Malnutrition in subacute care

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General Declaration

In accordance with Monash University Doctorate Regulation 17.2 Doctor of Philosophy and Research Master's regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes one original paper published in a peer reviewed journal. The core theme of the thesis is malnutrition in subacute care. The ideas, development and writing up of the paper in the thesis was the principal responsibility of myself, the candidate, working within the Department of Nutrition and Dietetics under the supervision of Kate Huggins (primary supervisor).

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team based research.

Publication title Thesis Publication Nature and extent of chapter candidate's contribution status 3 100% search, data extraction, The effect of interventions to prevent Published and treat malnutrition in patients analyses; 80% manuscript admitted for rehabilitation: a preparation and revision; 50% systematic review with meta-analysis article selection, quality rating

In the case of chapter 3 my contribution to the work involved the following:

I have renumbered sections of published paper in order to generate a consistent presentation within the thesis

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Summary

Malnutrition is a significant problem across all healthcare settings because of its high prevalence and association with adverse outcomes for patients and increased healthcare costs. There is a paucity of research considering subacute patients' nutritional status and how this changes throughout inpatient stay. Additionally, a stronger evidence base for strategies to prevent and treat malnutrition specifically in this setting is required. This thesis aimed to address these research gaps to contribute to evidence based recommendations for clinical practice, healthcare policy and identify areas for future nutrition research.

A series of four related research investigations were conducted. An observational study (n=249) explored change in nutritional status during subacute care. Under usual conditions, nutritional status assessed with the full Mini Nutritional Assessment® improved for 27.7% of participants, did not change for 62.0% and deteriorated for 10.3%, which was associated with discharge to higher level of care. There were inconsistencies in findings using objective indicators and nutrition assessment tools to evaluate change in nutritional status. A systematic literature review identified few (n=10) studies exploring the effect of oral nutrition interventions among subacute patients. There was some evidence in favour of oral nutritional supplements and energy dense meals for increasing dietary intake, but other nutritional and functional outcomes were absent or inconsistent.

This prompted the design and evaluation of a novel nutrition intervention integrating a higher energy menu and an enhanced mid-meal delivery. A parallel controlled pilot study (n=122) tested its effects on patient-related outcomes and estimated the cost in comparison to the standard menu and usual foodservice. A complementary process evaluation used qualitative description and theoretical frameworks of behaviour change and implementation research to explore the experiences of foodservice staff (n=15) responsible for delivering the nutrition intervention.

It was demonstrated that participants who received the food and service based intervention had greater intake at day 14 of inpatient stay (mean difference (95% CI), 27 (9 – 44) kJ/kg/day, 0.3 (0.0 – 0.5) g protein/kg/day) and no reduction in

satisfaction with the foodservice. The additional cost of the intervention was AU\$7.47/participant/day. Five themes were identified, describing that implementation of the intervention was influenced by the: foodservice staff, patients, nutrition intervention, environment and implementation process. In particular, foodservice structure, time pressure and patients' resistance affected perceived sustainability and feasibility of the intervention. Foodservice staff's knowledge, beliefs and perceptions affected protocol fidelity.

Overall this research emphasised the variability in change in nutritional status under usual care or in response to nutrition intervention in the heterogeneous subacute patient group. Adequate multidisciplinary nutritional care, in conjunction with dietetic intervention, are essential to support the nutritional status of all patients throughout subacute inpatient stay. Nursing staff and dietitians need to give greater attention to monitoring patients' nutritional status during inpatient stay using appropriate tools to detect change. Increased recognition of the role the foodservice system and workforce plays in nutrition care is required. Future clinical and translational research that builds on these findings will assist to shape cost and clinically effective patient care to address malnutrition in subacute care.

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List of in text abbreviations

ANOVA	analysis of variance
ANCOVA	analysis of covariance
AROC	Australasian Rehabilitation Outcomes Centre
BIA	bioelectrical impedance analysis
BMI	body mass index
CC	calf circumference
CFIR	Consolidated Framework for Implementation Research
CI	confidence interval
COPD	chronic obstructive pulmonary disease
COM-B	Capability-Opportunity-Motivation Behaviour
FIM	Functional Independence Measure
FFM	fat free mass
FSA	foodservice assistant
FSS	foodservice supervisor
GEM	Geriatric Evaluation and Management
HGS	hand grip strength
IQR	interquartile range
LOS	length of stay
MAC	mid arm circumference
MDC	major diagnostic category

- Full MNA® Mini Nutritional Assessment (18 item tool)
- MNA® Mini Nutritional Assessment (6 item tool) (MNA®-SF)
- MST Malnutrition Screening Tool
- NCP nutrition care process
- NHMRC National Health and Medical Research Council
- ONS oral nutritional supplement
- RCT randomised controlled trial
- RR relative risk
- SD standard deviation
- SEM standard error of the mean
- SGA Subjective Global Assessment
- TDF Theoretical Domains Framework
- WMD weighted mean difference

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Chapter 1

Introduction

1.1 Context of this thesis

"Every careful observer of the sick will agree in this, that thousands of patients are annually starved in the midst of plenty..."

Florence Nightingale, 1860 (1) (page 63)

Over 150 years ago, nursing pioneer Florence Nightingale spoke of the high prevalence of inadequate dietary intake occurring among hospitalised patients. Despite advances in medicine, healthcare and nutrition, to this day, inadequate intake remains common in the healthcare setting, leading to impaired nutritional status. Malnutrition is highly prevalent among hospitalised patients worldwide and it increases risk of mortality, morbidity and healthcare costs. A number of factors put patients at risk of malnutrition. If left unchecked, exposure to these factors during hospitalisation may result in nutritional decline among patients who are well nourished or further deterioration among those who are already malnourished or at risk of malnutrition.

Importantly, malnutrition is largely responsive to nutritional therapy and therefore, the key to addressing malnutrition lies in the provision of nutritional care and dietetic intervention that is adequate, effective (i.e. evidence based) and accepted by patients. Healthcare facilities have a duty of care to deliver on this, which requires creating supportive social, cultural, economic and physical environments. This thesis malnutrition in subacute care investigates the longstanding and significant problem of hospital malnutrition, specifically considering subacute care; a fundamental service in the modern and future healthcare system.

1.2 Defining key terms

1.2.1 Malnutrition

Malnutrition is a condition of "deficiency, excess or imbalance of energy, protein and other nutrients causing measurable adverse effects on tissue/body form (body shape, size and composition), function or clinical outcome" (2) (page 3). This broad description captures a spectrum of nutrient imbalance, ranging from over nutrition (obesity) to under nutrition, and implicating energy, macronutrients or micronutrients. This thesis refers to malnutrition synonymous with under nutrition. Protein-energy malnutrition, disease-related malnutrition or hospital malnutrition are used in the literature to describe this condition. Nutritional status exists on a continuum from well nourished, at risk (i.e. short term inadequate dietary intake) through to severe malnutrition, with progressive decline anticipated if antecedents are not managed.

It is acknowledged that consistent definition, nomenclature, operationalism or diagnostic criteria for malnutrition recognised internationally are lacking. This has led to multiple efforts for consensus among expert organisations on the characteristics for malnutrition (3-6). This has been a dynamic process with some progress achieved over time. Consequently, there exists a range of recommended criteria proposed for the diagnosis of malnutrition (Box 1:1). The most recent recommendations suggest identifying malnutrition using body mass index (BMI), weight loss and fat free mass (FFM) (3). In addition, nutrition assessment tools can also be used to identify malnutrition (section 1.3.4).

Malnutrition can be further delineated into three sub-classifications that reflect its aetiology: [1] cachexia (severe loss of muscle and fat mass driven by disease related inflammation); [2] sarcopenia (age related loss of muscle mass (7, 8)) and; [3] starvation (pure deficiency of energy and protein intake (9)). Inflammation causing muscle catabolism, reduced appetite and altered requirements is the hallmark of cachexia and has been implicated in sarcopenia (7-9). In practice, patients may present with a combination of cachexia, sarcopenia and/or starvation and this terminology is not widely used or understood by dietitians (10, 11). Throughout this thesis these sub-classifications have not been distinguished however the implications of the aetiology of malnutrition are considered in chapters 2, 4 and 6.

Box 1:1 Criteria recommended by international organisations for the diagnosis of malnutrition

European Society of Clinical Nutrition and Metabolism, 2015 (3)

- BMI <18.5 kg/m²
- Unintentional loss of weight >10% indefinitely or >5% in the previous 3 months PLUS FFM index <15 kg/m² in women or <17 kg/m² in men OR PLUS BMI <20 kg/m² if <70 years or <22 kg/m² if ≥70 years

Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition, 2012 (4)^a

Two or more of the following characteristics:

- Inadequate energy intake
- Unintentional weight loss
- Loss of muscle mass^b
- Loss of subcutaneous fat mass^b
- Localised or generalised fluid accumulation^b
- Diminished functional status measured by HGS^c

Clinical nutrition expert group, 2010 (5)^d

- Low BMI
- Unintentional weight loss
- No nutritional intake

National Institute for Health and Care Excellence, 2006 (12)

- BMI <18.5 kg/m²
- Unintentional loss of weight >10% in the previous 3 6 months
- BMI <20 kg/m²
 - PLUS unintentional loss of weight >5% in the previous 3 6 months

BMI, body mass index; FFM, fat free mass; HGS, hand grip strength

^aspecific cut offs are provided for moderate or severe malnutrition in the context of acute illness or injury, chronic illness or social or environmental circumstances

^bassessed by physical examination, level of depletion judged subjectively

^clevel of depletion judged subjectively in comparison to manufacturers standards for HGS

^dcut offs not provided as expert panel unable to come to consensus

1.2.2 Subacute care

Internationally, there is inconsistent terminology to describe non-acute care (e.g. subacute care, continuing care, intermediate care, post-acute care, re-enablement etc.). In Australia, subacute care is defined as multidisciplinary, patient-centred care with the aim of optimising patients' function and quality of life and is delivered under the streams of rehabilitation, Geriatric Evaluation and Management (GEM), palliative care or psychogeriatric care (13). Facilities internationally providing comprehensive geriatric assessment, a key feature of GEM, may be referred to as acute care for elders or geriatric rehabilitation wards (14).

In this thesis, subacute care refers to goal based care that seeks to improve function and independence in activities of daily living, delivered through rehabilitation and GEM inpatient services. Typically patients are older adults, debilitated due to acute and/or chronic illness and/or social factors. Patients admitted to rehabilitation present with an "impairment, activity limitation or participation restriction due to a health condition" in contrast, GEM patients have "multidimensional needs associated with medical conditions related to ageing" (e.g. falls, reduced mobility or cognitive impairment), potentially in addition to complex psychosocial problems (13) (pages 11-12). The primary reasons for admission are varied (13) and a number of comorbidities may be present.

Subacute inpatient services play an essential role in the healthcare landscape, bridging the gap between acute hospital and the community (Figure 1:1). The growing demand for and importance of subacute care will continue into the future due to the ageing population (15, 16). The average length of inpatient stay in subacute care is 12.1 days in the United States (107), 16.2 days in Australia (108) and 23 days in the United Kingdom (109). This critical window provides a fundamental opportunity for elderly patients to make functional gains, reduce the risk of mortality and the likelihood of discharge to residential aged care, thereby potentially reducing healthcare costs and maintaining quality of life (17). However, an overlay of malnutrition may jeopardise the potential benefits that may be achieved during subacute inpatient stay.

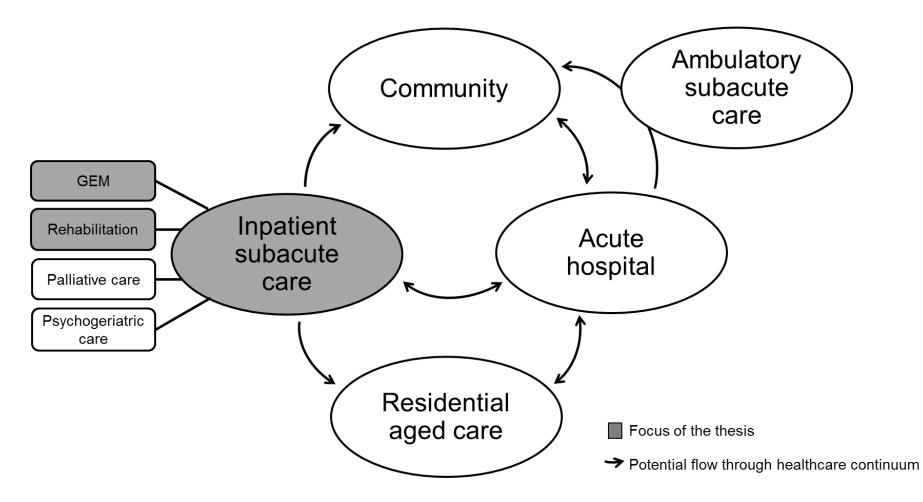


Figure 1:1 Simplified schematic of the position of inpatient subacute care services within the healthcare landscape

GEM, Geriatric Evaluation and Management

GEM, rehabilitation, palliative care and psychogeriatric care are streams of subacute care in Australia Nutrition intervention

Nutrition intervention is defined as "purposefully planned actions designed with the intent of changing a nutrition-related behaviour, risk factor, environmental condition, or aspect of health status for an individual, target group" (18) (page 1066). In the context of this thesis it refers to oral based (i.e. eating and drinking) processes or strategies undertaken by an organisation, department, multidisciplinary team or health professional to support the nutritional status of patients. Enteral or parenteral nutrition should be considered only after interventions via the oral route have been exhausted or are contraindicated, and are not considered in this thesis (12).

Nutrition intervention is used in this thesis as an umbrella term encompassing nutrition care and dietetic intervention. The recipients and providers are reflected in this distinction. Nutrition care is available to all patients, regardless of their nutrition status, and is broad patient care that aims to maximise nutrient intake or minimise the risk of or identify inadequate intake (19). It relates to systems or structures occurring at a ward or department level including clinical care processes, foodservice interventions and enhanced eating environments (defined and discussed further in chapter 3). Nutrition care is the responsibility of the multidisciplinary team, although nursing, foodservice staff and dietitians play a central operational role. In contrast, dietetic intervention is targeted; tailored to meet the individual needs of a patient with a nutrition diagnosis (i.e. malnutrition, malnutrition risk, inadequate intake). This is provided by a dietitian as part of the standardised Nutrition Care Process (NCP) (18). Oral nutritional supplements (ONS), dietary prescription and dietary counselling are common oral nutrition dietetic interventions.

1.3 Background

The nutritional status of subacute patients is of significance since it can make a difference to their outcomes and experience during inpatient stay, and their quality of life, health and longevity more broadly.

1.3.1 Prevalence of malnutrition

Malnutrition is unfortunately common in healthcare settings and among elderly populations due to its association with disease and ageing. Internationally, in subacute care facilities it is reported that between 29 - 51% of patients are malnourished (20-23) and 41 - 62% are at risk of malnutrition (20, 21, 23). While the majority of subacute patients are malnourished or at risk, a proportion are well nourished resulting in a widely heterogeneous population. Higher rates of malnutrition have been reported in rehabilitation units compared to acute hospital (22-24). Due to the nature of the care type, patients moving from acute to subacute care (as opposed to home, with or without ambulatory rehabilitation) are deconditioned and malnutrition is frequently implicated in this clinical picture.

1.3.2 Causes of malnutrition

The aetiology of malnutrition is complex (Figure 1:2). Ultimately, malnutrition results from inadequate dietary intake leading to progressive loss of muscle and fat mass, although disease is inextricably linked to this process. Inadequate intake is all too common among hospitalised patients (25-28). Rehabilitation patients consume significantly less energy and protein compared to estimated requirements, with only a quarter meeting estimated requirements (25). A number of factors may influence patients' ability to consume sufficient food to meet requirements (Figure 1:2).

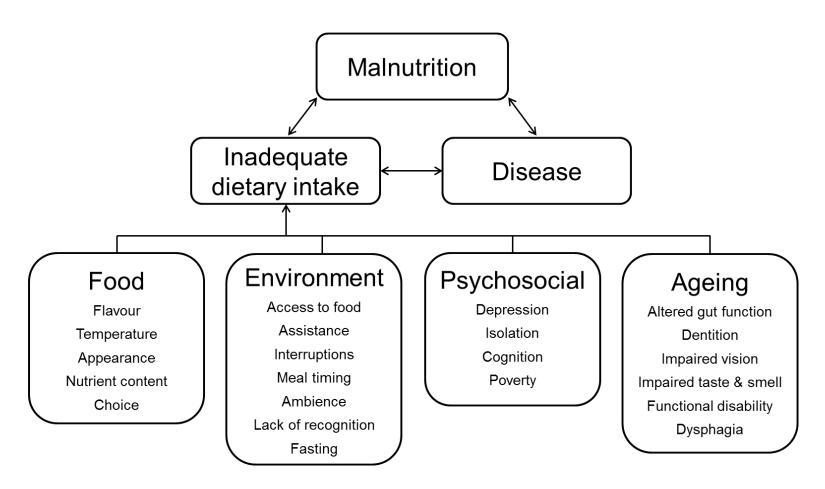


Figure 1:2 Overview of factors contributing to malnutrition

Acute and chronic disease states contribute to inadequate intake and malnutrition directly and indirectly. Anorexia (loss of appetite) often mediates the relationship between disease and inadequate intake. For example, nausea, pain, vomiting and/or drug-related side effects can reduce appetite. Injury, surgery and/or trauma increase or alter demands for energy, protein and other nutrients due to metabolic changes to support inflammatory and recovery processes. Particular disease states can cause malabsorption (e.g. pathology of stomach, intestines, pancreas or liver) or increased nutrient losses (e.g. diarrhoea, vomiting, surgical drains, fistulae, stomas) which further exacerbate requirements to achieve nutrient balance (29).

Psychological and social factors may influence food intake, particularly in the community where they may have long term influence (i.e. years or decades) meaning patients may be admitted to hospital (and subacute care) with well established malnutrition. Socioeconomic disadvantage and social isolation can limit access to food (30, 31). Depression, low mood, anxiety and impaired cognition can affect the ability and desire to prepare and eat food (32). These factors can also exist among hospitalised patients.

Risk of malnutrition increases with age (28, 33). Elderly populations experience additional risk factors for malnutrition due to physiological changes associated with ageing. These are described in a number of reviews and summarised here (32, 34-37). These factors influence the adequacy of dietary intake at multiple points in the process of food consumption. Accessing food (i.e. purchasing and preparing food in the community setting or reaching the tray table and opening packages in the hospital setting) can be inhibited by impaired vision and functional disability, leaving patients reliant on assistance from others. Anorexia of ageing, chemosensory losses in taste and smell and chewing and swallowing difficulties due to poor dentition or dysphagia affect ingestion of food. Changes in gut function (e.g. gastric emptying, hormonal regulation of satiety, absorptive surface) reduce the breakdown, absorption and utilisation of nutrients.

Aspects of the hospital experience and environment may occur to the detriment of nutrition. Flavour, palatability, appearance and variety of food influence intake (38) although hospital food is often sub-optimal in these regards (26, 39-42). Hospital meal time environments are frequently observed to not be conducive to eating, with

issues of poor ambience (smells, lighting etc.), atmosphere and interaction, interruptions or lack of assistance with meal set-up and feeding (43-46). Periods of fasting or absence at meal times due to medical procedures reduce opportunities for eating. Naithani *et al.* (42) identified that inflexible meal times, lack of availability of food between meals and difficulty interpreting menus were barriers to accessing food in hospital.

It stands to reason that the number of risk factors experienced and the duration of exposure will mediate nutritional status and change over time. Subacute patients are predominantly elderly requiring admission as a consequence of disease or for psychosocial reasons. This alone means patients are already vulnerable to malnutrition. Poor environments and poor food further compound the problem however, these factors may be most amenable to change.

1.3.3 Effects of malnutrition

Malnutrition affects almost every organ and body system and has been represented pictorially elsewhere (29, 35). As such, malnutrition has multiple negative consequences for physical and psychological health and recovery from illness. In turn, this has negative implications for the healthcare system. If malnutrition prevalence and incidence of new cases can be reduced this will have benefits for patients and healthcare in terms of cost savings. The interdependent relationship whereby malnutrition is both a consequence and contributor to disease (Figure 1:2, page 9) is of relevance because it is difficult to isolate malnutrition from disease and definitively determine the cause of negative outcomes. However, the consistent findings internationally across different patient groups strengthen the evidence of an association between malnutrition (33, 47-49), malnutrition risk (50) or inadequate intake (27, 48) and detrimental clinical outcomes.

Effects for the patient

There is substantial evidence describing the adverse effects of malnutrition on morbidity and functional impairment. The relationship between nutrition, morbidity and function is particularly important as this likely has a direct impact on malnourished patients' ability to achieve multidisciplinary care goals during subacute inpatient stay. Malnourished patients in acute care experience more complications including infections, impaired wound healing and pressure injuries (47) although this has not been established in the subacute setting specifically (51). It is postulated that the consequences are similar. In subacute care, malnutrition has been associated with longer length of stay (LOS) (20, 21, 51-53) and the likelihood of discharge back to acute hospital (54).

As malnutrition leads to reduced muscle mass, impaired functional status and frailty are observed. Malnourished hospitalised patients are more likely to demonstrate deficits in muscle strength (55, 56), activities of daily living (53, 57, 58) and mobility (59). Impaired nutritional status may impinge on patients' ability to participate in therapy and achieve functional goals during subacute care. A recent study identified 18 – 26% of older malnourished or at risk patients had poor participation in inpatient rehabilitation activities compared to 4% of well nourished patients (51). This study also indicated that malnourished patients had greater functional improvement than well nourished patients receiving the same multidisciplinary care during inpatient rehabilitation, however analyses did not take into account malnourished patients worse functional status on admission (51). Frailty, seen alongside malnutrition and sarcopenia, is associated with impaired mobility, balance, muscle strength, motor processing, cognition, nutrition, endurance (e.g. fatigue and exhaustion) and physical activity (60, 61). Together, these factors impact on independence and quality of life and can lead to institutionalisation following discharge from rehabilitation (62) or acute care among older patients (63, 64).

Malnutrition conveys an increased risk of mortality, independent of disease, among patients with a range of chronic or acute illnesses (47). There is a lack of studies examining this relationship in the subacute setting. Malnutrition has been found to be associated with mortality during admission (24) and following discharge from subacute care in some but not all studies (62). One large (n=2076) retrospective Australian study found the risk of mortality 18 months following discharge from subacute care was 3.4 times greater among older malnourished patients compared to well nourished patients (52). Additionally, multinational cross sectional data indicates an association between inadequate food intake in hospital (consuming \leq 25% of food served) and mortality, independent of nutritional status (27, 48). This illustrates the contribution of food intake in the picture of malnutrition.

Implications for the healthcare system

Greater healthcare time and resources are required to manage the effects of malnutrition which subsequently increases healthcare costs. This occurs in addition to the costs accrued for the primary reason for admission, which are becoming more frequent due to the ageing population. In a largely publically funded healthcare system (e.g. Australia), these costs are incurred by tax payers and therefore have relevance for the wider community. No data have been identified that comprehensively estimates the cost of malnutrition in subacute care. However, estimates from the acute setting that report costs may be up to 21 - 61% higher for patients with impaired nutritional status compared to well nourished patients adequately depicts the gravity of this situation (33, 49, 65, 66).

The economic burden of malnutrition is attributable to the cost associated with providing treatment for complications (e.g. medications to treat infections) and meeting higher care needs (e.g. nursing assistance to complete activities of daily living) over a longer LOS. Bed days make a substantial contribution to the total cost of a healthcare admission. Charlton *et al.* (20) performed a crude economic analysis in 2008 and identified that the difference in LOS between well nourished and malnourished patients (18.5 days) and between well nourished and at risk patients (12.4 days) amounted to AU\$12,765 and AU\$8,556 per patient, respectively. In Australia, there are also economic implications of malnutrition via foregone reimbursement through the case-mix funding model due to under recognition and documentation of malnutrition in medical records (67, 68). The extensive adverse effects of malnutrition described here provide a strong case for identifying and taking action on malnutrition.

1.3.4 Identifying malnutrition

Malnutrition screening

Identifying malnutrition and malnutrition risk is the first step in providing dietetic intervention to those with impaired nutritional status. Lack of recognition and documentation of malnutrition and low rate of dietetic referral for patients at risk of malnutrition have been reported (68-71). This may lead to patients going without the nutrition intervention they require and short falls in hospital funding. In an attempt to

overcome this, a two-step standardised process of malnutrition screening at admission followed by nutritional assessment if required (i.e. screened positive) is advocated by best practice clinical guidelines (12, 72-75) and mandated in some countries (76).

