutrition besprekingen	2017	3
- Course Scientific Writing	2018	1.5
- BROK course	2018	1
- Journal Club Klinimetrie	2019	1
- Course Scientific Integrity	2019-2021	0.5
- WUR MENU-D besprekingen	2019	2.5
- Summer School European Academy of Nursing Science	2020	1.5
- Course Presentation skills	2021	1.75
- Summer School European Academy of Nursing Science	2022	1.00
- Course Grant Writing and Presenting for Funding Committees	2022	1.75
- Summer School European Academy of Nursing Science*		
b) ***Seminars & lectures^***	2017	0.25
- Wetenschapsavond ZGV	2017	0.25
- Presentatie voedingsonderzoek verpleegkunde aan WUR studenten		
- Presentatie PhD-traject voor CHE-collega's	2017	0.25
- V&VN Reumatologiecongres	2018	0.2
- abstract committee of the RIHS PhD Retreat 2019	2019	0.1
- Wetenschapsavond ZGV	2019	0.25
- Lezing Tandartsenkring Regio Ede-Wageningen	2019	0.25
- Presentatie PhD-traject EANS summerschool	2019	0.25
- Lezing EBP Nursing	2021	0.5

c) ***Symposia & congresses^***	2016	1.5
- 5th European Nursing Congress, Rotterdam, 2 posters	2017	0.2
- Tussen Weten en Doen II, Utrecht, 1 poster	2017	0.5
- ESPEN 2017, Den Haag, 1 poster	2018	0.25
- Nationale voedingscongres, Veenendaal 1 poster	2018	0.2
- Tussen Weten en Doen II, Nijmegen, 1 oral	2019	1.5
- CARE 4, Leuven, 1 oral, 1 poster	2019	0.5
- ILC Denmark, Aalborg	2020	0.2
- Symposium Voedingszorg rondom de Operatie in ZGV	2020	0.25
- Voeding NL, 1 oral	2021	0.2
- Seminar Alliantie voeding, online, 1 Oral	2021	0.5
- ESPEN 2021, online, 1 poster	2022	0.25
- Nationale Voedingscongres, online, 1 oral	2022	1.0
- CARE4 congres, 1 oral	2022	0.5
- V&VN Oncologiedagen	2022	0.25
- Summer Conference European Academy of Nursing Science, 1 poster		

TEACHING ACTIVITIES

a) ***Lecturing***	2017	1.0
- Scholing Verpleegkundige Ontwikkeldagen Streekziekenhuis Koningin Beatrix, Winterswijk	2019-2022	0.6
- Review scientific publications (n=6)	2020	3
- Basis kwalificatie afstudeerbegeleiding (BKA)	2020	3
- Basis kwalificatie examinering (BKE)		
b) ***Supervision of internships / other***	2016-2021	23.0
- 23 projects with bachelor students, Verpleegkunde, HAN / CHE		
- 3 projects with bachelor students, Mondzorgkunde, HU	2018-2020	3.0
- 1 project with bachelor students Voeding & Diëtetiek, HAN	2021	1.0
- 3 master students, Clinical Health Science - Nursing Science, Utrecht University	2019-2022	3.0
TOTAL		**66.95**

*intended at 4th- 8th of July, 2022 in Vilnius, Lithuania

Radboud University Radboudumc university medical center

Dankwoord

Mijn promotieonderzoek is klaar. Af. Om deze studies zit een kaft, met mijn naam erop. En hoewel ik daar trots op ben, besef ik me meer en meer dat deze eer niet evenredig verdeeld is. Want gedurende dit hele traject heb ik een enorm goed team om me heen gehad, stimulerende collega's gehad, veel mooie mensen leren kennen en van kunnen leren, en altijd een fijne thuisbasis gehad. Tijdens de projecten was de bijdrage van patiënten cruciaal. Zonder respondent geen data, zonder data geen onderzoek. Jullie allen hartelijk dank voor jullie openheid en bijdrage. En naast patiënten, heb ik op heel veel verschillende manieren vaardigheden opgedaan, of ben ik aangestuurd of bijgestuurd of wat dan ook, die leidde tot dit proefschrift. Om iedereen dan nu te noemen is onbegonnen werk. Toch ga ik een poging doen om iedereen te bedanken.

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Dan **Prof. dr. Ben Witteman**. Beste Ben, hoewel je wat later betrokken raakte, was je al snel niet meer weg te denken. Je was een welkome aanvulling in het team. Je medische blik was een toevoeging op onze verpleegkundige focus. Voor concepten die voor mij als verpleegkundige vanzelfsprekend geworden waren dat niet direct ook voor jou als medicus. Je daagde me uit om mijn teksten aan te scherpen voor een bredere doelgroep en het daarmee nog duidelijker uit te leggen. Je bent enthousiast, ziet altijd mogelijkheden, en liet zien een kundige en gedreven arts te zijn. Dank voor

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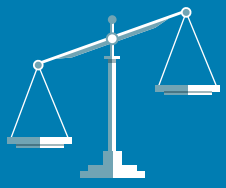
...

Giving seed tot the sower, bread for the hunger
So shall the word of the Lord be with a sound like thunder

...

We shall be led in peace
And go out with joy



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