Malnutrition screening is a short, simple process completed by an appropriately trained healthcare professional (usually nursing staff) to identify patients at risk of malnutrition. A number of malnutrition screening tools have been validated for use among subacute patients (54, 77-79). When linked to appropriate follow up (i.e. assessment and intervention) malnutrition screening can improve identification of malnutrition and lead to cost savings through improvement of clinical outcomes (19). Despite greater adoption of malnutrition screening practices in healthcare facilities, lack of or inaccurate screening occurs (80). Audits of malnutrition screening in Australian hospitals report completion rates of 3 - 70% (81, 82). Barriers to screening by nursing staff include competing priorities, knowledge and skills, attitudes and value of clinical judgement (80).

Nutritional assessment

Patients identified as at risk of malnutrition during nutritional screening should be referred to a dietitian for nutritional assessment. This is "a comprehensive approach to defining nutritional status that uses medical, nutritional and medication histories; physical examination; anthropometric measurements and; laboratory data" (83) (page 16). Essentially, this confirms the presence of malnutrition and the factors contributing to its occurrence (e.g. food, environmental, psychosocial, ageing processes or disease related factors). Interpreting this information enables the dietitian to make a nutrition diagnosis and plan and implement tailored intervention/s as part of the NCP (18).

Due to the complexity, dynamic nature and spectrum of nutritional status there is no single, validated tool or method recommended to differentiate between well nourished and malnourished individuals, which presents a significant challenge for researchers and clinicians. In practice, a range of objective and subjective methods are used as surrogate markers of nutritional status. Donini *et al.* (84) describe that nutritional status can be represented by: [1] the balance between nutrient

requirements and intake in the short term; [2] body function in the intermediate term and; [3] body composition in the long term. Assessment of these constructs individually or in combination can be used to provide insight into nutritional status.

Indices of nutritional status

There are a number of objective indicators of nutrition that measure a single parameter known to be associated with nutritional status. These include anthropometric, functional and biochemical measures. Dietary intake can also provide information to provide insight into nutritional status, however due to the bias inherent to dietary assessment means these data are rarely objective. Diagnostic criteria proposed for the diagnosis of malnutrition utilise a range of indicators of nutritional status (Box 1:1, page 4).

Dietary assessment aims to establish the extent to which nutritional requirements are being met. The difficulties associated with estimating energy and nutrient requirements mean that arbitrary estimates or predictive equations are used in the clinical and research settings (85). Similarly, there are a number of methods to assess food or nutrient intake, each with strengths and limitations (86). Prolonged inadequate intake leads to malnutrition, but it is unclear the duration or magnitude of insufficiency that conveys malnutrition risk through to severe malnutrition. Various cut offs have been proposed (4, 12, 27, 48).

Anthropometric measurements identify body weight and states of body composition associated with impaired nutritional status. Weight is a cornerstone of nutritional assessment. Unintentional weight loss, low body weight and low BMI are predictive of worse outcomes (87). Suitable measures of body composition for the clinical setting must be simple, portable and non-invasive, in addition to being valid and reliable. Bioelectrical impedance analysis (BIA) can be used at the bedside to allow derivation of fat mass and FFM from empirically derived statistical relationships based on results of resistance and reactance to an electrical current (88-90). Measurements of muscle circumference may also provide crude assessments of body composition (87). Limitations of anthropometric measures include measurement error (i.e. due to altered hydration status) and the need for cut off points appropriate to the population under study, which are the subject of much debate (5).

Biochemical measurements also have a role in nutritional assessment. Serum proteins (e.g. albumin, pre-albumin) are no longer considered reliable indicators of nutritional status in the clinical setting as they are influenced by inflammation (91). These biochemical data better reflect disease severity. Measures of functional status have been a component of nutrition assessment for many years (92), however they have been criticised as not being "nutrition specific enough" for the diagnosis of malnutrition (3) (page 337). Hand grip strength (HGS) is a contemporary functional measure that reflects muscle strength and mass. Studies have demonstrated HGS correlates with nutritional status (93, 94), independent of factors known to confound this association (95). Low HGS is predictive of mortality, disability, complications and increased LOS in hospital (96). Unlike anthropometric and biochemical outcomes HGS is not influenced by hydration state or inflammation, which is advantageous among hospitalised patients, although sufficient cognitive capacity is required to complete the measurement (91). Hand grip strength may be influenced by a range of factors (e.g. body position, effort and encouragement) that aim to be attenuated by using a standardised protocol (97).

Nutrition assessment tools

Multidimensional assessment of nutritional status overcomes the risk that single indicators of nutritional status may be confounded by other non-nutrition related factors. For convenience in clinical practice, comprehensive nutrition assessment tools have been developed and validated to identify malnourished patients. These multidimensional questionnaires consider medical/health status, function, dietary intake and/or anthropometry to classify nutritional status as normal or impaired. They are administered by a trained and experienced health professional, frequently a dietitian, and require the clinician or the patient to make subjective judgements about certain aspects of nutritional status. The full Mini Nutritional Assessment (full MNA®) (98, 99), MNA® (79, 100), Subjective Global Assessment (SGA) (101) and the Scored Patient Generated Subjective Global Assessment (102) are the most widely researched and are valid and recommended for use with a range of patient groups, including patients in subacute care (103).

Reassessing nutritional status

Ongoing nutritional monitoring and evaluation is required to identify change in nutritional status over time. This may provide evidence of the effectiveness of dietetic intervention among patients who are malnourished or at risk (18) or identify new cases of malnutrition risk. Functional changes occur prior to anthropometric changes in response to nutritional depletion or repletion and therefore, consideration needs to be given to the suitability of the outcome measure over a given time between assessment and reassessment (91). Guidelines recommend that clinical, functional, anthropometric or biochemical indices or nutrition assessment tools may be appropriate to use to reassess nutritional status (72).

1.3.5 Taking action through nutrition intervention

Treating malnutrition or malnutrition risk and maintaining the nutritional status of well nourished patients has the capacity to mitigate or circumvent the negative effects experienced by patients and the impact on the healthcare system described in Section 1.3.3. Put simply, this occurs through nutrition intervention that aims to ensure all patients' nutritional requirements are met or exceeded (Figure 1:3). A comprehensive review demonstrated that nutrition interventions can improve outcomes for patients and reduce healthcare costs, however the volume and strength of the evidence varies according to type of intervention, disease states and healthcare settings (72).

It is proposed that a combination of nutrition care and dietetic intervention are required to support the nutritional status of all patients during subacute care. Adequate nutrition care, enacted through clinical care processes, foodservice interventions and enhanced eating environments, must coexist to provide a strong foundation to support all patients' nutrition. In practice, the high prevalence of malnutrition and malnutrition risk relevant to the capacity of the dietetic workforce make it challenging to provide timely dietetic intervention (and associated assessment, review and monitoring) to all patients in need. This is further compounded by failure to identify and refer those patients in need to a dietitian for intervention. There is a call to action from the Alliance to Advance Patient Nutrition for a collective effort from the multidisciplinary team to value and prioritise nutrition care (104).

In Australia, there are now accreditation benchmarks for 15 areas of action for quality and safety in patient care relevant for all hospitals and day procedure centres (105). The inclusion of Management of Nutrition in Standard 12 Provision of Care (75) of the Evaluation and Quality Improvement National (EQuIPNational) accreditation program has distinguished the importance and elevated the role of nutrition in patient care. This standard sets out the actions required to ensure that the organisation: [1] proactively manages patient-centred nutritional care; [2] adopts a strategic and multidisciplinary approach to managing and monitoring nutritional care for all patients and; [3] ensures that healthcare providers and other staff understand the role of nutrition in clinical care and integrate nutrition with other care planning (75). In essence, these standards make nutrition the responsibility of everybody in the healthcare organisation; from the executive through to the ward level.

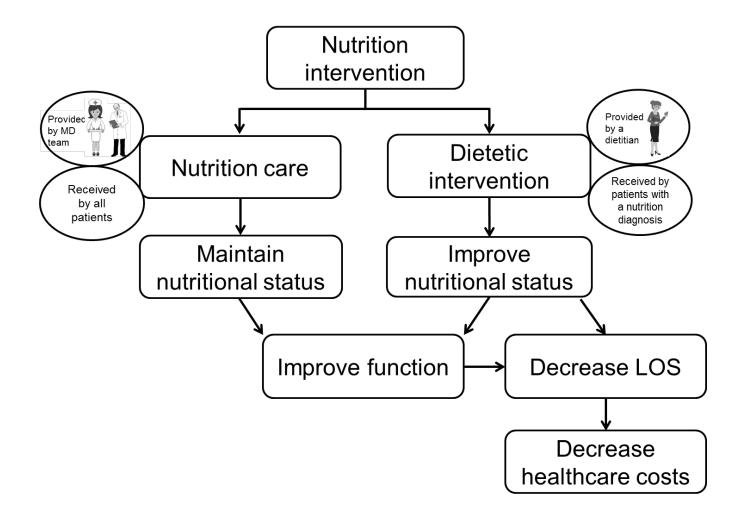


Figure 1:3 Proposed pathway to positive outcomes for patients and the healthcare system through nutrition intervention in subacute care

MD, multidisciplinary; LOS, length of stay

The role of foodservice

The hospital foodservice (i.e. catering) is an essential component of nutrition care as the majority of patients are reliant on this system to provide adequate and appropriate food and drink to meet their nutritional needs. Foodservice has traditionally been perceived as a hotel service however there is growing emphasis on valuing the therapeutic role of hospital food in supporting the precarious nutritional status of patients (106, 107). In Australia and internationally, standards exist that advise on the composition of meals and menus in healthcare facilities to meet estimated dietary requirements of an average patient and patient groups with special needs (e.g. malnourished or at risk patients) (108-112).

In addition to the need for foodservice systems to provide nutritious food that complies with these standards, there is pressure to meet patients' expectations, minimise food waste and operate on tighter budgets. Balancing these challenges has driven changes in the way that food is sourced (outsourced to central production kitchen or produced internally), prepared (cook chill, cook freeze, cook fresh), ordered (visual, spoken or written menu), plated (centralised or de-centralised) and delivered (point of service or pre-plated) in healthcare settings. The rise of technology and the patient centred approach to care has also fuelled reform of foodservice systems.

Traditionally, hospital foodservice utilised paper menus and cook fresh systems but this is no longer the case (113, 114). Major redesign of foodservice systems have resulted in improvements in outcomes. For example, bedside spoken menus show higher patient satisfaction, patient preference, tray accuracy and food intake compared to a traditional system (115) (116). In a systematic review evaluating point of service meal provision, significant benefits were observed for patients' satisfaction (12/12 studies), energy intake (8/9 studies) and plate waste (6/8 studies) (117). Room service is a recent innovation in foodservice in Australia, with the first hospital implementing this system in 2015. Evaluations identify that giving patients control of what they eat and when improves satisfaction and subsequently reduces plate waste and increases nutrient intake (118-120). Undoubtedly there are significant costs for healthcare associated with establishing entirely new foodservice models. Small changes that integrate some novel aspects may be a possible compromise. Regardless, foodservice is a dynamic operation and healthcare staff must be open and responsive to change and innovation. Further progress in hospital food and foodservice systems, and research on this topic, will help to establish its position as an important aspect of nutrition care.

Food based interventions

In addition to changes to foodservice processes and systems, a number of interventions that modify the food itself have been observed. These have considered the amount, type, nutritional content and appeal of food that patients receive with the intention of improving the nutritional intake of patients. The main advantage of food based interventions in comparison to ONS is that putting food first reflects normal eating behaviour. Appendix 1 summarises the impact on dietary intake of 13 studies trialling food based interventions that increased the energy content of menus in a range of healthcare settings. Critical analysis indicates some strengths and limitations of the effectiveness and feasibility of these interventions. Food fortification and mid-meal snacks appear to be the most common food based interventions trialled across healthcare settings, with some evidence supporting food fortification (Appendix 1).

Food fortification involves increasing the energy content of foods without substantially increasing the volume of food. This strategy has been reported as the most desired by dietitians, nurse unit managers and foodservice staff for improving intake of elderly long stay hospital patients (113). In terms of feasibility, it was also perceived by staff to be 'somewhat easy' to implement (113). Fortifying meals in bulk (e.g. preparation stage) or individually (e.g. plating stage) is an important practical consideration. The majority of studies reported in Appendix 1 indicate that food fortification can result in greater energy intake (with or without greater protein intake) compared to standard meals alone (121-127).

The provision of food snacks and beverages at mid-meals give patients more opportunities during the day to eat and achieve estimated requirements. Mid-meals are recognised as an important aspect of foodservice, particularly for patients with poor appetite and intake. In practice, the nutrient content of mid-meals varies, and may be minimal if tea, coffee and plain biscuits are the only items available. A snack trolley delivering a buffet of food and drink options for patients to select from is an alternate approach that has been trialled. Pre-packaged portion controlled items may be used to eliminate tray waste. Two studies of mid-meal snack provision described in Appendix 1 showed no favourable effect of mid meal snacks on energy intake in comparison to oral nutritional supplements (128, 129). However, snacks were more cost effective, had a lower rate of refusal and greater patient satisfaction (128, 129). Additionally, Appendix 1 includes two studies comparing a hot breakfast with a traditional continental breakfast report conflicting findings (121, 130). High energy cooked items such as eggs, baked beans or pancakes are not routinely available on the menu at publically funded hospitals however they may be appealing to patients.

A systematic review of mealtime interventions in residential aged care identified four studies that aimed to improve the flavour and appeal of foods by adding sauce and monosodium glutamate to meals (131). In contrast to the studies described above and in Appendix 1, the energy content of meals was not substantially altered. Two randomised controlled trials (RCT) were included in a meta-analysis and no significant effect on weight (weighted mean difference 0.4 kg, 95% CI –0.8 to 1.7 kg, p = 0.50) or energy intake (weighted mean difference –5 kcal, 95% CI: –36 to 26 kcal, p = 0.74) was found. Inconsistent findings were found in the two other studies. It appears that flavour enhancement is insufficient and more substantial changes to the nutrient content of food provided to hospital patients (e.g. through menu redevelopment or fortification) may be more effective at improving intake.

An important limitation and common criticism of food based interventions is that little is known about their effect on anthropometric, functional and clinical outcomes for patients. Many studies report intake (energy or protein intake or plate waste as a surrogate) as the primary or only outcome. Where weight (126, 128, 129, 132) or function (123, 132) have been reported, generally there is largely no change within group or difference between groups. Alterations to usual service or food undoubtedly have implications on time and cost. Although these are important considerations for understanding the feasibility and sustainability of these interventions, these data are also rarely captured.

The role of the environment

As described in Figure 1:2 (page 9), environmental factors including interruptions, lack of assistance and poor ambience can influence the nutritional intake of patients and contribute to malnutrition. Over one third of subacute care patients at Eastern Health have been identified as requiring assistance at mealtimes (45). The prevalence of elderly patients in need of assistance has been reported to be as high as 70% in another Australian study (133). Assistance is commonly required for tasks essential to food intake, yet difficult for unwell elderly patients, including opening packaging, cutting up food or physical feeding. Nursing staff are responsible for providing assistance but this can be challenging for a number of reasons, including competing priorities (42). Dedicated strategies to reorientate nursing time to focus on eating or delegating assistance to other staff or volunteers have been implemented.

Three systematic literature reviews provide a comprehensive summary of the effect of assistance provided at mealtimes for elderly hospital patients (131, 134, 135). Positive findings of mealtime assistance have been reported for food intake in the residential care setting (131), energy (weighted mean difference 486 kJ, 95% CI: 11 to 961 kJ, p=0.04) and protein (weighted mean difference 5.86 g, 95% CI: 1.09 to 10.63 g, p=0.02) intake among elderly in acute or subacute care (134) and food intake and assistants' satisfaction when volunteers provide assistance (135). A limitation is the lack of high quality, robust studies and insufficient evidence relating to other outcomes (e.g. anthropometry, function or cost).

A specific strategy designed to enable the provision of mealtime assistance is protected mealtimes. These are "periods when all ward based activities (where appropriate) stop to enable nurses, ward based teams, catering staff and volunteers to serve food and give assistance and support to patients" (136). Local data indicate that three quarters of patients in subacute care experience negative interruptions and only half experience positive interruptions, while almost all patients receive the mealtime assistance required (45). Although there is an established need to improve aspects of the mealtime environment, there is conflicting evidence that protected mealtimes does actually achieve this. A decrease (137, 138), increase (139) and no change (44, 140) in meal time interruptions have been reported following implementation of this strategy. Consequently, the effect of protected mealtimes on

dietary intake is limited, with no studies reporting significant positive findings (44, 138-141).

Optimising the physical setting in which patients consume their meals has also been explored. A systematic review of mealtime interventions in the residential aged care setting identified 11 studies that addressed the mealtime environment (131). Strategies were heterogeneous and included music, lighting, family style meals or meals shared with staff. Study design, quality ratings and findings were variable, making it difficult to draw firm conclusions. Studies pooled in meta-analysis did not reveal significant effects on energy intake (n=2, weighted mean difference 181.10 kcal, 95% CI - 4.91 to 367.11 kcal, p=0.06) or weight change (n=3, weighted mean difference 1.06 kg, 95% CI - 0.70 to 2.82 kg, p=0.24). These interventions are less feasibly in the acute or subacute setting where patients usually consume their meals in their rooms. As an alternative, dining rooms have been trialled and found to significantly increase energy intake of hospitalised patients (142, 143) and facilitate a positive eating experience (144).

1.4 Statement of the problem

It has been established that the prevalence of malnutrition and nutrition risk are high in subacute care and this results in worse outcomes for patients and healthcare (20, 52). This provides the rationale for seeking solutions to this issue. Impaired nutritional status affects patients' ability to gain the most clinical and functional benefit from multidisciplinary care provided at this stage of the healthcare continuum. Investment by health services in nutrition intervention provided throughout the subacute inpatient stay to combat this is sensible and worthwhile. As discussed further in the proceeding chapters, previous research on malnutrition in healthcare has not focused specifically on the subacute setting. Consequently, little is known about the nutritional status of this heterogeneous population or the most appropriate (i.e. effective and accepted) strategies of nutrition intervention.

1.4.1 The nutrition profile of subacute patients

Further investigation of patients' nutritional status, change in nutritional status and receipt of nutrition intervention will further our understanding of the current 'state of play' in subacute care. Observation of patients' nutritional status, in particular change in nutritional status is warranted to provide information that can be used to develop appropriate interventions, which may improve efficiency and effectiveness of service delivery. For example, this may identify gaps in current nutrition care or patients who are high priority for dietetic intervention (i.e. responsive to intervention, at greatest risk of decline or with most severe malnutrition).

To date, the majority of observational studies conducted in subacute care have focused on the prevalence of malnutrition at admission and its effects on patient outcomes (20, 21, 52-54). Point prevalence estimates of the nutritional status of subacute populations are variable, likely resulting in part from methodological issues (i.e. diagnostic criteria or assessment tools used, sample population) and in part from genuine differences in malnutrition prevalence over time and internationally. Little consideration has been given to patients' nutritional status at other time points of subacute inpatient stay, change over time or the outcomes of a decline in nutritional status. The trajectory of nutritional status during subacute inpatient stay is uncertain. In comparison to acute care, subacute patients are medically stable (145) and therefore acute disease-related factors may have less of an impact on dietary intake and nutritional status. The longer LOS may provide sufficient time for detectable changes in nutritional status to occur, first through dietary intake, then function and body composition. There is substantial opportunity for patients to be exposed to a range of risk factors (Figure 1:2) that may cause malnutrition among those who were previously well nourished or a decline in nutritional status for those already at risk or experiencing malnutrition. Alternatively, the provision of nutrition care and dietetic intervention have the capacity to influence nutritional status positively, if instigated.

1.4.2 Nutrition intervention for subacute patients

There is growing recognition of the role of nutrition in patient care, reflected in nutrition guidelines and standards that direct health service delivery (72, 73, 83, 104). Gaps remain in all areas of clinical care processes, eating environments and foodservice that mean nutrition care is yet to be optimised. A range of nutrition interventions have been implemented in healthcare settings to address one or more of the factors that contribute to malnutrition (Figure 1:2). It is recognised that a suite of strategies are required to address malnutrition in subacute care.

Many nutrition interventions have been implemented routinely in practice despite a lack of good quality evidence (ideally from RCTs) in support of their effectiveness (146). In the absence of evidence, there is no certainty that an intervention conveys benefits in terms of health outcomes or costs; that it is 'worth it'. Evidence based practice is a principle of dietetic practice and subacute service delivery. This relies on ongoing research to generate evidence, systematic literature reviews to collate and appraise the evidence and communication and translation of evidence into practice. As such there is opportunity for further research effort to contribute to this process to benefit subacute patients and the healthcare system.

1.5 Contribution of this thesis

This thesis seeks to address the following research questions:

- 1. How does patients' nutritional status change during subacute inpatient stay?
 - 1a. Which patients are vulnerable to deterioration in nutritional status during subacute inpatient stay?
 - 1b. What are the consequences of a change in nutritional status during subacute inpatient stay?
- 2. What is the state of the evidence describing oral nutrition interventions that aim to increase dietary intake among patients in subacute care?
- 3. What is the effect of a novel oral nutrition intervention to improve dietary intake of patients in subacute care on patient-related outcomes and cost?
- 4. What are the experiences of healthcare staff involved in the implementation of the novel oral nutrition intervention in subacute care?

1.5.1 Thesis structure

Each of the four research questions outlined above were addressed in discrete, sequential research investigations that are reported in the subsequent chapters. The direction of the thesis evolved during the candidature as reflections and results from each investigation informed successive research questions, hypotheses and study design. In this way, this thesis tells a story of malnutrition in subacute care through a series of original, individual yet interrelated investigations.

This chapter has defined key terms, presented relevant background information and summarised the problem and research questions that are explored in this thesis. chapters 2, 3, 4 and 5 present the aims, methods, results and discussion of each research investigation. Chapter 2 explores the profile of patients' nutritional status and usual dietetic practice in subacute care. Chapter 3 is a published systematic literature review of oral nutrition interventions to prevent and treat malnutrition in subacute care. Chapter 3 and 5 are a pilot study and qualitative process evaluation,

respectively, of a novel foodservice model of nutrition care. Chapter 6 integrates the key findings presented in the previous chapters and discusses the broader implications of this body of research for clinical practice, policy and future research.

All aspects of this research were undertaken by the candidate (Jorja Collins), referred to throughout the thesis as 'the researcher (JC)'. Other members of the research team (Kate Huggins, KH; Judi Porter, JP; Claire Palermo, CP) who contributed to data collection or analyses have been identified at relevant points of the thesis with their initials.

1.5.2 Research setting

The clinical research investigations reported in chapters 2, 4 and 5 of this thesis were undertaken at inpatient subacute care facilities at Eastern Health, a public multi-site metropolitan healthcare network in Victoria, Australia. All subacute patients receive multidisciplinary healthcare including medical, nursing and allied health (physiotherapy, occupational therapy, social work, psychology, speech pathology, dietetics and podiatry). Eastern Health is committed to ensuring "access to safe, appropriate and adequate food and fluid choices for all of its patients and consumers...that are clinically and culturally appropriate to support their nutritional care and delivered in a coordinated service wide approach" (147). Their Nutritional Care Standard and associated practice guidelines (e.g. malnutrition identification and management) integrate evidence based recommendations (72) and external standards related to malnutrition and nutritional care (75, 108) described previously in this chapter.

Chapter 2

Change in the nutritional status of patients during subacute inpatient stay

This chapter relates to:

The manuscript;

 Collins J, Porter J, Truby H, Huggins CE. How does nutritional state change during a subacute admission? Findings and implications for practice. Accepted for publication 11th Nov 2015 by Eur J Clin Nutr.

The presentations;

- Collins J, Huggins C, Truby H, Porter J. Mapping the nutritional state of patients admitted to rehabilitation. Monash Health Research Week, Melbourne, Australia. 2013. Poster and oral presentation.
 - Awarded Third prize Ageing and rehabilitation poster category.
- Collins J, Huggins C, Truby H, Porter J. The change in nutrition state between admission and discharge among rehabilitation patients.
 Victorian Allied Health Research Conference, Melbourne, Australia.
 2014. Oral presentation.
- Collins J, Huggins C, Truby H, Porter J. Mapping the nutritional state of patients admitted to rehabilitation. Dietitians Association of Australia 31st National Conference, Brisbane, Australia. Nutr Diet. 2014;71(supp 1):4. Oral presentation.

2.1 Abstract

Background Nutritional status influences patients' clinical and functional outcomes. Understanding the evolution of nutritional status during subacute inpatient stay may assist with the prioritisation and provision of nutrition care. The aims were to identify changes in nutritional status under usual care conditions during subacute care, predictive patient characteristics and associated clinical outcomes.

Methods A longitudinal observational study was undertaken with consecutive patients admitted to subacute care wards. Change in classification (malnourished, at risk of malnutrition, well nourished) of the full Mini Nutritional Assessment (full MNA®) between admission and discharge was the primary outcome. Secondary outcomes included change in weight (kg), mid-arm and calf circumference (cm) and, among a consenting subgroup, change in hand grip strength (kg) and fat free mass (kg). Clinical outcome data were collected at discharge and one year later.

Results Participants (n= 248) had a median age of 80 years, 36.7% were male and 29.4% were malnourished on admission. Full MNA® classification remained stable for 62% of participants (n=132); declined for 10.3% (n=22) and improved for 27.7% (n=59). There was no change in hand grip strength (n=46) but there was a decline in mean fat free mass (-1.1kg, 95% CI -0.1 – -2.2kg, p=0.043, n=24). Impaired cognition (OR=0.240, p=0.002) reduced the odds of improvement. An unfavourable change in nutritional status was associated with discharge to a higher level of care (p=0.036).

Conclusions Overall multi-disciplinary care supports the nutritional status of most patients admitted to subacute care. Nonetheless nutritional decline occurs and may result in worse outcomes. There is a need to ensure adequate monitoring of nutritional status using appropriate, responsive methods. In particular, those with cognitive impairments may benefit.

2.2 Introduction

2.2.1 Background

Admission to hospital can expose patients to a number of factors that convey risk of malnutrition and there is a common perception that nutritional decline occurs during hospitalisation. The seminal study (over 20 years old) observing change in nutritional status in the acute setting identified 65% of patients lost weight after a week and 20% were reclassified as having a worse nutritional status (70). There is a paucity of recent data exploring the regression (or progression) of nutritional status during hospitalisation. The extent to which the decline observed in acute hospitals occurs similarly in the subacute setting is unclear. A recent review commented on the unfortunate absence of studies repeating nutritional assessments at the time of discharge from rehabilitation (62). Only two studies, now 5 - 15 years old, have reported change in nutritional status during subacute care with improvement observed in both (24, 148). These studies are limited by small and restricted samples (n=32, cognitively intact elderly patients without cachectic conditions) and the lack of statistical testing of relevant outcomes.

It is imperative to identify modern trends in the longitudinal change in nutritional status during subacute care inpatient stay. The longer length of stay (LOS) relative to an acute care admission, is on average 16.2 days in Australia and 12.1 days in the United States (149, 150). This presents a window of opportunity for patients' nutritional status to either improve or decline, which is likely to influence clinical and functional progress. Understanding how nutritional status changes, which patients are likely to improve or decline and the consequences of change in nutritional status will assist clinicians to prioritise and tailor malnutrition screening, monitoring and dietetic assessment and intervention. Targeting resources to patients in need may result in improved efficiency and cost effectiveness of service delivery.

2.2.2 Aims

This research took a pragmatic approach to investigate the evolution of nutritional status under usual care conditions in the subacute setting. The aims were to:

- Determine how the nutritional status of patients in subacute care changes during inpatient stay using multiple tools or measurements to evaluate nutritional status.
- Identify characteristics of patients known at the time of admission to subacute care that are predictive of an improvement or decline in nutritional status during inpatient stay.
- 3. Explore the relationship between change in nutritional status during subacute inpatient stay and clinical outcomes at the time of discharge and one year following discharge.

Subsidiary aims were to:

- 4. Investigate the function of two nutritional assessment tools for identifying change in nutritional status over time.
- 5. Describe the usual dietetic care practices occurring to address malnutrition and inadequate intake in the subacute setting.

2.2.3 Hypotheses

It has been hypothesised that:

- 1. There will be change in nutritional status of a proportion of patients during subacute inpatient stay.
- 2. Patient characteristics at baseline that are predictive of a change in nutritional status will be identified.
- 3. Decline in nutritional status will be associated with worse clinical outcomes.
- 4. There will be agreement in change in nutritional status evaluated using two nutrition assessment tools.

2.3 Methods

2.3.1 Study design

A longitudinal observational study was conducted under usual care conditions with data collected prospectively. During subacute inpatient stay, nutritional status was evaluated at admission and discharge using a range of indicators of nutritional status. The primary outcome was change in nutritional status evaluated using the 18 item full Mini Nutritional Assessment (full MNA®) (Appendix 2). Secondary outcomes included change in nutritional status evaluated with additional data derived from assessment with the full MNA® (full MNA® score, 6 item MNA® classification and score) and change in anthropometry (weight, mid arm circumference (MAC), calf circumference (CC)). In a sub-group of participants, change in nutritional biochemistry, hand grip strength (HGS) and fat free mass (FFM) estimated using bioelectrical impedance analysis (BIA) were also included as secondary outcomes (referred to as the sub-study). Data on clinical outcomes were collected at the time of discharge and at follow up, one year after discharge from subacute care.

The Human Research and Ethics Committees at Eastern Health (E08/1213) (Appendix 3a) and Monash University (CF12/2630 - 2012001428) (Appendix 3b) approved this research. Approval was granted to complete full MNA® assessments and collect follow up data under a waiver of consent to include as many eligible patients as possible to improve the generalisability of results. Written informed consent was obtained from the sub-group of participants completing additional measures as these were not standard care practices at the Healthcare Network. This research was unfunded.

2.3.2 Subjects and setting

<u>Setting</u>

Participants were recruited from three Geriatric Evaluation and Management (GEM) and rehabilitation wards at a dedicated single subacute facility at Eastern Health. All participants received usual foodservice and multidisciplinary care from medical, nursing and allied health staff. The foodservice system was cook-chill providing three meals daily across a range of therapeutic diets. Three mid-meal snacks were also provided. The dietetic service at this facility consisted of 2.6 equivalent full time to provide clinical services to 128 subacute beds.

Inclusion and exclusion criteria

All adult patients were eligible to be recruited into the study. Where time permitted, participants were invited to participate in the sub-study if they met the eligibility criteria of ability to provide consent (i.e. no cognitive impairment and English speaking) and sufficient ambulatory capacity to complete procedures. Sub-study participants with pacemakers or other implanted electrical devices, obstructing orthotic devices or receiving intra-venous fluids at the time of assessment were excluded from FFM measurements as these conditions are contraindicated for BIA use.

Sample size

One hundred and eighty patients providing complete data was the target sample based on a sample size calculation for regression analyses including 12 predictor variables with 15 participants per predictor (151). The minimum time needed to recruit 180 participants was four to five weeks, estimating the average LOS was 16.2 days (150) and the 98 beds available remained open. A recruitment period of ten weeks was allocated to account for the staggered admission of potential participants and to oversample to allow for loss to follow up.

2.3.3 Procedure

Upon admission to subacute care, consecutively admitted patients were recruited into the study and assessed for eligibility and invited to participate in the sub-study. Data were collected within 72 hours following admission and again within 72 hours prior to discharge, irrespective of LOS. Information on patient admissions and discharges was sought daily (Monday – Friday) from ward staff. Full MNA®, weight, CC and MAC were obtained for all patients while HGS and FFM were completed for the sub-group of participants only at both admission and discharge. These measurements were completed at the bedside by the researcher (JC) for the purpose of this study.

2.3.4 Inpatient data collection

Mini Nutritional Assessment

The primary outcome was change in classification of nutritional status (malnourished, at risk of malnutrition or well nourished) during inpatient stay evaluated using the full MNA®. The full MNA® was administered via researcher (JC) led interview with the participant or a proxy (i.e. family member, nursing staff) according to recommended protocol (152).

The full MNA® is a multidimensional nutrition assessment tool recommended for evaluating the nutritional status of elderly patients across a range of settings (153-155). It consists of 18 questions and measurements across four domains of: anthropometry (items B, F, Q, R), global assessment (items C, D, E, G, H I), dietary assessment (items A, J, K, L, M, N) and subjective assessment (items O, P) (Appendix 2) (www.mna-elderly.com). A weighted score is allocated to each question and the total score classifies nutritional status as well nourished (score of 24 - 30), at risk of malnutrition (score of 17 - 23.5) or malnourished (score of less than 17). The original validation study reported the sensitivity and specificity of the full MNA® as 96% and 98%, respectively, against clinical status (153). It has since been validated among older patients in the rehabilitation setting (21, 156).

The full MNA® has been streamlined into a shortened version consisting of six items (items A-F), which has been validated as a stand-alone tool to identify malnutrition, referred to as the MNA® (the preferred abbreviation) or the MNA® Short Form (MNA® SF) (previously used in the literature) (100). To distinguish between these two versions of the Mini Nutritional Assessment in this thesis, the 18 item tool is referred to as the full MNA® while the 6 item tool is referred to as the MNA®.

Data were available for nutritional status defined by the MNA® at admission and discharge as the MNA® is a component of the full MNA®. Compared to the full MNA®, the MNA® (using body mass index (BMI)) has a sensitivity of 89.3% and specificity of 94.3% (100). While the MNA® is recommended for use in clinical practice as it is quicker to administer, the full MNA® provides more comprehensive information on the reasons for malnutrition and less chance of misclassification and therefore may be better suited for research purposes.

Participants who were identified as malnourished or at risk of malnutrition as a consequence of full MNA® assessment on admission were referred to the ward dietitian. For participants who were malnourished or at risk of malnutrition with a history of weight loss, the Nutrition Care Process (NCP) involving further assessment (not collected as outcome data) and individualised dietetic intervention was initiated by the ward dietitian as per standard practice. Those at risk of malnutrition with no weight loss history were monitored by nursing staff, as per the recommended protocol (152).

Anthropometry

Change in weight (kg), CC (cm) and MAC (cm) during inpatient stay were included as secondary outcomes. BMI (kg/m²), CC and MAC were required to complete the full MNA®, however can also be considered independently as objective indicators of nutritional status, as described in chapter 1.

Weight was measured to the nearest 0.05kg using a single set of calibrated seated scales with the participant dressed in light clothing and no shoes or light footwear. If weight was unable to be measured on admission it was reported by the participant, a family member or obtained from medical records. Actual weight was measured which did not take into account fluid status, orthotic or prosthetic devices. Participants who were wheelchair bound were weighed in their chair using bariatric platform scales, later adjusting for the weight of the chair alone.

BMI was calculated using weight measured as described above and height estimated from knee height. Knee height (cm) was measured to the nearest 0.1 cm at admission only with the participant in a seated position (Figure 2:1) as this has a higher participation rate than the supine position (157). The measurement was taken on the left leg using sliding knee callipers, positioned as described in guidelines (152). Three predictive equations appropriate for the most common cultural backgrounds of the sample (Caucasian, Chinese and Italian) were used to estimate height (158-160). MAC and CC were measured to the nearest 0.1 cm according to recommended protocol (152). MAC was measured at the mid-point of the nondominant arm (Figure 2:2). CC was measured on the left leg at the widest part of the calf with the participant in a seated position (Figure 2:3).



Figure 2:1 Measuring knee height with the participant in the seated position



Figure 2:2 Measuring mid arm circumference at the mid-point of the non-dominant arm



Figure 2:3 Measuring calf circumference at the widest part of the left leg

Hand grip strength

HGS was measured using a calibrated digital Jamar® Plus + Hand Dynamometer (Sammons Preston Rolyan, Illinois) which is considered the gold standard device (97). Measurements were taken with the handle in the second position, with participants seated upright in a chair or in bed with the elbow flexed at 90°, the forearm neutrally positioned and the wrists dorsi-flexed at 30° (97) (Figure 2:4). The process was demonstrated and standard instructions were provided before each test to minimise variance in motivation: *"Squeeze as hard as you can...harder...harder...relax"* (161). Three measurements were taken on the dominant hand (the non-dominant hand was used if injuries were present) and the mean result (kg) was recorded as per previous nutrition studies (55, 162, 163). This value (actual HGS) was compared with age and gender specific reference values to calculate percentage (%) of predicted normal HGS, where 100% of predicted HGS is equivalent to the average normal HGS for the reference group (164, 165).

Bioelectrical Impedance Analysis

FFM was estimated using the Bodystat QUADSCAN (Bodystat Limited, Isle of Man) tetra polar BIA machine. The measurement was taken with participants lying in the recommended supine position with limbs adducted (88) (Figure 2:5). Reactance and resistance values obtained were used to derive FFM (kg) estimates from a predictive equation validated against dual-energy x-ray absorptiometry in a large sample of healthy adult and elderly subjects [FFM = $-4.104 + (0.518 \text{ x height}^2/\text{resistance}) + (0.231 \text{ x weight}) + (0.130 \text{ x reactance}) + (4.229 \text{ x sex}); where men=1, women = 0; height cm; weight kg] (166).$

Nutritional biochemistry

Serum albumin was collected as a biochemical indicator of nutritional status. No blood samples were taken for the purpose of this research. Where available, albumin was recorded from participants' medical records. As albumin has a half-life of 18 days, data from the day of admission or up to 18 days before admission and data from the day of discharge or up to 18 days before discharge (but after admission) were used.



Figure 2:4 Measuring hand grip strength using the dominant hand with the participant in the seated position



Figure 2:5 Conducting Bioelectrical Impedence Analysis with the participant in the supine position

Participant characteristics

Demographic information were collected to describe the sample and explore the relationship with change in nutritional status. Data were collected from participants' medical records and included: age (years), gender, primary diagnosis, type of diet, cognitive status (impaired, not impaired), preadmission residence (home, high or low level aged care facility, other), Functional Independence Measure (FIM) score at admission, LOS (days) in acute care prior to the subacute admission and the number of hospital admissions to Eastern Health in the past year. These characteristics were selected as they were known at the time of admission to subacute care, potentially making them useful predictors of subsequent improvement or decline in nutritional status during the length of stay.

Cognitive status was not assessed for study purposes rather determined from documented past medical history and history of presenting complaint. Major diagnostic categories (MDC) or Australasian Rehabilitation Outcomes Centre (AROC) impairment codes were used to define the primary diagnosis for participants on GEM and rehabilitation wards, respectively (167, 168). MDC and AROC impairment codes describe the primary diagnosis in reference to a single body system or disease aetiology. AROC impairment codes were used for participants on rehabilitation wards as the most common MDC category assigned to these participants 'Factors influencing health status and other contacts with health services' was felt to lack detail. AROC impairment codes were matched to MDC categories for a consistent response set. The FIM is a validated and responsive tool measuring level of independence with activities of daily living (169, 170). Scores range from 18-126 with higher scores indicating greater independence. Previous hospital admissions within the past year were classified as those involving an overnight stay in an acute or subacute facility. Emergency department presentations, short stay procedures (e.g. dialysis, day oncology, day procedures), ambulatory care and outpatient appointments were not included.

Dietetic care practices

The number of documented dietetic consultations (initial assessment or review) that occurred during inpatient stay and the type of nutritional care provided (enteral

nutrition, oral nutritional supplements (ONS), food fortification, high energy/protein foods, education, other strategy, monitoring only) were identified from participants' medical records. Only dietetic consultations and intervention related to malnutrition, malnutrition risk or inadequate intake were considered.

2.3.5 Follow up data collection

Clinical outcomes included change in FIM score, LOS (days) in subacute care and discharge destination (home, high or low level aged care facility, acute hospital, other). These were considered shorter term outcomes as they were relevant to the subacute inpatient stay captured in the study. Change in FIM score was calculated as the difference between FIM score assessed by nursing staff at admission and discharge. FIM is routinely completed by trained nursing or allied health staff at this site and at other rehabilitation sites across Australia as part of standard data collected by the AROC. The availability of FIM data make this a useful functional outcome measure. A discharge destination that provided a higher level of care in comparison to preadmission residence was considered to be a worse outcome.

Longer term clinical outcomes occurring within the year following discharge from subacute care were the number of hospital readmissions and inpatient mortality occurring during hospital readmissions. Hospital readmissions were classified as those involving an overnight stay. Emergency department presentations, short stay procedures (e.g. dialysis, day oncology, day procedures), ambulatory care and outpatient appointments were not included.

Clinical outcome data were collected from participants' medical records. Participants or next of kin were not contacted to obtain follow up data. As medical records were only accessible electronically for Eastern Health (where the subacute admission occurred), long term clinical outcome data were not available for other Healthcare Networks or private hospitals.

2.3.6 Statistical analyses

Data were analysed using IBM© SPSS© Statistics (Version 20). Mean and standard deviation (SD) were reported for normally distributed variables, median and interquartile range (IQR) for non-parametric variables and number (n) and percent

(%) for categorical data. P values <0.05 were considered statistically significant. Descriptive statistics were used to report demographic characteristics. Comparisons between groups were made for demographic data using Chi² test, independent samples t-test or Mann Whitney U test. Primary and secondary outcome data collected at admission and discharge were compared for participants providing data at both time points.

Change in classification of nutritional status assessed with the full MNA® (primary outcome) or MNA® was defined as improvement, no change or decline. Improvement was a transition to a better classification category (e.g. moving from malnourished to at risk, or at risk to well nourished) and *vice versa* for decline. These categorical response options were collapsed to form two variables (improvement, yes/no; decline, yes/no) for analyses requiring a dichotomous outcome (e.g. sensitivity and specificity calculations, logistic regression and relative risk calculations).

Change in classification of nutritional status evaluated using the full MNA® was reported using descriptive statistics and not statistically analysed. No statistical tests were appropriate to enable meaningful comparison of categorical data for related samples (i.e. Chi² test invalid). Wilcoxon Signed Rank test was used to analyse the change in full MNA® and MNA® scores (full MNA® range 0 – 30, MNA® range 0 – 14) (treated as continuous data). Paired samples T-test was used to compare admission and discharge results for weight, MAC, CC, HGS and FFM, with some variables transformed to achieve normal distribution. A series of bivariate correlations were conducted to explore the relationship between change in full MNA® score and individual anthropometric outcomes. The correlation coefficient (r) was derived using Spearman Rank Order correlation for change in full MNA® score and change in WAR and CC and Pearson correlation for change in MNA® score and change in HGS and FFM.

Agreement between classifications of change in nutritional status (improvement, no change, decline) obtained with the MNA® and full MNA® were presented as percentage agreement (171) and compared using Cohen's kappa (κ), suitable for categorical variables. κ was interpreted as follows: 0.00 poor, 0.00–0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial and 0.81–1.00 almost perfect

(172). Comparison between methods of assessment was possible as the MNA® was a component of the full MNA® and therefore not subject to bias that would occur if both tools were administered by the single researcher (JC) at the same time.

The sensitivity and specificity of the MNA® compared to the full MNA® were calculated for both the dichotomous (i.e. 2 x 2 table) characterisation of improvement (improvement versus no change or decline) and decline (decline versus no change or improvement) in change in classification of nutritional status as described by Altman DJ and Bland JM (173). The full MNA® was considered the 'gold standard' against which the MNA® was tested as it is more comprehensive.

Multiple regression was used to identify factors predictive of change in nutritional status. Logistic regression modelling explored whether the independent variables were predictive of improvement (yes/no) in classification of nutritional status assessed with the 18 item full MNA® (Model 1) and the 6 item MNA® (Model 2). Linear regression modelling also performed using change in full MNA® score as a continuous dependent variable (Model 1a). Independent variables for all regression approaches were characteristics of participants known at the time of admission to subacute care (refer to 2.3.4 Participant characteristics). All independent variables were entered at once. Assumptions were checked for regression models including linearity and multicollinearity.

Clinical outcomes were compared between groups of participants who demonstrated an improvement, no change or decline in full MNA® classification using Kruskall Wallis test and Chi² test. RR of inpatient mortality during readmissions was calculated as the incidence of mortality in the exposed divided by the incidence of mortality in the unexposed, where 'exposure' was an improvement in full MNA® classification. The formula used for calculating the 95% confidence interval (CI) for the RR is described in Appendix 4.

2.4 Results

2.4.1 Recruitment and retention

There were 285 consecutively admitted patients during the ten week recruitment period between October to December 2012. Recruitment and retention are shown in Figure 2:6. In total, 87% (n=249) of these eligible patients were recruited and data were collected at both admission and discharge for 213 participants (85.5%) for full MNA® and weight and 211 for MAC and CC. Participants being discharged at short notice to acute care was the most common reason (n=22, 61%) for non-retention. Clinical outcome data were accessible through electronic medical records at discharge and at follow up one year after discharge for all participants completing both assessments with the full MNA® during inpatient stay. All data were excluded for one outlier with an excessive length of stay (>120 days).

One or more additional sub-study measures were completed for 58 (23.3%) of the sample. All those who were invited (when time permitted) consented to participate in the sub-study. Data were collected at admission and discharge for 46 (82.1%) participants for HGS, 24 (57.1%) for BIA and 13 (27.6%) for albumin. Ten participants were unable to complete HGS measurements at discharge and 19 participants were unable to complete BIA (Figure 2:6). Albumin data were not used as complete data were available for only a small number of participants (27.6%), with no pathology data obtained at discharge as part of usual care for 29/34 participants (data are reported in Appendix 5).

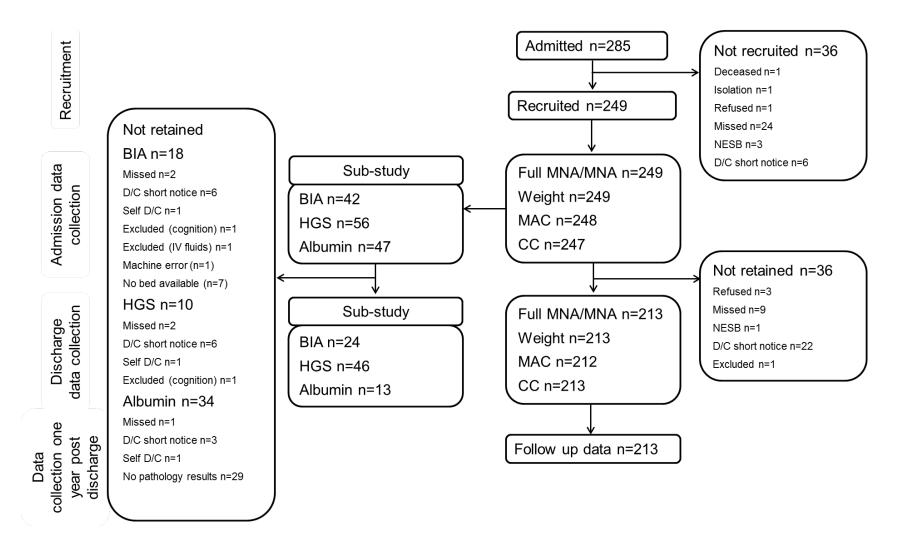


Figure 2:6 Recruitment and retention of participants

NESB, non-English speaking background; D/C, discharged; Full MNA,18 item Mini Nutritional Assessment; MNA, 6 item Mini Nutritional Assessment; MAC, mid arm circumference; CC, calf circumference; BIA, bioelectrical impedence analysis; HGS, hand grip strength

2.4.2 Participant characteristics

Characteristics of participants whose nutritional status were assessed at admission are shown in Table 2:1. Overall, the median age of participants was 80 years, with approximately one third being male. The full MNA® identified one third of patients were malnourished at admission to subacute care. In comparison to participants completing both the full MNA® and MNA® assessments (n=213), participants lost to follow up (n=35) were more likely to be male (33.8% versus 54.3%, p=0.032) and have a different usual place of residence (home 95.8% versus 91.4%, high/low level care 3.8% versus 2.9%, other 0.5% versus 5.7%, p=0.031), respectively.

Participants in the subgroup who completed HGS and/or BIA measurements at admission (n=56) were significantly younger (median (IQR), 76 (68 – 84) years versus 81 (74 – 87), p=0.010), more independent (median (IQR) FIM score, 87 (73 – 95) versus 73 (58 – 86), p<0.005) and less likely to be malnourished (malnourished 25.0% versus 30.7%, at risk of malnutrition 44.6% versus 55.2%, well nourished 30.4% versus 14.1%, p=0.019) than those who did not complete these measurements (n=192), respectively.

Characteristic	Result	
Age (years), media	80 (73 – 84)	
Male, n (%)	91 (36.7)	
MDC, n (%)	Circulatory, respiratory, kidneys and urinary tract	23 (9.3)
	Nervous system	34 (13.7)
	Factors influencing health status	58 (23.4)
	Musculoskeletal system and connective tissue	117 (47.2)
	Other diagnoses	16 (6.5)
Diet type, n (%)	Vegetarian or vegan	2 (0.8)
	Enteral or parenteral nutrition	2 (0.8)
	Culturally specific diet	3 (1.2)
	Texture modified food or fluids	15 (6.0)
	Food or fluids for medical reasons	66 (26.6)
	Regular	160 (64.5)
Preadmission	Home	236 (95.2)
residence, n (%)	High/low level aged care facility	9 (3.6)
	Other	3 (1.2)
Full MNA®	Malnourished	73 (29.4)
classification at	At risk	131 (52.8)
admission, n (%)	Well nourished	44 (17.7)
BMI (kg/m ²), media	25.1 (21.9 – 30.2)	
Impaired cognition	58 (23.4)	
FIM score at admis	77 (61 – 90)	

Table 2:1 Participant characteristics (n=248)

MDC, major diagnostic category; Full MNA®, 18 item Mini Nutritional Assessment; BMI, body mass index; FIM, Functional Independence Measure

2.4.3 Evaluation of nutritional status at admission and discharge

Change in nutritional status using the Full MNA® - primary outcome

Favourable changes in nutritional status during subacute inpatient stay were observed using the full MNA® (i.e. 18 item tool). The prevalence of malnutrition decreased by approximately 9% during inpatient stay, with the majority of participants remaining at risk of malnutrition (Table 2:2). Full MNA® classification improved for 27.7% (n=59), remained stable for the majority of participants (n=132, 62.0%) and declined for a small proportion (n=22, 10.3%) (Figure 2:7). Of those whose full MNA® classification improved, 52.5% were malnourished at admission. Participants experiencing nutritional decline were well nourished (n=11, 50%) or at risk of malnutrition (n=11, 50%) on admission.

Change in nutritional status using the full MNA® score

Overall there was an increase in the full MNA® score between admission and discharge (Table 2:2). Change in full MNA® score was significant for participants who were malnourished on admission (median (IQR), admission 14.5 (12.5 - 16.0), discharge 17.25 (13.4 - 20.0), p<0.005), at risk of malnutrition (median (IQR), admission 20.5 (19.25 - 22.0), discharge 22.0 (19.5 - 23.75), p<0.005) but not well nourished (median (IQR), admission 24.5 (24.0 - 25.5), discharge 24.75 (23.5 - 26.5), p=0.964). There was a significant increase in the median score for all domains of the full MNA® except for the anthropometry domain where a significant decrease was observed (Table 2:2).

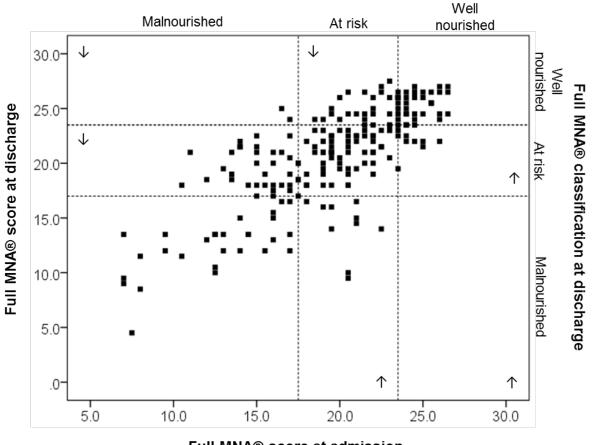
Change in nutritional status using the six item MNA®

Using the MNA® (i.e. six item tool) to evaluate nutritional status, the prevalence of malnutrition decreased by 6% and there was a significant difference in the median MNA® score between admission and discharge (Table 2:2). MNA® classification improved for 59 participants (27.7%), remained stable for 138 (64.8%) and declined for 16 (7.5%). It was not possible to determine the statistical significance of the transition in MNA® classification between admission and discharge due to small sample sizes in response categories.

Table 2:2 Nutritional status at admission and discharge from subacute care evaluated using the full MNA® and the MNA® (n=213)

		Admission	Discharge	P value
Full MNA®	Malnourished	62 (29.1)	42 (19.7)	-
classification	At risk of malnutrition	113 (53.1)	114 (53.5)	
n (%)	Well nourished	38 (17.8)	57 (26.8)	
Full MNA® score, median (IQR)		20 (16.8 – 23.0)	21.5 (18.0 – 24.0)	<0.001
Full MNA®	Anthropometry	7.0 (5.0 – 8.0)	6.0 (5.0 - 8.0)	0.020
domain score	Global	5.0 (4.0 – 5.0)	5.0 (4.0 - 6.0)	<0.001
median (IQR)	Dietary	7.0 (5.5 – 8.0)	7.5 (6.5 – 8.5)	<0.001
	Subjective	2.5 (1.5 – 3.0)	3.0 (2.0 – 3.0)	<0.001
MNA®	Malnourished	76 (35.7)	66 (31.0)	-
classification	At risk of malnutrition	128 (60.1)	106 (49.8)	1
n (%)	Well nourished	9 (4.2)	41 (19.2)	1
MNA® score, median (IQR)		9.0 (6.0 – 11.0)	9.0 (7.0 – 11.0)	0.020

Full MNA®, 18 item Mini Nutirtional Assessment , MNA®, 6 item Mini Nutritional Assessment Domains of Full MNA® - Anthropometry domain (items B, F, Q, R), global domain (items C, D, E, G, H I), dietary domain (items A, J, K, L, M, N) and subjective domain (items O, P)



Full MNA® classification at admission

Full MNA® score at admission

Figure 2:7 Full MNA® score and classification at admission and discharge from subacute care (n=213)

Full MNA®, 18 item Mini Nutritional Assessment

Dotted lines indicate full MNA® classification; score <17=malnourished, score 17-23.5=at risk of malnutrition, score 24-30=normal nutritional status, , the bottom left, middle and upper right squares indicate no change in full MNA® classification, squares to the left display improvement (\uparrow) and squares to the right display decline (\downarrow), data points indicate each participant's nutritional status at admission and discharge according to the full MNA

2.4.4 Agreement between tools to evaluate change in nutritional status

Agreement for classification of change in nutritional status (improvement, no change, decline) was not classified the same way using the full MNA® and the MNA® for 79 participants (37.1%) and was slight (κ =0.278, p<0.005) (Table 2:3). Compared to the full MNA®, the sensitivity of the MNA® for classifying improvement versus no improvement (i.e. decline or no change) in nutritional status during inpatient stay was 55.9% and the specificity was 83.1%. For classifying decline in nutritional status versus no decline (i.e. improvement or no change) the sensitivity was 22.7% and the specificity was 94.2%.

Table 2:3 Agreement between change in classification of nutritional status using the fullMNA® and the MNA®

		Change in classification using Full MNA®, n			
		Decline	No change	Improvement	Total
Change	Decline	5	10	1	16
classification	No change	17	96	25	138
using MNA®, n	Improvement	0	26	33	59
	Total	22	132	59	213

Full MNA®, 18 item Mini Nutritional Assessment; MNA®, 6 item Mini Nutritional Assessment Shaded cells indicate lack of agreement between the Full MNA® and the MNA®

Change in nutritional status evaluated using anthropometry

Weight, MAC and CC were measured at admission and discharge for all study participants as anthropometric indicators of nutritional status. There was a small, *albeit* statistically significant decrease in weight (mean (SD) change -0.95 (3.05) kg, 95% CI -0.55 – -1.40kg, range -15.00 – 7.95 kg) and MAC (mean (SD) change -0.3 (1.6) cm, 95% CI -0.1 – -0.5 cm, range -5.5 – 3.8 cm) but not CC (mean (SD) change -0.1 (1.9) cm, 95% CI -0.1 – 0.4 cm, range -11.5 – 4.2 cm) between admission and discharge (Figure 2:8, Figure 2:9, Figure 2:10). There were weak and non-significant correlations between change in full MNA® score and change in weight (r=0.117, p=0.088), MAC (r=0.060, p=0.385) and CC (r=0.072, p=0.299).

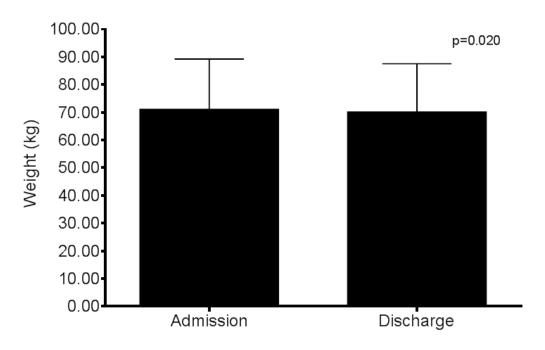


Figure 2:8 Weight at admission and discharge from subacute care (n=213)

Data analysed using paired samples T-test with transformed data Error bars indicate mean and standard deviation

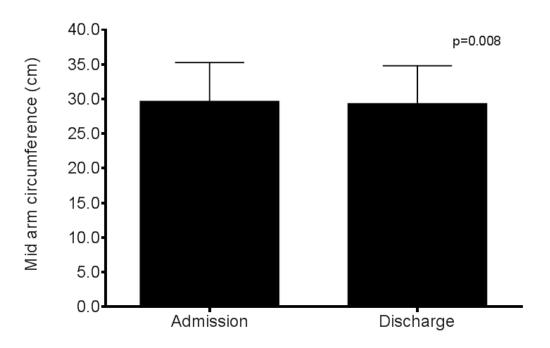


Figure 2:9 Mid arm circumference at admission and discharge from subacute care (n=211)

Data analysed using paired samples T-test with transformed data Error bars indicate mean and standard deviation

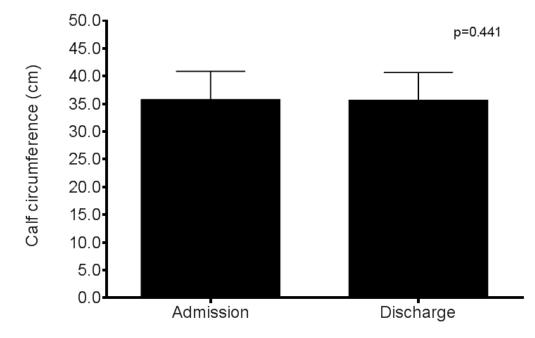


Figure 2:10 Calf circumference at admission and discharge from subacute care (n=211)

Data analysed using paired samples T-test with transformed data Error bars indicate mean and standard deviation

Change in nutritional status in the sub-group

In a subgroup of participants (n=56), HGS and FFM analysis were measured at admission and discharge as non-standard, non-invasive nutritional indices. Among this sub-group, the change in full MNA® classification and weight were consistent with the trends observed among all participants (Table 2:4). There was no change in HGS but there was a significant decline in FFM during subacute inpatient stay (mean (SD) change -1.1 (2.5) kg, 95% CI -0.1 – -2.2 kg, range -7.4 – 3.1 kg) (Table 2:4). The correlations between change in full MNA® score and change in HGS and FFM were weak and not significant (HGS (kg) r=0.200, p=0.183; HGS (% normal) r=0.258, p=0.084; FFM r= -0.198, p=0.354).

		Admission	Discharge	р
				value
Full MNA®	Malnourished	7 (15.2)	1 (2.2)	-
classification	At risk of malnutrition	24 (52.2)	26 (56.5)	
n (%), n=46	Well nourished	15 (32.6)	19 (41.3)	
Weight (kg), mean (SD), n=46		76.00 (17.10)	75.20	0.014
			(16.55)	
HGS (raw) (kg), mean (S	D), n=46	21.8 (8.9)	21.8 (8.2)	0.894
Percent normal HGS (kg), mean (SD), n=46	83.8 (25.3)	83.9 (23.1)	0.929
FFM (raw) (kg), mean (S	D), n=24	48.6 (10.5)	47.5 (8.9)	0.043

Table 2:4 Full MNA® classification, weight, hand grip strength and fat free mass of the subgroup of participants at admission and discharge from subacute care

Full MNA®, 18 item Mini Nutritional Assessment; HGS, hand grip strength; FFM, fat free mass Percent of normal HGS calculated from reference data for age and gender (164, 165)

2.4.5 Admission characteristics predictive of change in nutritional status

A logistic regression model was used to identify participant factors known at the time of admission that predicted an improvement in full MNA® classification versus no improvement (i.e. no change or decline) during subacute inpatient stay. Primary diagnosis (MDC and AROC impairment codes) and usual place of residence were intended to be included in the model, but could not be. There were uneven sample sizes for response options and multiple categories to be included as independent variables, which would exceed the maximum number allowed for the given sample size according to calculations. The model (Model 1, Table 2:5) controlled for age, gender, cognition, FIM score at admission, LOS of prior acute admission and number of admissions in the past year. Together these factors explained 5 – 8% of the variance associated with improvement in full MNA® classification. Cognitive status had the greatest effect size and was the only significant predictor. The odds of improvement in full MNA® classification were 76% less among participants with impaired cognition (p=0.008).

Logistic regression modelling was repeated using change in the MNA® (i.e. six item tool) classification as the dependent variable to determine whether there was consistency in the admission characteristics predictive of an improvement in classification nutritional status using this shorter assessment tool. This model (Model 2, Table 2:5) explained a similar amount of variance associated with change in MNA® classification as was found using the full MNA® (Model 1, Table 2:5). None of the independent variables were significantly associated with change in MNA® classification and there were differences in the direction of the relationship and effect size of independent variables between Models 1 and 2 (Table 2:5).

To further explore the relationship between participant factors at admission and improvement in nutritional status during inpatient stay, change in full MNA® score was considered which indicates smaller improvement within a classification. Linear regression was performed with change in full MNA® score as the dependent variable (Model 1a, Appendix 6). The effect size remained greatest for cognitive impairment, conveying a -0.6 point change in full MNA® score (B= -0.566), although this was no longer significant (p=0.309).

It was not possible to use regression modelling to explore the association between participants' admission characteristics and decline in full MNA® classification as the sample size of participants experiencing decline was small (n=22). Descriptive analysis was undertaken to define the characteristics of these participants compared to those who did not experience a decline in full MNA® classification (i.e. no change or improved) (Table 2:6). Participants whose nutritional status declined appeared to be older, more likely to be male and less independent, though the significance of these differences were not investigated.

Table 2:5 Logistic regression model of admission characteristics predictive of an improvement in classification of nutritional status assessed with the full MNA® and the MNA® (n=210)

Variable	В	Standard	Adjusted	p value
		Error	odds	
			ratio	
Model 1 – Improvemen	t in full MN	A® classifica	tion	
Age (years)	-0.013	0.014	0.987	0.371
Gender (female=1)	0.207	0.344	1.229	0.548
Impaired cognition (yes=1)	-1.429	0.539	0.240	0.008
FIM score admission	-0.009	0.009	0.991	0.327
LOS acute admission	-0.001	0.015	0.999	0.948
Admissions in previous 12 months (n)	0.109	0.106	1.116	0.304
Model 2 – Improveme	ent in MNA®	elassificatio	on .	
Age (years)	0.014	0.015	1.014	0.359
Gender (female=1)	-0.035	0.341	0.966	0.918
Impaired cognition (yes=1)	-0.878	0.504	0.415	0.081
FIM score admission	0.015	0.010	1.015	0.140
LOS acute admission	-0.011	0.017	0.989	0.524
Admissions in previous 12 months (n)	-0.151	0.126	0.859	0.228

Full MNA®, 18 item Mini Nutritional Assessment; FIM, Functional Independence Measure; LOS,

length of stay; MNA®, 6 item Mini Nutritional Assessment

Model 1 - Cox & Snell R²=0.052; Nagelkerke R²=0.078

Model 2 - Cox & Snell R²=0.055; Nagelkerke R²=0.079

Table 2:6 Admission characteristics of participants experiencing a decline and no decline infull MNA® classification during subacute inpatient stay

Variable	Participants experiencing decline n=22	Participants not experiencing decline n=191
Age (years), median (IQR)	84 (76 – 88)	79 (72 – 87)
Male, n (%)	10 (45.5)	62 (32.5)
Impaired cognition, n (%)	5 (22.7)	41 (21.5)
FIM score admission, median (IQR)	74 (58 – 86)	80 (62 – 91)
Rate of previous admissions	1.00	0.75
LOS acute admission, median (IQR)	9 (5 – 19)	8 (5 – 14)

Full MNA®, 18 item Mini Nutritional Assessment; FIM, Functional Independence Measure; LOS, length of stay

Rate of previous admissions calculated as n previous admissions/n participants

2.4.6 Dietetic care practices under usual care conditions

The majority of participants who were classified as malnourished (94.5%) or at risk of malnutrition (74.8%) at admission were seen by the ward dietitian for assessment and initiation of the NCP as per usual practice. Approximately half of the participants experiencing nutritional decline (n=12, 54.4%) were not seen by the dietitian. The average number of dietetic consultations that malnourished or at risk participants received during their inpatient stay was two (median (IQR) 2 (1 – 3), ranging from 1 – 20), with almost half (n=75, 45.5%) being seen only once. The most commonly used individualised dietetic interventions employed by the ward dietitian were prescription of ONS (n=84, 50.3%) and additional high energy/protein food items (n=59, 35.3%). Enteral nutrition was received by two participants. One third (n=59, 35.3%) of malnourished or at risk participants seen by the ward dietitian received no additional intervention except monitoring of their weight and dietary intake by nursing staff.

2.4.7 Clinical outcomes associated with change in nutritional status

Clinical outcomes were considered for participants completing both full MNA® assessments at admission and discharge from subacute care (n=213).

Outcomes at discharge from subacute care

The majority of participants were discharged from subacute care to home (n=167, 78.4%) with the remaining participants discharged to a residential aged care facility (n=33, 15.5%), acute hospital (n=7, 3.3%) or other destination (n=6, 2.8%). In total, 15.9% (n=33) were discharged to a destination providing a higher level of care than the preadmission residence. There was a significant difference overall (an exposure-response type relationship) in the proportion of participants discharged to a higher level of care among those who experienced a decline, no change or improvement in their nutritional status during inpatient stay evaluated using the full MNA® (Figure 2:11). The median (IQR) LOS for all participants was 17 (13 – 29) days (range 4 – 88). Overall there was an increase in FIM score during subacute inpatient stay (median (IQR) change 22 (14 – 29)). There was no difference in median LOS or change in FIM score during subacute inpatient stay between participants who experienced a decline, no change classification during inpatient stay (Figure 2:12, Figure 2:13).

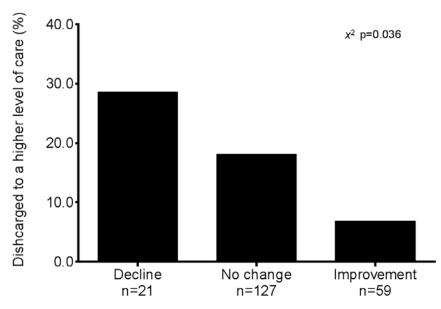
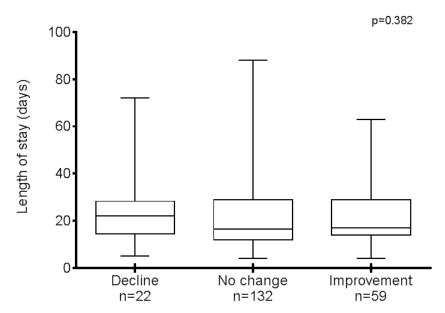
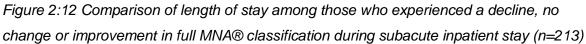


Figure 2:11 Proportion of participants discharged to a higher level of care among those who experienced a decline, no change or improvement in full MNA® classification during subacute inpatient stay (n=207)

Full MNA®, 18 item Mini Nutritional Assessment tool

Data analysed using Chi^2 test (p=0.036) with post hoc test of standardised residuals (p>0.05) Analyses exclude participants who were discharged to 'other' destination (n=6)





Full MNA®, 18 item Mini Nutritional Assessment tool

Data analysed using Kruskall Wallis test

Box plots indicate median (middle line in box), IQR (edges of box) and range (shorter lines)

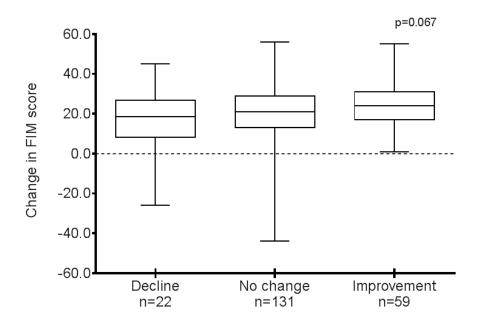


Figure 2:13 Comparison of change in FIM score among those who experienced a decline, no change or improvement in full MNA® classification during subacute inpatient stay (n=212)

Full MNA®, 18 item Mini Nutritional Assessment tool; FIM, Functional Independence Measure Data analysed using Kruskall Wallis test

Box plots indicate median (middle line in box), IQR (edges of box) and range (shorter lines)

Outcomes one year following discharge from subacute care

In the year following discharge from subacute care, one third (n=77, 36.2%) of participants were readmitted at least once (range 1 - 6) to an healthcare service within Eastern Health (where this study was undertaken). Of the 145 readmissions, the majority were to acute hospital (n=101, 70.1%), some were to subacute care (rehabilitation or GEM, n=27 18.8%) and the remainder of readmission episodes (n=16, 11.1%) were to other care types (palliative care, transitional care program, psychogeriatric care, hospital in the home). There was no difference in the proportion of participants readmitted to a healthcare service once or more in the year following discharge among those who experienced a decline, no change or improvement in full MNA® classification during the study observation period (Figure 2:14).

Amongst those who were readmitted to an Eastern Health healthcare service in the year following discharge from subacute care (n=77) 13 participants died during a readmission. The relationship between change in nutritional status during the initial subacute inpatient stay (i.e. during the study observation period) and mortality during readmission over the follow up 12 months was explored through relative risk. For participants whose full MNA® classification improved during subacute care, there was a non-significant lower relative risk of mortality (RR=0.43, 95% CI 0.10 – 1.78) than for those whose full MNA® classification did not improve (i.e. no change or decline) (Appendix 4).

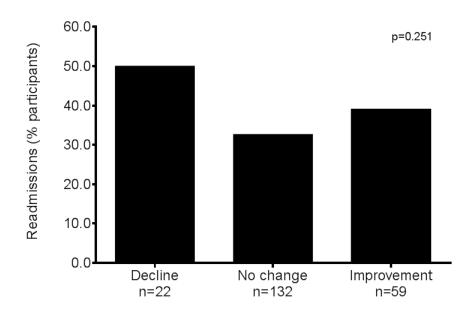


Figure 2:14 Proportion of participants readmitted to Eastern Health one year following discharge from subacute care among those who experienced a decline, no change or improvement in full MNA® classification during subacute inpatient stay (n=213)

Full MNA®, 18 item Mini Nutritional Assessment tool Data analysed using Chi² test

2.5 Discussion

This study explored change in patients' nutritional status during subacute inpatient stay under usual care conditions and found that overall, the majority of participants did not demonstrate a decline in full MNA® classification. There was substantial variability in the direction and magnitude of progression or regression of nutritional status during actual (also variable) LOS among this heterogeneous subacute population. The prevalence of malnutrition decreased by about 9% and over half of participants who were malnourished on admission had an improvement in full MNA® classification at discharge. These data suggest that usual multidisciplinary subacute care supports a positive change in participants' nutritional status, particularly for those who are malnourished on admission, regardless of the underlying medical condition. Usual dietetic intervention largely focused on the tailored provision of ONS to address nutrient deficit and was consistent with clinical recommendations (12, 72).

Although the focus of subacute care is on improving function and independence, patients also appear to make nutritional gains. The findings from this study are consistent with the improvement in nutritional status of subacute patients seen in two smaller studies conducted 5 - 15 years ago (24, 148) and local studies conducted at the same time as this research (174, 175). In the subacute setting, improvement in nutritional status has been shown to occur among 22 - 50% of participants, with variability attributable in part to the different methods used to evaluate nutritional status (148, 174, 175). Although there is evidence from this study and others that nutritional decline does occur among a proportion of patients in both subacute and acute care (174-177), the overall perception of widespread and significant nutritional decline during inpatient stay may be more severe than is supported by the literature.

2.5.1 Characteristics predictive of change in nutritional status

Participants with impaired cognition were less likely to show an improvement in nutritional status, even when controlling for other demographic characteristics. This is consistent with the known impacts of impaired cognition on nutrition. Dementia and confusion affect the desire and ability to eat, with dysphagia, reduced food intake and weight loss characteristics of the dementia process (178). Consequently, nutrition care should be prioritised for patients with impaired cognition due to their

vulnerability. This includes monitoring nutritional status over the course of inpatient stay and providing nutrition intervention, including individualised dietetic care to those identified as malnourished or at risk or with declining nutritional status.

Other factors predictive of change in nutritional status were not identified in regression analyses but are likely to exist given that the models explained only a small amount of variance associated with nutritional improvement. In particular, type and severity of illness may be associated with change in nutritional status, due to the interdependent relationship between disease and malnutrition. It is a limitation that MDC and AROC impairment codes were unable to be controlled for in regression modelling. In the absence of this analysis, the effect of primary diagnosis on change in nutritional status is unable to be investigated or untangled. Allard *et al.* (176) demonstrated cancer diagnoses and surgery were more common among acute hospital patients with a deteriorating nutritional status. The medical stability and disease acuity of subacute patients in contrast to acute patients may convey differences in progression of nutritional status among these populations, although no studies have made direct comparisons to investigate this.

There appeared to be preferential improvement in nutritional status among malnourished patients compared to those at risk or well nourished. This is likely due to their greater capacity for repletion and/or receipt of nutrition intervention (nutrition care plus dietetic intervention). The progression of nutritional status among the half of participants who were malnourished on admission whose nutritional status did not improve was unclear. It was not possible to identify decline among these participants due to the categorical nature of the primary outcome (change in full MNA® classification). Given that the aetiology of malnutrition can influence the capacity for recovery, nutritional decline may be anticipated among patients with cachexia or sarcopenia in contrast to starvation, where traditional nutrition intervention can be futile if underlying inflammatory processes are not addressed (179, 180).

2.5.2 Effects of change in nutritional status on clinical outcomes

Unfavourable changes in nutritional status appear to be associated with worse outcomes, although it is difficult to separate cause and effect. In this study, fewer participants experiencing improvement in full MNA® classification were discharged to a higher level of care. Decline in nutritional status has been shown to be associated with increased healthcare costs, complications and longer LOS among acute and subacute patients (174, 176, 177). One study has found opposing results for LOS (24). Through statistical modelling Allard *et al.* (176) demonstrated in a large study of hospital patients with a LOS of at least seven days the relationship between longer LOS and nutritional decline existed independent of nutritional status at admission, change in disease status and demographic characteristics. Additionally LOS was not different for patients with an improvement in nutritional status compared to those whose nutritional status remained stable (176). This provides a convincing argument for the need to identify and prevent nutritional decline in all patients, in addition to treating malnutrition identified on admission.

2.5.3 Evaluating change in nutritional status

Like there is lack of unanimity on the criteria of malnutrition there is uncertainty about what constitutes change in nutritional status. Furthermore there is no single, simple, bedside gold standard method to monitor change in nutritional status over time due to the complexity of nutrition assessment, body composition in the elderly and the constraints (practically and economically) of the healthcare environment. This presents challenges for both clinicians and researchers. Multiple outcome measures were used in this study in an attempt to overcome this limitation, with a focus on practical bedside tools to maintain relevance for clinical practice.

Objective nutritional indices were included to explore the practicality of their use in the real-world subacute setting and triangulate with full MNA® outcomes. As described in chapter 1, objective anthropometric (weight, MAC, CC, FFM) and functional (HGS) indices measure a single parameter known to be associated with nutritional status. These measurements are recommended for use in clinical and research environments and provide an alternate or adjunct method for nutritional surveillance, with the advantage of being portable, cheap, quick and low burdensome (72).

Although it was anticipated that the objective outcomes would show a change over time consistent with the full MNA®, this was not observed. The cause and clinical significance of this is unclear. This discrepancy may be due to error in weight and circumference measurements due to orthotic devices or changes in hydration status. Normal variation in weight of well hydrated, older subacute patients is reported to be 1.1 - 3.6%, which equates to 0.77 - 2.52 kg for participants (based on median weight at admission 69.90 kg, n=213) (181). Weight fluctuation is known to be associated with time of day weighing occurs, which could not be controlled in this study due to logistical constraints (181). The absence of change in HGS seen in the subgroup are likely due to the lack of statistical power (small size) for this additional measure. What was clear is that although not used routinely in practice, HGS and FFM measures are likely to be feasible in this population.

There appeared to be substantial differences in the way the two versions of the Mini Nutritional Assessment functioned as a tool for evaluating change in nutritional status over time. The shorter MNA® is recommended for clinical use (152). While this tool has been established as suitable for differentiating between nutritional states of elderly patients (100), the findings draw attention to the uncertainty of the MNA® to reliably identify change in nutritional status. Compared to the 18 item full MNA®, the six item MNA® misclassified change in nutritional status for over a third of participants and was inconsistent at identifying factors predictive of improvement in nutritional status. Although this study and other similar research (175) identified that the MNA® can identify statistically significant change in nutritional status using MNA® score or classification, caution and clinical judgement should be exercised when interpreting findings.

2.5.4 Strengths and limitations

A strength of this study is that the complete sampling strategy make the findings related to change in full MNA®, weight, MAC and CC generalisable to other subacute populations where usual care including foodservices (cook chill), multidisciplinary care, nutrition care and dietetic intervention is similar. As the study was conducted at one site, the effect of variation in these aspects of care on change in nutritional status was not captured. It is acknowledged that referral of malnourished or at risk participants (on admission) to the ward dietitian was optimised as a result of the research protocol and therefore dietetic intervention may be an overestimation of true clinical practice. All patients were eligible to participate

including those aged less than 65 years to reflect the actual subacute populations. However, the full MNA® and MNA® have not been validated in an adult population.

Overall, the attrition rate for full MNA® data was 14% which compares favourably with a similar local study (175). This study attempted to re-evaluate the nutritional status of all participants regardless of LOS. This is a strength and contrasts to other studies that have only captured subacute patients with a LOS of 14 or 21 days (174, 175). Consideration must be given to those who were not retained or recruited into the sub-study, as this may affect interpretation of findings. The majority of participants who did not have complete data for full MNA® assessments (primary outcome) were discharged at short notice back to acute setting due to a deterioration in clinical condition. The change in nutritional status of these participants (n=9) is unclear however it is likely that worsening health will have a negative effect on nutritional status. Consequently, nutritional decline may be underrepresented. Other reasons for loss to follow up (Figure 2:6) do not appear to be associated with a particular pattern of change in nutritional status.

Due to time restraints, sub-study measurements were completed with a convenience sample of consenting participants. As recruitment and retention rates were suboptimal and participants were not representative of the subacute population, these data are unlikely to be generalisable. Nevertheless, inclusion of these outcomes was valuable to explore their feasibility in this setting.

The small number of patients who experienced deterioration of nutritional status prevented statistical investigation of demographic factors predictive of decline in full MNA® classification. Follow up data on hospital readmissions and inpatient mortality in the year following discharge are likely to underestimate true results as data were only available for Eastern Health. Linkage to complete mortality and readmissions data available in the National Death Index and the Victorian Admitted Episodes Dataset was intended however cost was prohibitive.

The full MNA® was selected as the primary outcome because it is a valid nutrition assessment tool in elderly populations and is accepted internationally. The minimum time suggested between repeated assessments with the full MNA® is one to three months, though a shorter period was allowed in this study (72, 152). The full MNA®

captures general health related items (e.g. pressure injuries, number of medications) that may improve due to convalescence alone which may confound results. For these reasons the use of the full MNA® is a limitation, although unavoidable in the absence of alternate comprehensive bedside tools with well-established responsiveness (ability to detect change). Pathology was not completed as a routine aspect of usual care at admission or discharge and limited resources prevented it from being obtained specifically for study purposes in the subgroup of participants. The lack of biochemical outcome data did not allow consideration of inflammation which is another limitation.

2.5.5 Future directions

The findings of this research highlight that subacute care provides an important window of opportunity for the provision of nutrition intervention to improve the nutritional status of patients. The question arises as to whether more can and/or should be done in subacute care to capitalise on the opportunity to intervene and improve the nutritional status of more patients. In this study, 82.2% of participants were malnourished or at risk of malnutrition on admission and 10.2% experienced a decline in nutritional status. Over half of participants experiencing nutritional decline and quarter of participants at risk of malnutrition were not seen by a dietitian. Providing tailored, sufficient and timely dietetic care to all nutritionally vulnerable groups (malnourished patients, patients at risk of malnutrition and those with declining nutritional status) will be a challenge, if not impossible, due to the high prevalence of these conditions in relation to the capacity of the dietetic workforce.

Reconsidering indicators and priorities for dietetic intervention for patients with impaired nutritional status using additional information such as impaired cognitive status may assist to triage and manage the clinical case load. It is also essential that ward or department level systems or structures of nutrition care are in place to support the nutritional status of all patients, including those who may not receive dietetic intervention though theoretically may benefit from it. There may be a role for enhanced foodservice, clinical care (e.g. feeding assistance, protected mealtimes) or eating environments to optimise nutritional intake, with the strength of these approaches being that they are available to all patients due to their systematic nature. Evidence of their effectiveness needs to be considered.

70

2.6 Conclusion

This profile illustrates diversity in the nutritional status of subacute patients. Usual nutrition related practices resulted in the maintenance of nutrition status for the majority of participants in subacute care regardless of disease state. Improvement in nutritional status was observed particularly amongst those who were malnourished on admission while patients with cognitive impairments were less likely to have an improvement. The complexity of monitoring nutritional change was highlighted by inconsistencies in objective outcome measures and multidimensional nutrition assessment, and between two versions of a nutrition assessment tool.

Chapter 3

The effect of interventions to prevent and treat malnutrition in the patients admitted for rehabilitation: A systematic review with meta-analysis This chapter presents the published manuscript (Appendix 7);

 Collins J, Porter J. The effect of interventions to prevent and treat malnutrition in patients admitted for rehabilitation: a systematic review with meta-analysis. J Hum Nutr Diet. 2015;28(1):1-15.

This chapter relates to the presentation;

 Collins J, Porter J. A review of the effect of oral-nutrition related interventions to address malnutrition in the rehabilitation setting.
 Victorian Allied Health Research Conference, Melbourne, Australia.
 2014. Poster presentation.

Declaration by candidate

In the case of Chapter 3, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Conducted literature search	100%
Selected articles for inclusion	50%
Extracted data from included articles	100%
Rated quality of included articles	50%
Conducted analyses	100%
Prepared manuscript for publication	80%
Revised manuscript as per journal requests	80%

The following co-authors contributed to the work. If co-authors are students at Monash University, the extent of their contribution in percentage terms must be stated:

Name	Nature of contribution
Judi Porter	Supervised the review process, independently selected articles for
	inclusion, independently rated the quality of included articles and
	critically reviewed the manuscript and its revisions.

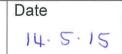
The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the candidate's and co-authors' contributions to this work*.

Candidate's Signature

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Main Supervisor's Signature

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Dates	
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*Note: Where the responsible author is not the candidate's main supervisor, the main supervisor should consult with the responsible author to agree on the respective contributions of the authors.

Notes;

Due to formatting requirements for the journal, energy is described in calories. To convert units: 1 kcal = 4.2 kJ.

The term 'rehabilitation' is used in the manuscript although this referred to all types of subacute care (i.e. rehabilitation, geriatric evaluation and management). The full search strategy (Appendix 8) lists the range of subacute care settings included in the review. The term 'rehabilitation' was felt to be more widely recognised and understood by an international (particularly British) audience compared to 'subacute care'.

Some content of the introduction and discussion sections of this chapter have been amended slightly for consistency and to link with previous chapters. Subheadings not included in the manuscript have also been introduced in these sections for consistency throughout the thesis.

3.1 Abstract

Background Malnutrition occurs frequently among patients in rehabilitation, leading to poorer outcomes. Evidence of the effects of interventions to prevent or treat malnutrition is required to guide clinical practice in this setting. This systematic review aimed to determine the effect of oral nutrition interventions implemented in rehabilitation on nutritional and functional outcomes.

Methods Five databases were searched to identify relevant publications; intervention trials of oral nutrition interventions (such as oral nutrition supplements, foodservice interventions, clinical care processes, enhanced eating environments) conducted with patients admitted for rehabilitation, reporting dietary intake, anthropometric, biochemical or functional outcomes. The reviewers determined study eligibility and assessed the included studies for risk of bias. Outcome data were combined narratively and by meta-analyses.

Results From 1765 publications, 10 studies trialling oral nutrition supplements, foodservice interventions and clinical care processes (of neutral or positive quality) were identified. Compared to meals alone, oral nutritional supplements significantly improved energy and protein intake, with some evidence for improvements in anthropometry and length of stay. There was little evidence that speciality supplements were beneficial compared to standard versions. Meta-analyses demonstrated significantly greater energy [weighted mean difference (WMD) = 324 kcal, 212–436 kcal 95% confidence interval (CI)] and protein (WMD = 9.1 g, 0.2–17.9 g 95% CI) intake with energy dense meals. Opposing results were reported in studies investigating enhanced clinical care processes.

Conclusions The provision of oral nutrition supplements and energy dense meals improved energy and protein intake and therefore may comprise effective strategies for addressing malnutrition in rehabilitation. The effect of these strategies on other nutritional and functional outcomes should be explored further.

3.2 Introduction

3.2.1 Background

Malnutrition research has largely focussed on acute hospitals and, more recently, on residential aged care facilities, with little attention given to the rehabilitation setting despite growing demand for this type of health care. Rehabilitation is "care in which the primary clinical purpose or treatment goal is improvement in the functioning of a patient with an impairment, activity limitation or participation restriction due to a health condition" (13) (page 11). Data from the UK and Australia indicate that admissions to rehabilitation facilities increased by over 20% between 2007/2008 to 2011/2012 and 2006/2007 to 2010/2011, respectively (13, 182, 183).

A recent review found that malnourished patients have worse function and quality of life following discharge from rehabilitation to the community, and are more likely to be discharged to higher level care or an acute hospital (62). Malnutrition among rehabilitation patients is also associated with longer length of stay and inpatient mortality (24, 52). As a result of its adverse effects, interventions that are clinically, nutritionally and cost effective are required to prevent and treat malnutrition.

As introduced in chapter 1, a range of nutrition interventions to prevent and treat malnutrition and malnutrition risk exist. Strategies that promote adequate intake of nutrition via an oral route include dietetic interventions (including oral nutritional supplements (ONS)) and foodservice interventions, clinical care processes and an enhanced eating environment. ONS are whole protein enteral products, usually in drink or pudding form, specifically designed for clinical use to manage malnutrition (184). Foodservice interventions are based on manipulation to the food production, preparation, selection or provision system. Clinical care processes are systems or policies implemented by clinicians, or to support clinicians, with the aim of identifying, preventing, treating or monitoring malnutrition and its risk factors. Enhanced eating environments can be considered as settings that have been modified to make the eating experience more enjoyable.

Malnutrition guidelines report no evidence underpinning the efficacy or effectiveness of many interventions that nevertheless are implemented in rehabilitation, because of a lack of studies in this setting (72). The findings of nutrition research conducted in the hospital environment with acutely unwell patients or in aged care settings with residents with functional or psychological deficits may be translatable to rehabilitation patients but should be confirmed through evaluative studies specifically recruiting these patients. As such, currently, there is a lack of evidence on which to base nutrition-related clinical care and multidisciplinary practice within the rehabilitation setting.

3.2.2 Aims

This review examined the evidence to determine whether oral nutrition interventions that aim to enhance dietary intake improve nutritional and functional outcomes in patients admitted for rehabilitation compared to alternate interventions or standard/usual care.

3.3 Methods

A systematic literature review was conducted according to recommendations outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (185). The review was registered on the PROSPERO International prospective register of systematic reviews (CRD42013003937).

3.3.1 Eligibility criteria

Criteria for study inclusion were developed using the Participant – Intervention – Comparator – Outcomes – Study design (PICOS) format (Figure 3:1). Studies conducted with adult inpatients in rehabilitation, Geriatric Evaluation and Medicine (GEM) wards or similar were considered. Research conducted in residential aged care facilities, acute hospital wards, mental health facilities or drug and alcohol rehabilitation were excluded, in addition to those recruiting participants living in the community, receiving palliative care, or outpatient or ambulatory rehabilitation. Studies describing interventions initiated in the acute setting with follow-up occurring following discharge to rehabilitation were also excluded.

Studies that tested an oral nutrition intervention (e.g. ONS, foodservice procedures, therapeutic diets, meal environment, ward support or education etc.) and compared this with an alternate intervention or standard/usual care were eligible for inclusion. Interventions designed to optimise nutritional status via enteral or parenteral nutrition, vitamin and mineral supplements, chemical additives (e.g. monosodium glutamate) or medications (e.g. steroids to stimulate appetite) were not considered because the focus was on oral nutrition approaches to preventing or treating malnutrition. Similarly, multifactorial interventions with only a single component relating to nutrition were also excluded.

The primary outcome measures were dietary intake (energy intake, protein intake), anthropometry (weight, body mass index (BMI), fat free mass (FFM), triceps skin fold, mid arm circumference (MAC), mid arm circumference (MAC) etc.), nutritionrelated biochemistry (albumin, pre-albumin) or structured nutritional assessment score or classification (e.g. Subjective Global Assessment, Mini Nutritional Assessment). The secondary outcomes were function, including measures capturing the need for assistance, physical capacity or strength (e.g. the Functional Independence Measure (FIM), Barthel Index, lung function test, 6-min walk test, grip strength) and length of stay (LOS). Outcomes measured during the rehabilitation inpatient stay only were considered.

Studies with level of evidence of II (randomised controlled trials (RCT)), III-1 (pseudo RCT), III-2 (comparative study with concurrent controls), III-3 (comparative study with non-concurrent controls) or IV (case series) were eligible to be included (186). These levels of evidence rank the strength of the evidence based on the study design and its appropriateness in addressing the research question, ranging from level I (strongest) to IV (weakest). Observational studies and cross-sectional studies were excluded because no intervention was tested. Publications in a language other than English were ineligible.

Population	Adults, inpatients, rehabilitation
Intervention	Oral nutrition related intervention
Comparator	Alternate intervention, standard/usual care
Outcomes	Dietary intake, anthropometry, biochemistry, nutrition assessment,
	function, length of stay
Study design	Intervention study, level of evidence of IV or above

Figure 3:1 Study eligibility criteria based on PICOS framework

Level of evidence based on National Health and Medical Research Council (NHMRC) criteria (186)

3.3.2 Search strategy

Ovid Medline (from 1946), PsycINFO (from 1806), CINAHL (from 1937), Embase (from 1947) and the Cochrane Central Register of Controlled Trials (from 1991) were searched in March 2013 to identify relevant publications. Reference lists of included publications and review articles related to nutrition interventions retrieved from the database search were hand searched to identify additional studies for inclusion (187-190). The search terms were determined through exploration of key words used in the relevant literature and refined after consultation with a librarian with health science expertise. The subject heading and phrases were searched to ensure maximum retrievals. Details of the full search strategy are available in Appendix 8.

3.3.3 Study selection

Studies were selected using the recommended process of identification, screening and eligibility assessment (185). After removing the duplicates, two authors independently screened titles and abstracts to exclude those not meeting the inclusion criteria, and then reviewed full texts of the remaining publications to identify the studies to be included in the review. Conflicting opinions were resolved through consensus. Because there were a range of terms used internationally to describe non-acute care facilities (e.g. continuing care, long-term geriatric care, geriatric rehabilitation, subacute care), the authors referred to the description of the patient group, including the average LOS, functional and clinical status, treatment provided and researchers' affiliations, to determine whether the study was conducted in an eligible setting.

3.3.4 Data extraction and assessment

A standard template was used to collate data relating to study method (e.g. level of evidence, intervention), results (e.g. outcome, clinical relevance), internal validity (e.g. randomisation, compliance) and external validity (e.g. generalisability, applicability). Both authors independently rated study quality using the Quality Criteria Checklist for Primary Research and came to consensus through discussion to assign a rating of negative (weak quality; does not adequately address inclusion/exclusion, bias, generalisability, data collection and analysis), neutral (neither exceptionally strong nor exceptionally weak quality) or positive (strong

quality; adequately addresses inclusion/exclusion, bias, generalisability, data collection and analysis) (191). A negative rating was assigned if six or more validity items were not adequately addressed and a positive rating was provided if validity items two, three, six, seven and one other were adequately addressed (Refer to footnote of Table 3:2 for description of validity items) (191). This tool includes criteria that are associated with decreased bias and improved validity in primary research and is specific for studies in the field of nutrition and dietetics.

3.3.5 Analysis

Eligible studies were grouped according to the type of intervention and results were described narratively, with a greater emphasis placed on findings from studies achieving high-quality ratings. The mean and standard deviation (SD) or standard error of the mean (SEM) were reported for energy and protein intake in each group (or before and after for case series). The change in mean and SD (or SEM) were reported for other outcomes, including anthropometry, biochemistry and functional measures for each group. Units were converted to a consistent format (e.g. kcal, kg, g/L). Data were determined from graphs or sought from authors when necessary.

Meta-analyses were undertaken using STATA® Version 11 (Stata-Corp, College Station, TX, USA) where there were at least three studies testing the same type of intervention and reporting the same outcome. The unstandardized weighted mean difference (WMD) and 95% confidence interval (CI) between groups was calculated using a random effects model. This model was selected *a priori* because independent studies were assumed not to be functionally equivalent as a result of different protocols and participant groups, and therefore lacking a common effect size. The I² statistic was calculated to indicate heterogeneity between studies, with 25%, 50% and 75% classified as low, medium and high variance, respectively (192).

3.4 Results

3.4.1 Study selection

Ten studies out of 1468 retrieved publications fulfilled the inclusion criteria for the present review (Figure 3:2). Eight studies were identified from the database search, one study was identified via hand searching references lists of reviews, and one study known to the authors was also included. No additional relevant studies were located from the reference lists of included publications. The majority of studies were excluded at the final stage because the study population was recruited from an ineligible setting. One study with a multi-arm design was referred to as the 'main study' or 'substudy' and considered separately in the analyses (121). One study recorded outcomes at two time points that have also been considered separately (193).

3.4.2 Study characteristics

The included studies were conducted with elderly patients with a mean age ranging from 65 to 83 years with non-specific and specific clinical conditions including hip fracture (162, 194), stroke (195) and chronic obstructive pulmonary disease (COPD) (196) (Table 3:1). The participants in most studies were frail, malnourished or at risk of malnutrition. Studies trialled a range of interventions: ONS (n=3), ONS with a modified nutrient content or delivery schedule (speciality ONS) (n=3), foodservice interventions (n=4) and clinical care processes (n=2).

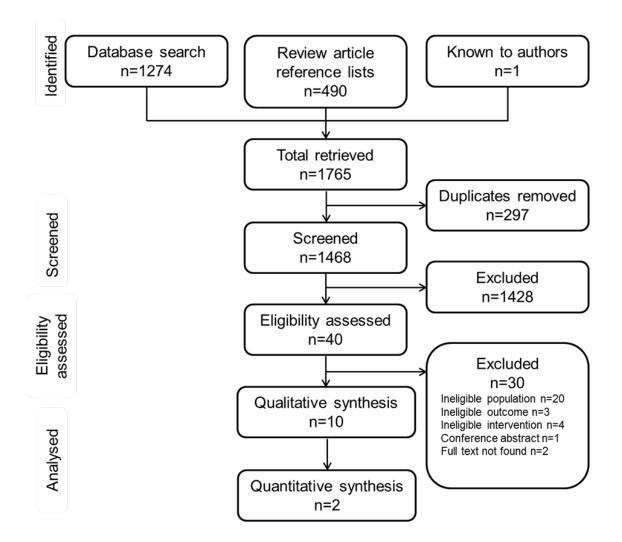


Figure 3:2 Study selection process

Table 3:1 Characteristics and outcomes of studies investigating oral nutritional interventions to prevent and treat malnutrition in rehabilitation facilities

Study	Population	Intervention	Comparator	Ancillary	Sample size	Duration	Outcomes		
				treatments	(% retained)				
Oral nut	Dral nutritional supplements								
	Malnourished elderly with	Standard meals	Standard	8 week	64 (I)	8 weeks	Energy intake; protein		
et al.	COPD. Mean age 65	plus ONS	meals	inpatient	28 (C)	(I or C)	intake; weight;		
	years. Eligibility included			pulmonary	Retention not		albumin; FFM;		
tzberg (196)	malnutrition (based on			rehabilitation	reported		maximum inspiratory		
Creutzberg (196)	BMI, FFM or BMI plus			program			mouth pressure; 12		
0	weight loss)						minute walk distance		
	Elderly patients with hip	Standard meals	Standard	Inpatient	65 (94) (I)	Maximum	Energy intake; protein		
2)	fracture. Mean age 81-82	plus ONS	meals	rehabilitation	61 (98) (C)	4 weeks	intake; BMI; albumin;		
Myint <i>et al.</i> (162)	years. Eligibility included			therapy;		(I or C)	MAC; TSF; FIM;		
et al.	BMI<25			vitamin D			elderly mobility scale;		
int ∈				supplement;			hand grip strength;		
My				calcium			quadriceps strength;		
				supplement			LOS		
al.	Frail elderly. Mean age 81	Standard meals	Standard	None reported	10 (70) (I)	8 weeks	Energy intake; protein		
	years.	plus ONS plus	meals		10 (70) (C)	(I or C)	intake; weight;		
Hankey <i>et</i> (193)		beverages with					albumin; MAC; AMC		
Haı		glucose polymer							

Study	Population	Intervention	Comparator	Ancillary	Sample size	Duration	Outcomes		
				treatments	(% retained)				
Special	Speciality oral nutritional supplements								
et	Elderly patients with hip	High protein	Standard	None reported	22 (82) (I)	Maximum	Albumin; pre-albumin;		
ann 94)	fracture. Mean age 83	ONS	ONS		24 (83) (C)	4 weeks	FIM (mobility		
Neumann <i>al.</i> (194)	years. Eligibility included					(I or C)	subscale); LOS		
S Se	BMI< 30kg/m ² .								
al.	Elderly patients post	Energy and	Standard	Inpatient	58 (88) (I)	Entire	Weight; albumin; pre-		
et i)	stroke. Mean age 74-75	protein dense	ONS	rehabilitation	58 (88) (C)	LOS (~3.5	albumin; FIM; 2 min		
Rabadi <i>e</i> . (195)	years. Eligibility 2.5%	ONS		therapy		weeks)	walk test; 6 min walk		
Ral	recent weight loss.					(I or C)	test; LOS		
(6	Malnourished elderly	ONS delivered	ONS	Education and	32 (78) (I)	2 weeks	Energy intake; protein		
(129)	patients. Mean age 80-81	during	delivered at	tailored	33 (76) (C)	(I or C)	intake; weight; albumin		
et al.	years. Eligibility included	medication	mid-meals	nutritional					
elle	malnutrition (based on	round		advice about					
Campbell <i>et al.</i>	SGA category B or C).			improving					
Car				nutrition					

Study	Population	Intervention	Comparator	Ancillary	Sample size	Duration	Outcomes
				treatments	(% retained)		
Foodse	rvice interventions		1		I	1	ł
Campbell <i>et al.</i> (129)	Malnourished elderly patients. Mean age 76-81 years. Eligibility included malnutrition (based on SGA category B or C).	Food snacks self selected at mid-meals	ONS delivered at mid-meals	Education and tailored nutritional advice about improving nutrition	33 (73) (I) 33 (76) (C)	2 weeks (I or C)	Energy intake; protein intake; weight; albumin
Barton <i>et al.</i> (121) (main study)	Heterogeneous elderly. Mean age 75-77 years.	Smaller meals fortified with energy	Standard meals	None reported	27 (I/C) Retention unclear	Repeat 2 weeks (I), 2 weeks (C) until discharge/8 weeks	Energy intake; protein intake
Barton <i>et al.</i> (121) (substudy)	Heterogeneous elderly, Mean age 77-78 years.	Cooked breakfast	Standard meals	None reported	8 (I) 27 (C) Retention unclear	8 weeks (I) (C as above)	Energy intake; protein intake
Lorefalt <i>et al.</i> (122)	Heterogeneous elderly. Mean age 82 years	Smaller meals fortified with energy and protein	Standard meals	None reported	12 (83) (I/C)	3 days (I) then 3 days (C)	Energy intake; protein intake

Study	Population	Intervention	Comparator	Ancillary	Sample size	Duration	Outcomes
				treatments	(% retained)		
Clinical	care processes						
	Heterogeneous elderly.	Enhanced	Usual	Occupational	345 (I and C)	Entire LOS	Weight; Barthel
	Mean age 84 years.	nutrition	nursing care	therapy for	Retention not	(~5 weeks)	Index; LOS
97)		related		functional eating	reported		
<i>I</i> . (1		nursing care		problems, as			
Poulsen <i>et al.</i> (197)				required; ONS or			
sen				extra food, as			
luo				required;			
ш				no involvement			
				by dietitians			
	Elderly patients at risk of	Nutritional	Standard	Improved	62 (I/C)	Entire LOS	Energy intake;
008	malnutrition. Mean age 81	assessment	care	nutritional	Retention	(mean LOS	protein intake;
al. 2	years. Eligibility included	by a dietitian,		screening	unclear	not	weight; albumin; pre-
Babineau <i>et al.</i> 2008	risk of malnutrition (based	care plan and				reported)	albumin; health
ieau	on BMI and weight loss or	dietetic					related quality of life
abir	albumin).	intervention					(physical functioning
Ш							subscale)

AMC, arm muscle circumference; BMI, body mass index; COPD, chronic obstructive pulmonary disease; FFM, fat free mass; FIM, Functional Independence Measure; LOS, length of stay; MAC, mid arm circumference; ONS, oral nutritional supplements; SGA, subjective global assessment; TSF, triceps skin fold; I, intervention group; C, control group

3.4.3 Study quality

A quality rating of positive, neutral or negative was assigned to all studies based on performance against set criteria (Table 3:2). Five studies were rated as positive, suggesting a low risk of bias (162, 194-197). Of these, three were RCTs and therefore conveyed both high quality and a strong level of evidence (162, 194, 195). The majority of the studies (six of 11) were assessed as being of neutral quality and were considered to be at risk of bias.

Study	Study design	Level of	Quality				Va	lidity	y ite	ms°				Comments
olday		evidence ^a	rating [⊳]	1	2	3	4	5	6	7	8	9	10	Commente
Myint <i>et al.</i> (162)	RCT	11	Positive	~	~	~	~	N/A	~	~	~	~	~	Dietary intake methodology not described
Neumann <i>et al.</i> (194)	RCT	11	Positive	~	~	~	~	~	~	~	~	x	x	Limitations not described; supported by nutrition company
Rabadi <i>et al.</i> (195)	RCT	11	Positive	✓	~	~	~	~	~	~	~	~	~	
Creutzberg <i>et al.</i> (196)	Historical control study, case series	III-3 - IV	Positive	~	~	~	~	N/A	~	~	~	~	~	Concurrent controls not used
Lorefalt <i>et al.</i> (122)	Case series	IV	Positive	>	~	N/A	~	N/A	~	~	~	~	~	
Hankey <i>et al.</i> (193)	RCT	11	Neutral	~	x	~	~	N/A	~	~	~	~	x	Inclusion or exclusion criteria not described; funding sources not described

Table 3:2 Quality of studies investigating oral nutritional intervention to prevent and treat malnutrition in rehabilitation facilities

Barton <i>et al.</i> (121) (main study)	Randomised cross over trial	11	Neutral	~	x	N/A	x	N/A	~	~	~	x	✓	Inclusion or exclusion criteria not described; limitations not described
Barton <i>et al.</i> (121) (substudy)	Non-randomised controlled study	III-2	Neutral	~	x	x	x	N/A	~	~	~	x	✓	Inclusion or exclusion criteria not described; comparability of groups not described; limitations not described
Campbell <i>et al.</i> (129)	Non-randomised controlled study with 3 arms	111-2	Neutral	~	~	x	~	N/A	~	~	~	~	~	Groups not comparable at baseline; Concurrent controls not used
Poulsen <i>et al.</i> (197)	Quasi experimental controlled trial	-2	Neutral	x	~	~	~	N/A	x	N/A	~	~	~	Intervention not described sufficiently
Babineau <i>et al.</i> (198)	Case series	IV	Neutral	x	~	N/A	~	N/A	x	~	~	~	~	Intervention not described sufficiently

RCT, randomised controlled trial; N/A, not applicable

^aLevel of evidence based on National Health and Medical Research Council (NHMRC) criteria; level I (strongest) to IV (weakest) (186)

^bQuality rating based on Academy of Nutrition and Dietetics (formerly American Dietetic Association) guidelines (191)

^cValidity items: [1] research question stated; [2] subject selection free from bias; [3] comparable study groups; [4] method for withdrawals described; [5] blinding used; [6] interventions described; [7] outcomes stated, measurements valid and reliable; [8] appropriate statistical analysis; [9] appropriate conclusions, limitations described; [10] funding and sponsorship free from bias. Grey indicates validity items that must be satisfied for a positive quality rating.

3.4.4 Outcomes

Oral nutritional supplements versus food

Three studies compared the provision of ONS plus usual meals with usual meals only as the control (162, 193, 196). Hankey *et al.* (193) provided two supplement drinks as part of the medication round at mid-morning and mid-afternoon (652 kcal/day, protein content not reported) and a glucose polymer prepared as a drink (up to 358 kcal) as the intervention. Myint *et al.* (162) supplied two 240-mL supplement drinks/day (500 kcal/day, 18–24 g protein/day), whereas Creutzberg *et al.* (196) gave ONS (drinks or puddings) one to three times a day between meals (average 670 kcal/day, protein content not reported), according to patient preferences.

These studies found that the consumption of ONS led to significantly greater energy and protein intake, although this did not consistently result in improvements in anthropometric or biochemical outcomes (Table 3:3). There was no difference in weight or BMI change in two studies (162, 193) however, a significant increase was demonstrated among COPD patients (196). Creutzberg *et al.* (196) also used bioelectrical impendence analysis (BIA) to measure FFM in subjects and showed a significant increase within the supplemented group and between groups. Arm muscle circumference improved in the supplemented group in another study (193). No studies demonstrated a significant change in albumin. Two studies reported the effect of ONS on a range of outcomes relating to function and indicated mixed results (162, 196). The study reporting LOS found that patients in the intervention group had a significantly lower LOS in rehabilitation (162). Table 3:3 Outcome data for studies testing oral nutritional supplements to prevent and treat malnutrition in the rehabilitation setting

Outcome	Study	Intervention	Control	p value
Energy intake	Hankey <i>et al.</i> (193)	1741 (102) ^a	1143 (116) ^a	<0.01
(kcal/day)	Myint <i>et al.</i> (162)	1480 (208)	1127 (211)	<0.001
	Creutzberg et al. (196) (change)	436 (NR)	N/A	<0.001
Protein intake	Hankey <i>et al.</i> (193) (g/day)	64.0 (6.2) ^a	43.7 (4.1) ^a	<0.05
	Myint <i>et al.</i> (162) (g/day)	73.6 (10.6)	63.5 (12.3)	<0.001
	Creutzberg et al. (196) (change g/kg/day)	0.3 (NR)	N/A	<0.001
Weight change (kg)	Hankey <i>et al.</i> (193) (4 weeks)	2.35 (NR)	0.00 (NR)	NS
	Hankey <i>et al.</i> (193) (8 weeks)	3.53 (NR)	-1.25 (NR)	NS
	Creutzberg <i>et al.</i> (196)	2.15 (0.27) ^a	0.08 (0.19) ^a	<0.05
BMI change (kg/m²)	Myint <i>et al.</i> (162)	-0.25 (0.83)	-0.72 (0.91)	0.012
Albumin change (g/L)	Hankey <i>et al.</i> (193) (4 weeks)	0.9 (NR)	-0.7 (NR)	NS
	Hankey <i>et al.</i> (193) (8 weeks)	0.2 (NR)	-1.3 (NR)	NS
	Myint <i>et al.</i> (162)	4.28 (3.39)	3.85 (3.12)	NS
	Creutzberg et al. (196)	0.9 (NR)	N/A	NS
MAC change (cm)	Hankey <i>et al.</i> (193) (4 weeks)	0.59 (NR)	0.00 (NR)	NS
	Hankey <i>et al.</i> (193) (8 weeks)	0.00 (NR)	-0.62 (NR)	NS
	Myint <i>et al.</i> (162)	-0.01 (0.99)	-0.09 (0.83)	NS
AMC change (cm)	Hankey <i>et al</i> . (193) (4 weeks)	1.23 (NR)	-0.63 (NR)	<0.05
	Hankey <i>et al.</i> (193) (8 weeks)	3.12 (NR)	-0.62 (NR)	<0.05
FFM change (kg)	Creutzberg et al. (196)	1.00 (0.31) ^a	-0.85 (0.38) ^a	<0.05

TSF change (mm)	Hankey et al. (193) (4 weeks)	0.0 (NR)	0.3 (NR)	NS
	Hankey <i>et al.</i> (193) (8 weeks)	-0.5 (NR)	-1.2 (NR)	<0.05
	Myint <i>et al.</i> (162)	-0.13 (1.16)	-0.66 (1.78)	NS
FIM score change	Myint <i>et al.</i> (162)	13.38 (7.11)	12.00 (7.91)	0.416
Elderly mobility scale	Myint <i>et al.</i> (162)	8.63 (4.13)	8.50 (4.66)	0.763
Handgrip strength change (kg)	Myint <i>et al.</i> (162)	-0.14 (1.61)	0.10 (1.71)	0.545
	Creutzberg et al. (196)	1.2 (NR)	N/A	0.004
Quadriceps strength change (kg)	Myint <i>et al.</i> (162)	1.91 (1.44)	1.97 (1.61)	0.663
12 min walk change (m)	Creutzberg et al. (196)	132 (NR)	N/A	<0.001
Max inspiratory mouth pressure change (cm H ₂ O)	Creutzberg et al. (196)	4.3 (1.3) ^a	2.0 (2.2) ^a	<0.05
LOS (days)	Myint <i>et al.</i> (162)	26.2 (8.2)	29.9 (11.2)	0.040

NR, not reported; NS, not significant; N/A, not applicable due to case series study design; BMI, body mass index; MAC, mid arm circumference; AMC, arm muscle circumference; FFM, fat free mass; TSF, triceps skin fold; FIM, Functional Independence Measure; LOS, length of stay

Data are mean (SD) unless when indicated by ^a where data are mean (SEM)

Myint et al. (162) tested significance for the change in outcomes over three time points including follow up beyond discharge from rehabilitation

Speciality oral nutritional supplements versus standard oral nutritional supplements

Three studies tested ONS that had modified nutrition formulations or delivery times (129, 194, 195). These were deemed speciality ONS for the purpose of this review because they were designed to be superior and hypothesised to offer additional benefits over standard ONS. In these studies, the intervention group received speciality ONS, whereas the control group received standard ONS, with both groups also receiving regular meals. One study contrasted two 237ml high protein drinks (480 kcal/day, 30 g protein/day) with standard supplements (500 kcal/day, 18 g protein/day) (194). Rabadi et al. (195) provided 120 ml of ONS every eight hours, with the intervention group receiving an energy dense supplement (720 kcal/day, 33 g protein/day) and the control group receiving a standard supplement (381 kcal/day, 15 g protein/day). One arm of the Campbell et al. (129) study explored a MedPass program, a dose-feeding strategy where a high energy dense supplement (e.g. 2 kcal/ml) was distributed multiple times/day as part of the medication round. In this study, those allocated to the med-pass intervention group received 60 ml of ONS four times a day with medications (475 kcal/day, 20 g protein/day), whereas the control group received two drinks provided at mid-morning and mid-afternoon (500-570 kcal/day, 18-26 g protein/day).

Overall, the three studies investigating the effect of speciality ONS demonstrated variable effects (Table 3:4). Energy intake and weight gain were greater in the intervention group, although this was not a statistically significant difference (129, 194). Neumann *et al.* (194) showed significantly greater intake of protein and increase in albumin levels among those receiving high protein ONS. There were some significant improvements in functional independence and exercise performance among stroke patients receiving speciality ONS but no difference in LOS (194, 195).

Table 3:4 Outcome data for studies testing speciality oral nutritional supplements to prevent and treat malnutrition in the rehabilitation setting

Outcome	Study	Intervention	Control	p value
Energy intake	Neumann <i>et al.</i> (194) (kcal/day)	1437 (NR)	1261 (NR)	0.215
	Campbell <i>et al.</i> (129) (kcal/kg IBW)	30.0 (7.0)	28.8 (7.7)	NS
Protein intake	Neumann <i>et al.</i> (194) (g/day)	62.6 (NR)	49.5 (NR)	0.048
	Campbell <i>et al.</i> (129) (g/kg IBW)	1.3 (0.3)	1.3 (0.3)	NS
Weight change	Rabadi <i>et al.</i> (195) (kg)	1.0 (3.3)	0.3 (3.8)	0.37
	Campbell et al. (129) (kg %BW)	1.5 (5.8)	0.4 (3.8)	NS
Albumin change (g/L)	Rabadi <i>et al.</i> (195)	-1.7 (3.5)	-1.6 (3.7)	0.87
	Neumann <i>et al.</i> (194)	7.0 (4.9)	2.0 (4.9)	0.019
	Campbell et al. (129)	2.8 (2.6)	2.3 (4.2)	0.960
Pre albumin change (mg/dL)	Rabadi <i>et al.</i> (195)	1.2 (5.7)	2.1 (6.1)	0.77
	Neumann <i>et al.</i> (194)	5.7 (6.7)	4.1 (4.8)	0.316
FIM score change	Rabadi <i>et al.</i> (195)	31.5 (14.3)	22.9 (11.8)	0.001
FIM (motor subscale) change	Rabadi <i>et al.</i> (195)	24.3 (11.8)	16.7 (9.6)	0.001
	Neumann <i>et al.</i> (194)	21.8 (NR)	20.0 (NR)	NR
2 min walk test change (Ft)	Rabadi <i>et al.</i> (195)	101.6 (79.4)	44.0 (62.5)	0.001
6 min walk test change (Ft)	Rabadi <i>et al.</i> (195)	299.3 (201.5)	170.6 (198.6)	0.001
LOS (days)	Rabadi <i>et al.</i> (195)	26.0 (10.1)	25.5 (7.3)	0.77
	Neumann <i>et al.</i> (194)	23.2 (1.3)	28.0 (2.6)	0.27

Table 3:4 continued

NR, not reported; NS, not significant; IBW, ideal body weight; BW, body weight; FIM, Functional Independence Measure; LOS, length of stay

Data are mean (SD)

It was assumed that Rabadi et al. (195) reported data as mean (SD) as units were not reported

Values for energy and protein intake in the study by Neumann et al. (194) were the average of five diet recalls including two administered post discharge

Foodservice interventions

Three studies compared energy dense meals with standard meals. Barton *et al.* (121) and Lorefalt *et al.* (122) implemented smaller, fortified meals and the substudy by Barton *et al.* (121) implemented a cooked breakfast. Comparison of up to two self-selected high energy and/or protein snacks (e.g. nuts, flavoured milk, crisps) and ONS between meals was undertaken by Campbell *et al.* (129).

There was a significantly higher daily energy and protein intake among patients receiving energy dense compared to standard meals (Table 3:5). Meta-analyses demonstrated that, overall, energy dense meals resulted in a significant mean difference of 324 (95% CI=212–436) kcal/day and 9.1 (95% CI=0.2–17.9) g of protein/day, in favour of the intervention) Figure 3:3, Figure 3:4). The heterogeneity between the studies was low to moderate for energy intake (I²=39.0%, p=0.194) and high for protein intake (I²=89.1%, p<0.001). Campbell *et al.* (129) found that patients who received mid-meal snacks consumed significantly less energy and protein compared to ONS (Table 3:5).

Table 3:5 Outcome data for studies testing foodservice interventions to prevent and treat malnutrition in the rehabilitation setting

Outcome	Study	Intervention	Control	p value
Energy intake	Barton et al. (121) (main study) (kcal/day)	1711 (195)	1425 (136)	0.001
	Barton <i>et al.</i> (121) (substudy) (kcal/day)	1744 (176)	1425 (136)	0.001
	Lorefalt <i>et al.</i> (122) (kcal/day)	2562 (490)	1864 (513)	0.01
	Campbell <i>et al.</i> (129) (kcal/kg IBW)	24.6 (5.9)	28.8 (7.7)	<0.05
Protein intake	Barton et al. (121) (main study) (g/day)	48.7 (6.3)	47.4 (6.5)	NS
	Barton <i>et al.</i> (121) (substudy) (g/day)	57.4 (6.0)	47.4 (6.5)	<0.05
	Lorefalt <i>et al.</i> (122) (g/day)	90 (7.5)	72.5 (10)	<0.05
	Campbell <i>et al.</i> (129) (g/kg IBW)	1.0 (0.3)	1.3 (0.34)	<0.05
Weight change (kg %BW)	Campbell <i>et al.</i> (129)	1.0 (3.1)	0.4 (3.8)	NS
Albumin change (g/L)	Campbell <i>et al.</i> (129)	1.9 (3.4)	2.3 (4.2)	0.960

NS, not significant; IBW, ideal body weight; BW, body weight

Data are mean (SD)

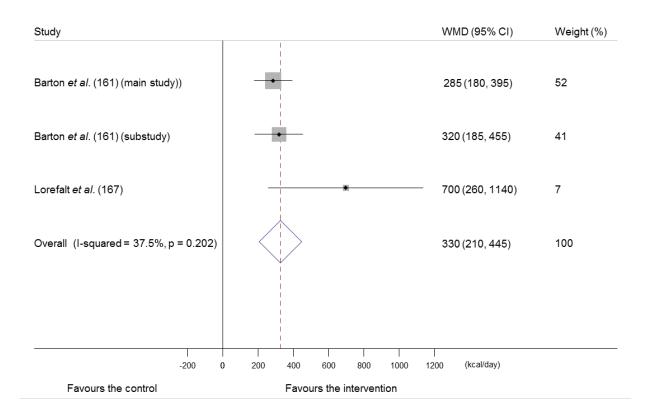


Figure 3:3 Meta-analysis of the effect of energy dense meals and standard meals on energy intake (kcal/day) among patients admitted for rehabilitation

WMD, weighted mean difference Data analysed using random effects analysis

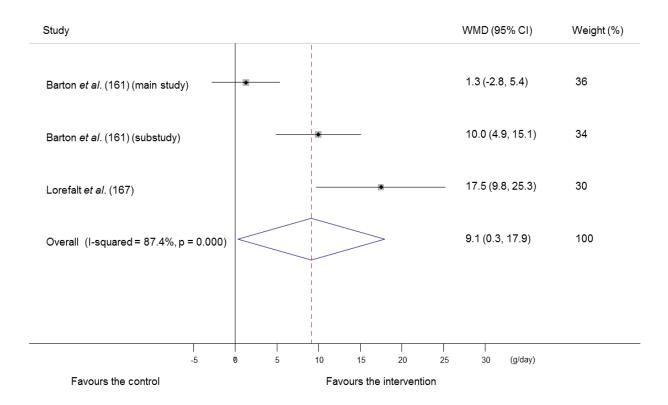


Figure 3:4 Meta-analysis of the effect of energy dense meals compared to standard meals on protein intake (g/day) among patients admitted for rehabilitation

WMD, weighted mean difference

Data analysed using random effects analysis

Clinical care processes

Interventions involved enhanced clinical care practices implemented by nursing and dietetic staff at the ward level. Babineau *et al.* (198) implemented a system of nutritional screening followed by nutritional assessment completed by a dietitian and the commencement of an individualised nutritional care plan with ongoing follow up and modifications as required. This enhanced care process significantly improved dietary intake, biochemistry and physical function (Table 3:6). Alternatively, trained nursing staff completed nutrition assessments and implemented individualised nutrition interventions in the study by Poulsen *et al.* (197). There was no significant difference in patients' weight or LOS under the control condition compared to the enhanced nurse-led clinical care process (Table 3:6).

Table 3:6 Outcome data for studies testing clinical care processes to prevent and treat malnutrition in the rehabilitation setting

Outcome	Study	Intervention	Control	p value
Energy intake (kcal/day)	Babineau <i>et al.</i> (198)	1627 (536)	1455 (456)	0.0001
Protein intake (g/day)	Babineau <i>et al.</i> (198)	64.4 (26.0)	59.0 (22.0)	0.01
Weight change (kg)	Babineau <i>et al.</i> (198)	0.2 (NR)	N/A	0.545
	Poulsen et al. (197)	0.0 (2.9)	-0.1 (2.8)	0.89
Albumin change (g/L)	Babineau <i>et al</i> . (198)	1.1 (NR)	N/A	0.001
Pre albumin change (g/dL)	Babineau <i>et al.</i> (198)	2.0 (NR)	N/A	0.003
Barthel Index score change	Poulsen et al. (197)	15.1 (NR)	15.6 (NR)	NR
Health related QOL (physical functioning) score change	Babineau <i>et al.</i> (198)	0.5 (NR)	N/A	0.044
LOS (days)	Poulsen et al. (197)	37.2 (29.8)	32.2 (24.9)	0.13

NR, not reported; N/A, not applicable due to case series study design; QOL, quality of life; LOS, length of stay

Data are mean (SD)

3.5 Discussion

The present review aimed to identify and collate the evidence relating to the effect of oral nutrition interventions among patients admitted for rehabilitation on nutritional and functional outcomes. There is convincing evidence that malnourished patients experience worse outcomes following discharge from rehabilitation (62). Effective, evidence based strategies to treat and prevent malnutrition during the rehabilitation period are essential for counteracting the course of decline observed in some and improving health outcomes for the majority of patients who are malnourished or at risk of malnutrition on admission (chapter 2). To this end, the findings of this review recommend the use of oral nutrition supplements or energy dense meals compared to standard meals alone, as potential solutions to improve energy and protein intake among patients in rehabilitation.

3.5.1 Oral nutritional supplements

There was some evidence indicating that the consumption of ONS in addition to regular meals improved energy and protein intake compared to consuming meals only (162, 193, 196). The patients who received ONS consumed on average an additional 350-600 kcal/day (1.5-2.5 mJ/day) and exceeded their estimated requirements, which is a clinically important outcome. There were positive changes in anthropometry, biochemistry, function and LOS, although not all outcomes were statistically significant or clinically meaningful. Past reviews and meta-analyses of studies conducted with patients with a range of clinical conditions in a variety of settings appear to show an overall effect in favour of ONS compared to standard care for improving weight, function, mortality, morbidity and LOS (2, 189, 199). It has been suggested that there may be a differential effect of supplements among different patient groups (200). Indeed, the most favourable results were reported this current review in a single study of nutritionally depleted patients with COPD receiving ONS during inpatient pulmonary rehabilitation (196). It was unclear whether beneficial outcomes were a consequence of ONS alone or if other aspects of the pulmonary rehabilitation program also contributed.

The three studies investigating speciality ONS (i.e. ONS with modified nutrition content or delivery schedule) were vastly different in their outcome measures, study

participants and the scope of the intervention. They included hip fracture patients receiving high protein ONS (194), stroke patients trialling high energy ONS (195) and a Med-pass program implemented with heterogeneous elderly (129), where all participants had compromised nutrition. Participants in the intervention and control groups demonstrated changes in outcomes in the same direction, with those receiving speciality ONS performing significantly better for only some measures. The current state of evidence remains inconclusive on whether speciality formulations or delivery schedules of ONS offer substantial benefits in excess of those achieved with standard or traditional ONS. Clinical guidelines emphasise individualising nutrition support to meet the nutritional needs of the patient in the context of their clinical condition, goals, progress and preferences (12, 72, 201). As such, clinical judgement should be used to determine whether modified supplements are more suitable.

3.5.2 Foodservice interventions

As an alternative to ONS, foodservice interventions (e.g. food fortification or midmeal snacks) can be used to address malnutrition in healthcare settings. The metaanalyses of the three neutral to positive quality studies of energy-dense meals with 113 participants demonstrated greater intake of energy (324 kcal; 1360 kJ) and protein (9.1 g) in favour of the intervention. It remains unknown whether the increase in dietary intake translates into clinically important endpoints as a result of the lack of inclusion of these outcomes. The majority of studies conducted in long-term care settings or acute hospitals have shown consistent findings, although there is scant evidence of additional clinical benefits (123, 125, 126, 132). Although food based interventions are potentially more acceptable to patients than ONS, they may fail to deliver energy and protein in adequate quantities to meet requirements and produce physiological changes.

3.5.3 Clinical care processes

Two studies relating to clinical care processes focussed on creating supportive environments to facilitate the delivery of nutrition care. Educating, training and supervising nurses to provide nutrition care to rehabilitation patients failed to demonstrate any benefits, potentially as a result of limitations of the design and the intensity of the education programme (197). BAPEN (73) recommend that dietitians are involved in planning and providing nutrition education to other health professionals, which was not apparent in this study (197). This contrasts with improved outcomes when dietitians commenced a NCP (198), supporting the importance of dietetic intervention and the contribution dietitians can make to the multidisciplinary teams effort to support patients' nutritional status.

3.5.4 Strengths and limitations

A strength was that function was measured as an outcome, which is of considerable importance in rehabilitation where the primary aim of treatment is to improve functional independence and physical capacity. A number of studies, those testing foodservice interventions in particular, only measured energy and protein consumption and therefore could not show whether improving dietary intake resulted in clinical or functional benefits. The range of terms used internationally to describe healthcare settings posed a challenge when assessing whether studies were conducted in a rehabilitation setting and therefore met the inclusion criteria for this review. The authors considered the description of the participants and the facility to determine eligibility. For example, a number of studies conducted in 'long-term care' were excluded because this was defined as catering for "older, more disabled longterm residents with medically complex conditions" with an average LOS of 835 days (202) (page 1554). Additionally, the search terms used in the review may not have been sufficiently extensive to retrieve studies conducted in a setting equivalent to rehabilitation but named alternatively. Limitations at the review level include the potential of publication bias and language bias because studies in languages other than English were excluded.

Study quality

A small number of studies were identified, reinforcing the paucity of malnutrition research conducted in the rehabilitation care setting, in contrast to the plethora of nutrition intervention studies undertaken in other healthcare settings, including acute hospitals and residential facilities. The quality and design of the majority of the studies was determined to be neutral because a number of publications failed to report critical elements of the study protocol, resulting in uncertainty about the risk of bias. Three well designed RCTs were exceptions, indicating that it is possible to

carry out robust, high quality studies despite the unpredictability of the clinical environment as a research setting.

3.5.5 Future directions

Despite the range of known oral nutrition interventions that aim to enhance dietary intake, the studies included in this review were limited to three types of interventions: ONS, foodservice interventions and clinical care processes. No studies relating to enhanced eating environments in the rehabilitation setting were identified. Creating a social and homely dining environment to improve dietary intake in the acute and aged care settings has yielded inconsistent results (203-205). Similarly, no studies relating to the provision of feeding assistance, general nutrition support or dietary counselling in the rehabilitation setting were identified. These clinical care processes have been evaluated in other healthcare settings with some positive outcomes noted (135, 184, 200, 206).

Future studies evaluating these and other new and innovative oral nutrition strategies in the rehabilitation setting are justified. Interventions conducted in acute hospitals and residential aged care facilities should be considered to inform clinical practice in the rehabilitation setting; however, the generalisability and applicability of the results may be limited by fundamental differences in the goals of healthcare, the environment and the characteristics of the patients in rehabilitation. There is an opportunity for further research to determine the translative capacity of findings of nutrition interventions across the continuum of healthcare. The inclusion of robust clinical (e.g. LOS, morbidity, mortality), functional (e.g. FIM, HGS) and cost outcomes in studies evaluating oral nutrition interventions are required to improve the relevance of research in this setting. The role of ONS and energy dense meals as effective strategies for addressing malnutrition in the rehabilitation setting will be strengthened by further evidence of improvements in these outcomes.

3.6 Conclusion

This review found that the provision of ONS or energy dense meals compared to standard meals alone may be effective strategies for preventing or treating malnutrition among patients admitted for rehabilitation. The small number of studies and the quality of the evidence, however, make it difficult to develop firm recommendations for clinical practice. There was consistent evidence from three studies for the role of ONS to significantly increase energy and protein intake. Additional improvements in anthropometry, function and LOS may be achieved with ONS, although it is unclear whether these benefits are limited to particular patient groups only. Meta-analyses found that higher energy meals including a cooked breakfast or smaller, fortified meals increased daily energy and protein intake; however, the subsequent effect on anthropometry, function and LOS is unknown. Other nutrition care strategies that aim to enhance dietary intake such as enhanced eating environments and clinical care processes (e.g. feeding assistance) show benefits in other healthcare settings, although their effects among patients admitted for rehabilitation remain unknown in the absence of evaluative studies undertaken in this setting.

Chapter 4

The menu reGEMeration study: A food and service based nutrition intervention for patients in subacute care

This chapter relates to:

The prepared manuscript;

 Collins J, Porter J, Truby H, Huggins CE. Re-orientating food and service delivery in subacute care: A pilot study of impact on patient outcomes and cost. For submission to Clin Nutr.

The presentations;

- Collins J, Truby H, Porter J, Huggins C. Evaluating an innovative foodservice approach to malnutrition in healthcare. The Nutrition Society of Australia Annual Scientific Meeting, Tasmania, Australia. Journal of Nutrition & Intermediary Metabolism. 2014;1:32-33. Oral presentation.
- Collins J &Porter. Do we agree? Investigating the inter-rater reliability of estimates of plate waste made by multiple observers. Dietitians Association of Australia 31st National Conference, Brisbane, Australia. Nutr Diet. 2014;71(supp. 1):37. Poster presentation.
- Collins J. Can a high-energy hospital menu and greater foodservice staffpatient interaction impact on anthropometry and patients' satisfaction with the foodservice? Dietitians Association of Australia, Victorian branch and foodservice interest group seminar, Melbourne, Australia. 2014. Invited oral presentation.
- Collins J, Huggins C, Porter J, Truby H. The menu reGEMeration study: exploring the effects of an alternative foodservice approach among Geriatric Evaluation and Management (GEM) patients. Eastern Health Research Week, Melbourne, Australia. 2014. Poster presentation.
 - o Awarded highly commended poster
- Collins J, Porter J, Truby H, Huggins C. Change in subacute patients' energy and protein intake during admission. Dietitians Association of Australia 33rd National Conference, Melbourne, Australia. 2016. Oral presentation.

4.1 Abstract

Background Effective strategies are required to support the nutritional status of patients in healthcare settings. This study aimed to develop a food and service based nutrition intervention and evaluate its effect on a range of participant outcomes and estimate its cost.

Methods A parallel controlled pilot study on a subacute care ward compared a higher energy menu and an enhanced mid-meal delivery with the standard menu and usual foodservice. In addition all participants received standard multidisciplinary care. Change in hand grip strength and weight between admission and day 14, energy and protein intake and patient satisfaction with the foodservice at day 14 were evaluated. Data were also collected on mortality, length of stay, discharge destination, function and cost.

Results The median (IQR) age of participants (n=122) was 83 (75-87) years and length of stay was 19 (11-32) days. A third (38.5%) were malnourished. There was no difference in mean (SD) hand grip strength change (1.7 (5.1) versus 1.4 (5.8) kg, p=0.798, n=68) or weight change (-0.55 (3.43) versus 0.26 (3.33) % kg, p=0.338, n=66) between the intervention and control groups, respectively. The intervention group had significantly higher mean (SD) intake of energy (132 (38) versus 105 (34) kJ/kg/day, p=0.003, n=67) and protein (1.4 (0.6) versus 1.1 (0.4) g protein/kg/day, p=0.035, n=67). Satisfaction with the foodservice was high in both groups. The intervention resulted in additional labour time and costs to foodservice.

Conclusions This nutrition intervention combining change to food and service improved nutritional intake and may be a useful strategy to address inadequate intake of subacute patients. Further consideration of clinical and cost implications is required.

4.2 Introduction

4.2.1 Background

Inadequate dietary intake in healthcare settings persists in Australia and internationally despite hospital menus having the capacity to provide sufficient energy and protein to meet patients' requirements (25, 26, 207). Strategies are required to promote adequate intake to prevent nutritional decline in well nourished patients and improve the nutritional status of malnourished and at risk patients. The hospital foodservice (i.e. catering system) plays a valuable and central role in providing therapeutic nutritional care. Modifying the options and service of food may be a practical approach to improve dietary intake among hospital patients (208). Additionally, a food-first approach to increasing intake is encouraged since eating is a normal part of daily life.

While previous studies in healthcare settings have trialled efforts to optimise food or service in isolation, it appears that to date no studies have incorporated both of these aspects at once. As described in chapter 1 (section 1.3.5, page 17), food based strategies that modify or increase the nutrient content of meals or mid-meals (e.g. food fortification, mid-meal snacks, hot breakfast) may improve energy and protein intake compared to standard meals alone. However, a lack of effect has been seen for anthropometric and functional outcomes. Other studies discussed in chapter 1 have considered the service of food and explored the manipulation of systems for food production (e.g. cook chill, cook fresh), delivery (e.g. plated, bulk) or menu information (e.g. visual, spoken or written menu). The findings indicate that changes to these aspects of foodservice operations can improve satisfaction, cost and capacity of the menu to meet nutritional standards (114, 117, 208-212).

While it is clear that in isolation, food or service enhancements demonstrate some benefits for patients and healthcare, further opportunities for future improvements exist. It remains to be seen if there is an additive or complementary effect when these strategies are implemented together. There is an opportunity and a need to develop innovative nutrition interventions that focus on nourishing, quality food and patient-centred service in unison. Food choice and interaction between staff and patients are key aspects of foodservice associated with better patient outcomes and experiences (40, 213-215). Evaluating the impact of novel strategies on important endpoints, including functional (e.g. hand grip strength (HGS)), anthropometric and health outcomes and cost, will assist in determining their clinical and cost effectiveness and role in practice.

4.2.2 Aims

Overall the goal of this study was to pilot a food and service based nutrition intervention. The aims, relevant to intervention design (aims 1 - 2, section 4.3) and evaluation (aims 3 - 7, sections 4.4 and 4.5), were to:

- Develop an innovative food and service based nutrition intervention within the confines of the existing hospital foodservice system with the aim of improving food intake.
- Develop an appetising hospital menu with the ability to provide an additional 2000 kJ/day in comparison to the standard menu.
- Evaluate the effect of the intervention in comparison to the standard menu and usual foodservice on objective indicators of nutritional status (HGS, weight) and clinical outcomes among subacute patients.
- 4. Evaluate the effect of the intervention in comparison to the standard menu and usual foodservice on dietary intake of subacute patients.
- Evaluate the effect of the intervention in comparison to the standard menu and usual foodservice on subacute patients' satisfaction with the foodservice.
- 6. Estimate the additional cost of the intervention incurred by Foodservice.
- A subsidiary aim of this research was to explore the relationship between length of stay (LOS) and dietary intake of subacute patients.

4.2.3 Hypotheses

The hypotheses to be tested related to the aims of the intervention evaluation (aims 3 - 7) described above. On the basis of existing literature it has been hypothesised that:

- There will be no difference in objective indicators of nutritional status (HGS, weight, clinical outcomes) between those who receive the intervention and those who receive the standard menu and usual foodservice.
- 2. Dietary intake will be higher among those who receive the intervention compared to those who receive the standard menu and usual foodservice.
- 3. Patients' satisfaction with the foodservice will be greater among those who receive the intervention compared to those who receive the standard menu and usual foodservice.
- 4. There will be additional costs associated with the intervention.
- 5. There will be a negative relationship between LOS and dietary intake.

4.2.4 Research structure

This study was conducted in two phases:

- Intervention design: Involved collaborative development and implementation of an innovative food and service based intervention to address aims 1 – 2. Section 4.3 describes what the nutrition intervention was and the rationale supporting it.
- Pilot: Involved the experimental evaluation of the effects of the nutrition intervention among subacute patients to address aims 3 – 7 and test hypotheses. Sections 4.4 and 4.5 describe the methods and results of the evaluation.

4.3 Intervention design

4.3.1 Intervention development

The intervention was developed through an in-depth, collaborative process that brought together multiple sources of information. The concept for the nutrition intervention was theoretically grounded from the literature, particularly the foodservice interventions described in chapter 3. Input was sought from multiple stakeholders including patients and healthcare staff to identify opportunities for change within the current menu and service and generate and refine ideas about the appropriateness and feasibility of new options and approaches.

An objective of this phase was to create an appetising higher energy menu that provided at least 2000 kJ/day more than the standard menu. This target was chosen to address the 1900 kJ/day energy deficit among subacute patients at Eastern Health identified in preliminary research (45). Additionally, this energy content was consistent with the standard oral nutritional supplements (ONS) provided to patients at Eastern Health as part of usual dietetic practice (i.e. 80ml Resource® 2.0 3/day containing 2000kJ and 20g protein). The intervention targeted energy content of the menu, rather than protein or micronutrient intake in addition to energy. This was on the basis that maintaining energy balance would preserve fat and muscle mass of participants. However, as protein, fat and carbohydrate are energy sources, their content in the menu was guaranteed to increase, albeit to varying degrees dependent on food selection. Micronutrients were not targeted as general micronutrient deficiency has not been established in the subacute population. Deficiencies of single micronutrients (e.g. vitamin D) have been reported in an elderly population, but are recommended to be managed through supplementation (216).

4.3.2 Collaboration with patients

Formal consultation with patients was undertaken through preliminary qualitative research. The aims were to determine patients' perceptions of the standard menu and their food preferences, to ensure the higher energy menu reflected their expectations. The Human Research and Ethics Committees at Eastern Health approved this preliminary research and all participants provided written informed

consent (LR23/1314) (Appendix 9a). Data collection occurred on one day via oneon-one semi-structured interviews conducted at the bedside. Participants were a convenience sample of adult patients from the Geriatric Evaluation and Management (GEM) ward where the pilot study was undertaken. Eligible patients were receiving oral nutrition, had a LOS of at least two days to ensure exposure to the menu and had capacity to provide written informed consent.

Prior to the interviews, participants were educated by the researcher (JC) about consuming sufficient food and drink to avoid weight loss, and an explanation of good food sources of energy and/or protein was provided. To prompt discussion regarding food preferences a picture card of items that could potentially be included in the higher energy menu was shown to participants. Data were transcribed *verbatim* and analysed for content to identify strengths and limitations of the standard menu and preferred food items.

Of 32 potential participants, seven met the inclusion criteria (22%) and five were recruited (71%) (n=1 declined to participate, n=1 unavailable). The mean age of participants was 80 years and four were female. Two participants had been seen by the ward dietitian and one was a strict vegetarian. The participants reported the foods currently provided at mid-meals (i.e. as part of usual care) were generally enjoyable. Hospital food was considered to be second-rate compared to home cooked meals. Perceived limitations of the hospital menu and foodservice included: hot meals and beverages that were not hot, tough meat, undercooked vegetables, large portion sizes of meat and unfamiliar items. Similar criticisms have been reported in the literature (41). While participants acknowledged that the menu could be improved, they appeared to feel that the limitations of the menu and the foodservice were unavoidable as a result of mass scale production.

The participants described the importance of choice at meals and mid-meals and the need to provide variety from day to day so there was *"something different"* on the menu to look forward to and bring enjoyment to mealtimes. The notion that food in hospital serves an important emotional purpose for patients has been described elsewhere (41). This emphasises the importance of food for patients and the difference in the perception of the role of food between patients (source of enjoyment) and nutrition professionals (source of nutrition).

When potential new food items were proposed via the picture cards, there were a wide range of responses reflecting variance in food preferences. The most popular items selected by participants from the picture cards were raisin toast, hot chocolate and bakery items (Table 4:1). A hot menu option at breakfast (eggs or baked beans) was also desired. A limitation of this preliminary research is that the views of participants are unlikely to be representative of all subacute patients due to the small sample size. Nonetheless, there were consistencies between the food items desired by patients and those recommended Nutrition Standards (110). The preferred food items indicated by participants were considered during collaboration with healthcare staff and included in the higher energy menu unless deemed not feasible (e.g. raisin toast).

Table 4:1 Participants' preferences for proposed new food items for inclusion in the higher energy menu as determined through bedside interviews (n=5)

Food items proposed on picture cards	Number of Responses
Breakfast option	1
Croissant	1
English muffin	1
Pikelets ^a	2
Crumpet	2
Raisin toast	4
Fruit muffin	0
Mid-meal beverage options	
Cold plain milk	0
Cold flavoured milk ^a	1
Hot chocolate ^a	4
Mid-meal food options	
Chocolate chip biscuit	1
Chocolate coated biscuit	1
Lamington	2
Cake ^a	2
Yoghurt ^a	1
Custard	1

^aIncluded in the higher energy menu

4.3.3 Collaboration with healthcare staff

The researcher (JC) engaged with foodservice, dietetic, nursing and speech pathology staff through a series of multidisciplinary and one-on-one meetings to assist with design of the intervention. The foodservice department provided input on budget, staffing and logistical considerations concerning the enhanced mid-meal service and the practicality and feasibility of the higher energy menu items proposed based upon patient interviews. Suitable training and instruction for the foodservice assistants were negotiated. A senior dietitian approved the nutritional content of the higher energy menu, with a particular focus on the diabetic diet code. A senior speech pathologist conducted a taste-test to ensure the soft diet higher energy menu met texture standards (217).

4.3.4 The intervention condition

The final food and service based nutrition intervention consisted of two complementary aspects: a higher energy menu and an enhanced mid-meal service.

Higher energy menu

The intervention menu had the capacity to provide 3680 kJ/day and 24 g protein/day more than the standard menu, based on a default menu for meals and a predicted selection for mid-meals (Table 4:2). The additional energy content of the higher energy menu exceeded the target of 2000 kJ, however it was recognised that actual energy intake was likely to be less than the menu could provide. The total energy content of the higher energy menu was closer to the target when plate waste of 30% (218) was taken into account. The following changes were made to the standard menu to create the higher energy menu:

- Lower energy dense items were removed (e.g. broth, tea, coffee, side salad and toast).
- Higher energy dense items were introduced at breakfast (e.g. pikelets and omelettes) and mid-meals (e.g. hot chocolate, muffins, cake, chocolate biscuits and yoghurt) (Table 4:3).

 The default menu was modified to provide hot meals at both lunch and dinner.

The higher energy menu was tailored to be suitable for full ward, soft, diabetic and vegetarian diet codes. The items included were selected for their desirable sensory properties (e.g. taste, texture, appearance, smell) to promote intake and satisfaction (219). Savoury and sweet options were included to appeal to both preferences. Respectively, targets of 700 kJ/serve and 400 kJ/serve for newly introduced food and beverage items were set to maximise the energy content of the menu. This was based on the requirement outlined in Nutrition Standards (110) that mid-meals must contain a minimum of 500 kJ/serve. Items meeting this energy target in a manageable portion size tended to be high in fat or sugar (carbohydrate) at the expense of protein.

The higher energy menu aimed to provide patients with more choice as this appears to improve satisfaction and food intake. Rehabilitation and nursing home patients who received choice of food at the time of meal service had significantly higher satisfaction with the foodservice (215). Autonomy or perceived control may be the factor mediating the relationship between choice and satisfaction with the foodservice (214). A large study of patients in rehabilitation and acute hospital found that lack of choice was attributed to non-consumption of hospital meals (26).

Table 4:2 Standard and higher energy default menus

Meal	Standard menu	Energy (kJ)	Protein (g)	Higher energy menu	Energy (kJ)	Protein (g)
	Cereal	480	3	Cereal	480	3
ast	Low fat milk	290	6	Full cream milk	410	5
Breakfast	1 x toast	350	3	2 x pikelets	460	3
Bre	+ margarine + jam	450	-	+ margarine + jam	450	-
	Tea or coffee	-	-	2 x juice	420	-
g	2 sweet biscuits	390	1	Muffin/s	800	2
Morning tea	Tea or coffee	-	-	Hot chocolate	440	2
	Soup of the day	300	3	Soup of the day	300	3
ch	Sandwich of the day	1200	20	Chef's selection hot meal	1500	34
Lunch	Daily dessert	700	4	Daily dessert	700	4
	Tea or coffee	-	-	Tea or coffee	-	-
u	Cheese and biscuits	440	5	Cake	900	3
Afternoon tea	Tea or coffee	-	-	Hot chocolate	440	2
	Chef's selection hot meal	1500	34	Chef's selection hot meal	1500	34
Dinner	Daily dessert	700	4	Daily dessert	700	4
Ō	Tea or coffee	-	-	Tea or coffee	-	-
_	Fruit cake	650	2	2 chocolate biscuits	810	-
Supper	Tea or coffee	-	-	Flavoured milk	820	10
	Meals only	5970	77	Meals only	6920	90
Total	Mid-meals only	1480	8	Mid-meals only	4210	19
	All	7450	85	All	11130	109

Food item	Serve size	Energy (kJ/serve)	Protein (g/serve)	Diet code
	Breakfast			
Full cream milk	1 x 150ml	410	5	All
Pikelets +	2 x 25g	460	3	All
margarine + jam	1 x 10g	280	0	
FURA	1 x 14g	170	1	
Plain omelette	1 x 120g	880	17	All
Ham and cheese omelette	1 x 120g	860	16	Not VEG
	Mid-meals			
Hot chocolate	25g powder	440	2	All
Flavoured milk (Breaka)	1 x 250ml	820	10	All
Cheese +biscuits	2 x 20g	680	10	Not SOFT
	2 x 7g	100	0	
Full cream voghurt	1x 175g	700	8	All
Muffins ^a	2 x 25g	700 – 950	2 – 3	All
Cake ^b	1 x 54 –	880 - 990	2 – 3	Not DB
	62g			
Chocolate biscuit	2 x 18g	810	0	Not DB,
(Tim Tam)				not SOFT
Chocolate	2 x 85g	1140	3	Not DB
mousse				

Table 4:3 Food and drink items introduced on the higher energy menu

VEG, vegetarian diet code; DB, diabetic diet code; SOFT, soft diet code

^aThree plated muffin varieties rotated daily

^bSix plated cake varieties rotated daily

Enhanced mid-meal delivery service

Foodservice staff provided an enhanced delivery service at the mid-meals (morning tea, afternoon tea and supper) that focused on interaction with patients. Communication and engagement between patients and staff can affect patients' experience at meal times (220). When compared to technical aspects (i.e. food aspects) interpersonal factors (i.e. 'human' aspects) account for three times the variance associated with satisfaction with the foodservice (214). Mid-meals were selected for service modification, rather than main meals, as a point of service delivery model not used at meals was in place and already necessitated communication at the patient-staff interface. Mid-meals can also make a substantial contribution to patients' daily intake, yet are not accessed by up to half of patients (26, 28, 122). It was anticipated that the enhanced delivery service would increase the number of patients receiving mid-meals and consequently their dietary intake.

Foodservice staff were trained to interact with patients in a manner that promoted patients' selection and consumption of higher energy menu items at mid-meals. Verbal prompting, encouragement and 'up-selling' techniques were employed to influence patients' food related behaviours (221, 222). Visual menus, specific to each mid-meal and diet code, were used to display the available food and drink options to facilitate food choice (Figure 4:1). It was perceived to be more appropriate than a visual or spoken menu as it overcame communication barriers due to language, hearing, aphasia or cognition difficulties that occur frequently among elderly hospital patients. A previous comparison of a printed visual menu with a traditional paper menu demonstrated no reduction in patient satisfaction (211). Furthermore, images supported decision making for some patients.

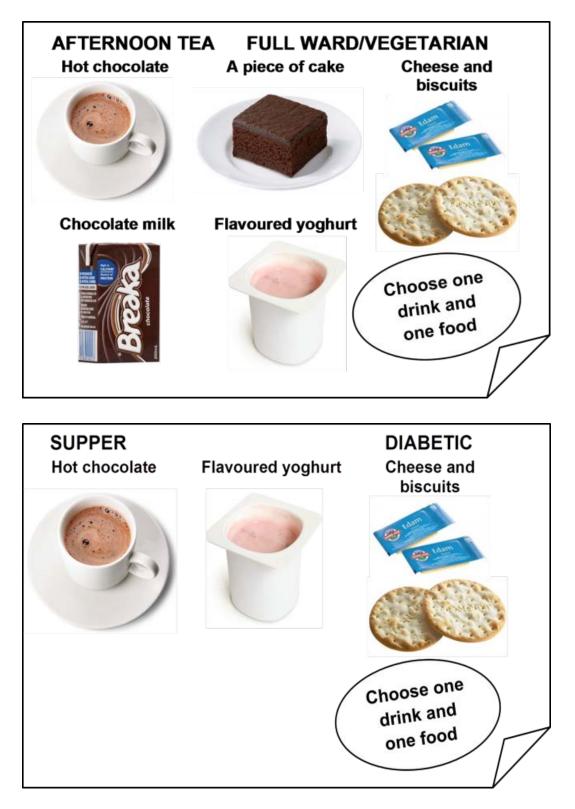


Figure 4:1 Examples of visual menus used to communicate the higher energy menu items at mid-meals for the intervention condition

4.3.5 Implementation of the intervention

Foodservice staff received face to face training and education regarding the pilot study on a number of occasions. The researcher (JC) discussed the purpose of the pilot and demonstrated the procedures associated with the intervention and the study design. Written instructions describing the practices required during the enhanced mid-meal service (e.g. suggested phrases to encourage patients' intake) were placed on the mid-meal trolley. Posters were displayed in the hospital kitchen to generate and maintain awareness of the pilot study. The intervention was rolled out for a week-long trial period during which time issues with implementation were identified and rectified. These included extending the work hours of one staff member to prepare the hot breakfast items, reorganising the order in which meals for each ward were plated and reducing the amount of muffins and cake portions defrosted at mid-meals to minimise food waste.

4.4 Methods – Pilot

4.4.1 Study design

To experimentally test the effects of the food and service based nutrition intervention on multiple outcomes, a non-randomised parallel controlled pilot study was undertaken comparing the intervention with the standard menu and usual foodservice. This was undertaken as a pilot study in order to trial the feasibility of the intervention and collect outcome data on objective indicators of nutritional status (HGS, weight) in order to determine required sample size for a fully powered study. The Human Research and Ethics Committees at Eastern Health (LR23/1314) (Appendix 9a) and Monash University (CF13/2773 – 2013001493) approved this research to be completed under a waiver of consent to include all eligible patients (Appendix 9b). Funding for the higher energy menu and labour were provided by Eastern Health Dietetic and Foodservice departments. This study was registered as a clinical trial on the Australian New Zealand Clinical Trials Registry (trial identification: ACTRN12613001076763). Deviations from the study design identified in the protocol are described in section 4.4.3.

4.4.2 Subjects and setting

<u>Setting</u>

This study was conducted on a 32 bed GEM ward within a large hospital at Eastern Health. GEM care and Eastern Health have been described in chapter 1. All hospital patients receive three meals (breakfast, lunch, dinner) and three mid-meals (morning tea, afternoon tea, supper) daily. The foodservice system is cook-chill, with prepared bulk meals sourced from an external central production kitchen, then heated and plated in a centralised kitchen. Patients' orders for main meals are placed through a computerised menu system ahead of meal service. A default meal is provided to patients who do not place an order. Patients select drinks and snacks from a point of service mid-meal trolley at the bedside. Foodservice staff are employed by Eastern Health and are responsible for taking and collating meal orders, plating, delivering and clearing all meals and mid-meals and providing ONS.

Inclusion and exclusion criteria

Consecutively admitted adult patients were eligible to participate. Eligibility was determined from patients' medical records upon admission to the ward. Exclusion criteria were:

- Receiving only enteral or parenteral nutrition.
- Receiving palliative care.
- Patients with significant food allergies, intolerances or other dietary restrictions that could not be catered for by the higher energy menu.
- Patients requiring smooth puree (texture B), minced and moist (texture C) and/or mildly thick (Level 150) or moderately thick fluids (Level 400) or extremely thick (Level 900) (217).
- Patients with a documented weight loss goal.

Patients were eligible to participate irrespective of their nutritional status at admission, in order to encompass patients at risk of malnutrition or nutritional decline as well as those who were malnourished. Additionally, provision of informed consent was not required (ethics approved) so that patients who had cognitive impairments or were non-English speaking could be included. Participants were withdrawn from the study if their condition changed and they no longer met the inclusion criteria.

Sample size

This research was a pilot study as there were insufficient data on which to model an effect size for the determination of sample size, due to lack of similar studies in the published literature. A time delineated approach was taken, with four months allocated for participant recruitment. Over this period it was estimated *a priori* that 166 participants (83 in each group) would be recruited, based on an average LOS of 19 days determined from ward admissions data, the assumption that all beds remained open and that a maximum of six out of every 32 admitted patients would be ineligible to participate.

4.4.3 Group allocation

Rooms on half of the ward were assigned as intervention (beds 1-16) or control condition (beds 17-32) for the duration of the study (Figure 4:2). Participants were assigned to a group based on their room allocation which was completed as per usual protocol by the bed manager who was unaware of the research. Room allocation was preserved to minimise participants' awareness of an alternate menu and for foodservice staff's convenience at mid-meal delivery. Resultantly, bed moves occurring for clinical reasons (e.g. end of life care, infection control) had the potential to result in group change. Although the registered protocol identified that the study was a randomised controlled trial (RCT), true randomisation was determined not to be feasible prior to study commencement. While it was also intended that there would be a cross over allocation blocks halfway through recruitment, this did not occur due to logistical challenges.

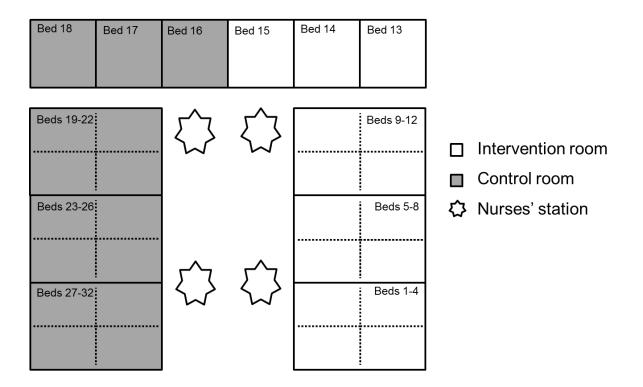


Figure 4:2 Intervention and control group arrangement on the ward

4.4.4 Control condition

The control group received the standard menu and usual mid-meal delivery services. The standard default menu consisted of a continental breakfast (toast, cereal, juice), lunch of soup, sandwich and dessert, dinner of a hot meal and dessert and tea with all meals. The items available at mid-meals were; tea, coffee, milo, 1 x cheese and 1x biscuit, fruit cake and sweet biscuits. In contrast to the intervention condition (section 4.3.4), usual mid-meal service did not focus on staff-patient interaction or utilise a visual menu.

4.4.5 Multidisciplinary care

All participants received standard multidisciplinary medical, nursing and allied healthcare. Allied health services available for goal-orientated therapy included physiotherapy, occupational therapy, social work, psychology, speech pathology, dietetics and podiatry. A group therapy program (1 hour) was conducted approximately three days/week with 5-10 suitable patients. Standard dietetic care was provided by the ward dietitian (0.8 equivalent full time dietetic services for 32 subacute patients) for all patients, with referrals generated for a range of nutritional issues. Additionally, study participants identified via nutrition assessment at admission as malnourished were referred. As per usual practice, the ward dietitian completed an initial assessment and generated an individualised nutrition care plan. Dietetic interventions available to address inadequate dietary intake included ONS, enteral nutrition, reduced/additional serve sizes, extra foods at meals (e.g. baked beans, eggs, hot chips, a pastie, a pie or plain chicken), prescription of standard menu items and/or education. Participants in the intervention group received these strategies as required, in addition to the intervention.

4.4.6 Procedure

Within 72 hours of admission patients were assessed for eligibility by the researcher (JC). Enrolled participants were provided with an information brochure that described the study. Demographic information and admission (i.e. baseline) measurements were obtained at this time. The electronic menu management system was used to commence the intervention for participants allocated to the intervention group. Participants received the intervention or control condition for their entire LOS, unless

group change occurred. Outcome data (section 4.4.7) were collected again at weekly/fortnightly intervals (\pm one day) until discharge. Day 14 of inpatient stay was the main time point for outcome data collection as this maximised the intervention period and aimed to capture the majority of participants prior to discharge. Data reported in chapter 2 identified the median (interquartile range (IQR)) LOS in subacute care at Eastern Health was 17 (12 – 29) days.

4.4.7 Outcome measures and data collection

Multiple outcomes were included to evaluate the nutritional, clinical and patientcentred effects of the nutritional intervention as well as its cost. All outcomes were measured at the bedside by the researcher (JC), with the exception of weight and the Functional Independence Measure (FIM).

Hand grip strength

HGS was measured at the bedside at admission and fortnightly until discharge, as well as at day 21 of inpatient stay. A Jamar® Plus + Hand Dynamometer was used with the handle in the second position (Sammons Preston Rolyan, Illinois). The measurement was taken with participants seated upright in a chair or in bed with the elbow flexed at 90°, the forearm neutrally positioned and the wrists dorsi-flexed at 30° (97). The process was demonstrated and the following standard instructions were provided before each test: *"Squeeze as hard as you can...harder...harder...relax"* (161). Three measurements were taken on the dominant hand (the non-dominant hand was used if injuries were present) and the mean (kg) was calculated. This value (actual HGS) was compared with age and gender specific reference values to calculate percentage (%) of predicted normal HGS, where 100% of predicted HGS is equivalent to the average normal HGS for the reference group (164, 165).

<u>Weight</u>

Weight was measured at admission and then at subsequent weekly intervals until discharge to calculate weight change. Admission weight was reported by participants or family if unable to be measured. Participants were weighed using a single set of calibrated seated scales and wearing light clothing and no shoes or lightweight

footwear. Weight was measured to the nearest 0.05 kg by the researcher (JC) or by nursing staff or allied health assistants if patients were classified as high falls risk. Total weight was measured; this did not take into account fluid status or orthotic or prosthetic devices.

Clinical outcomes

Change in FIM score, LOS (days), inpatient mortality and discharge destination (acute hospital, home, aged care facility, other) were determined from participants' medical records. The FIM was completed by nursing staff at admission and discharge and is a validated and responsive tool measuring level of independence with activities of daily living (169, 170). Change in FIM score was calculated as the difference between FIM score at admission and discharge. Scores range from 18-126 with higher scores indicating greater independence. A discharge destination that provided a higher level of care in comparison to preadmission residence was considered to be a worse outcome.

Energy and protein intake

Standard serve sizes and nutrient content of most food and drink items provided as part of the intervention and control conditions were known as they were packaged (i.e. portioned controlled) or sourced from the central production kitchen. For fresh items (e.g. vegetables and fruit) and miscellaneous items (e.g. cream and sauces), nutrient information was sourced from the Ausnut database (2007) and recommended serve sizes (108) were used. Internal auditing confirmed actual weight of these items was within $\pm 10\%$ of recommendations.

Daily energy (kJ) and protein (g) intake were estimated from plate waste data using FoodWorks® Version: 7.0 (Xyris Software, Australia). A one day record of plate waste captured intake from all food and drink (including items from non-hospital sources) and from commercial ONS (Resource 2.0, Sustagen, Fortijuce, Arginaid, sustagen pudding and Forticreme). Plate waste records were completed on admission and fortnightly thereafter. Data collected at day 14 of inpatient stay were used to compare energy and protein intake between the control and intervention groups, while pooled longitudinal data were used to explore change in intake over time. Over a 24 hour period, meals (breakfast, lunch and dinner) and mid-meals

(morning tea, afternoon tea, supper) were observed before and after consumption and the amount of food remaining on the plate was visually estimated for each item using a six point scale (all eaten, one mouthful eaten, $\frac{3}{4}$, $\frac{1}{2}$, $\frac{1}{4}$, none eaten) (223, 224). This scale has been validated against weighed food waste in the school and hospital setting (223, 224). The scale option 'one mouthful eaten' was classified as 5% consumed (224).

The method of visually estimating plate waste was trialled in preliminary research prior to study commencement to determine the agreement between; [1] weighed and the researcher's (JC) visual estimates of plate waste and [2] visual estimates of plate waste made by multiple observers compared to the researcher (JC). Visual estimates of patients' plate waste were made independently by the researcher (JC) and trained students (n=6) using a five point scale (all eaten, ³/₄, ¹/₂, ¹/₄, none eaten). Sixteen items of plate waste were also weighed.

A Bland Altman plot was generated using Microsoft Excel (2010) to compare weighed and visually estimated plate waste data. There was good agreement between these two methods however, agreement was poorer when less than half the food was consumed although there was no significant systematic bias (n=16 items, R^2 =0.2607, p=0.051) (225) (Figure 4:3).

Agreement between observations made by the researcher (JC) and trained students was explored using Cohen's Kappa (κ) and was found to be fair (κ =0.604, n=82 items) (225). Visually estimated plate waste appeared to be a suitable alternative to weighed plate waste and was therefore used in this pilot study to reduce the time burden of dietary intake assessment. As visual estimates of plate waste made by multiple observers were subject to variability, all observations were made by the researcher (JC) to avoid inter-rater error.

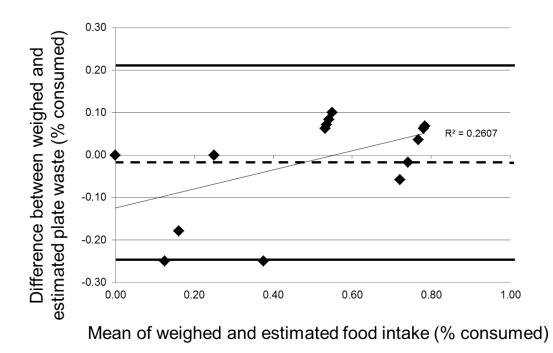


Figure 4:3 Bland Altman plot of the agreement between food intake based on weighed and visually estimated plate waste

Data points (diamonds) indicate the difference between two methods, solid black lines indicate 95% limits of agreement (-0.25 to 0.21%), dotted black line indicates mean difference (-0.02%)

Satisfaction with the foodservice

The Acute Care Hospital Foodservice Patient Satisfaction Questionnaire was administered verbally at day 14 of inpatient stay to measure participant satisfaction with the foodservice (226) (Appendix 10). This validated questionnaire consists of 18 items relating to the domains of meal service, food quality, staffing and service and physical environment as well as one statement of overall satisfaction. Items are evaluated using 5 point Likert response scales (always - never, very good – very poor).

<u>Cost</u>

A retrospective, simplified costing was conducted following the data collection period to estimate the additional cost of the food and service based intervention. All costs were calculated in AU\$ as at April, 2014. This estimate focused on the main costs of the intervention condition that were meaningful to the hospital Foodservice department in terms of budgetary and staffing considerations. The additional cost of the intervention were calculated as the sum of capital costs, additional food and drink and labour costs. Cost effectiveness analysis was not undertaken as it was not appropriate due to the small sample size and the absence of robust outcome data to express effectiveness (i.e. quality adjusted life years). Quality of life (to derive quality adjusted life years) was not collected as part of usual care at Eastern Health and was thus unlikely to be obtained under the waiver of consent, desired to improve representativeness of the sample.

Capital costs were fixed, once-off expenses required to establish the intervention. This consisted of the three coloured, laminated visual menus produced for each midmeal service. The existing kitchen facilities and equipment were not included. The additional cost of food and drink items were calculated as the difference in the daily cost per person between a default usual or higher energy menu (Table 4:2, page 123). Price information (inclusive of government services tax) was obtained from suppliers and the cost per single item was determined by dividing the number of serves in a standard bulk purchase by the total cost. ONS and additional food items prescribed as part of standard dietetic care were not incorporated in this costing analysis. Labour costs were calculated as time (hours/day) x hourly wage + on-costs (i.e. annual and sick leave, superannuation and work cover). The foodservice supervisor estimated the additional time taken and number of staff required for the foodservice department to complete the major tasks associated with the intervention (e.g. breakfast preparation, meal plating and mid-meal service). The supervisor was instructed to consider and reflect on their experience of the difference in the daily average time taken before (i.e. usual conditions) and during the pilot. The hourly rate for a fulltime food and domestic assistant (level HA1) was AU\$20.00 according to the enterprise agreement (227) and on-costs were estimated as 22% of the hourly wage. Therefore, the total cost of employing a foodservice assistant was AU\$24.40/hour.

Demographic information and nutritional status assessment

The following demographic information was determined from participants' medical records; age (years), gender, history of or current presentation with impaired cognition (yes/no), primary diagnosis and diet code. Cognitive status was not assessed for study purposes but determined from past medical history and history of presenting complaint reported in the medical notes. Diagnosis was classified as stroke, neurology, orthopaedic, falls/functional decline, oncology, amputation, respiratory, cardiology, cognitive decline, gastroenterology/hepatic or other. Diet code was classified as full ward diet (i.e. standard unrestricted), soft, diabetic or vegetarian.

Body mass index (BMI) was calculated and a nutrition assessment was completed at admission to provide information on participants' nutritional status. BMI (kg/m²) was calculated using weight obtained at admission and self-reported height. If height was unknown it was estimated from ulna length measured according to recommended protocol (228).

A nutrition screen was completed for all participants using the Malnutrition Screening Tool (MST) to identify participants who were malnourished or at risk of malnutrition (229). The Subjective Global Assessment (SGA) was used to assess the nutritional status of participants who were identified to be at risk of malnutrition by the MST (MST score or two or more). This two-step process reduced time taken to assess nutritional state as well-nourished patients were identified via the MST and did not require a full assessment. The MST and SGA are the standard tools used as part of usual care at Eastern Health. They were selected this study conducted under a waiver of consent instead of the full MNA® used in the study reported in chapter 2 to minimise deviations from usual care.

The MST is a validated screening tool that consists of two short questions relating to weight loss and dietary intake. The SGA is a validated nutrition assessment tool that considers medical history (weight history, diet intake, GI symptoms and functional impairment) and physical characteristics to classify nutritional status as severely malnourished (SGA=C), mild/moderately malnourished (SGA=B) or well nourished (SGA=A) (101, 230) (Appendix 11). In comparison to the SGA, the sensitivity and specificity of the MST have been reported to be 93% each, indicating a low chance of misclassification of nutrition risk (229). A validation study of the SGA demonstrated a sensitivity of 85.2% and specificity of 68.3% compared to objective anthropometry and biochemical data among elderly patients (231).

4.4.8 Statistical analyses

Statistical analyses were performed with IBM SPSS (Version 20). For patients who changed groups or were withdrawn from the study, data provided until that point were used in analyses. A p value of <0.05 was considered statistically significant, unless otherwise indicated. Normality of data was explored using the skewness statistic, histograms and Kolmogorov Smirnov test. Descriptive statistics (mean and standard deviation (SD), median and IQR, number (n) and frequency (%)) and parametric or non-parametric tests were used as appropriate.

Comparisons between the groups for demographic characteristics, weight and HGS at baseline were made using independent samples T-test, Mann Whitney U test or Chi² test. Difference in HGS and weight at admission stratified by SGA categories were explored using one way analysis of variance (ANOVA) and Kruskall Wallis test, respectively. Two approaches were planned to investigate the effect of the intervention on change in HGS and weight. Firstly, analyses of change between admission and day 14 of inpatient stay within group (paired samples T-test) and between group (independent sample T-test) were undertaken. Secondly, change between admission and the last data point (i.e. prior to discharge, group change or

withdrawal) was explored using analysis of covariance (ANCOVA). Group, length of participation (days) and the interaction between group and length of participation (in addition to other relevant independent variables informed by the literature) were included in the model as fixed effects or covariates. The strength of the Partial Eta Squared effect size was interpreted as small (0.01), medium (0.06) or large (0.138) (232).

Clinical outcomes were compared between groups using Mann Whitney U test, Chi² test or linear regression, controlling for potential confounding variables. Comparisons between the groups for daily energy and protein intake at day 14 of inpatient stay were made using independent samples T-test. Daily energy and protein intake from mid-meals and ONS only were compared between groups using Mann Whitney U test. Longitudinal change in daily energy and protein intake was investigated using paired samples T-test or repeated measures ANOVA for participants with data at both admission and day 14 and admission, day 14 and day 28, respectively.

The Acute Care Hospital Foodservice Patient Satisfaction Questionnaire was analysed by comparing responses to each item (collapsed to three point scale) across groups using Chi² test and scores for each domain using Mann Whitney U test. As per previous studies (209, 233) response options 'always – never' were converted to continuous scores 1 - 5, with reverse allocation for items 2, 4, 6, 8, 18. Domain scores were calculated as the sum of contributing items divided by the number of items (food quality, items 1, 5, 8, 9, 13, 16, 18; meal service, items 7, 10, 14; staffing and service, items 3, 11, 15; physical environment, items 2, 4, 6). Scores closer to 1.0 indicate higher levels of satisfaction.

Additional analyses

Where significant differences between groups were found during analyses, intention to treat analyses were conducted with appropriate parametric or non-parametric tests using data collected prior to group change or study withdrawal for subsequent time points where data were missing. Subgroup analyses were conducted for HGS, weight and energy and protein intake at day 14 of inpatient stay to investigate the effect of the intervention according to nutritional status at admission. Data were pooled for participants who were malnourished (mildly/moderately malnourished

(SGA=B) or severely malnourished (SGA=C)) and compared to participants who were well nourished (SGA=A or MST<2) on admission. Two way ANOVA was used with group (intervention or control) and nutritional status (malnourished or well nourished) included as main effects and group and nutritional status as an interaction effect.

4.5 Results

4.5.1 Recruitment and retention

This pilot study commenced in December 2013 and participant recruitment ended in March 2014. Data collection was ceased for remaining participants in May 2014. During this period 162 patients were consecutively admitted, of whom 122 were recruited into the study (n=61 intervention group, n=61 control group) (Figure 4:4). Of the 40 patients not recruited, 31 were ineligible due to: texture modified food or fluid (n=14), other dietary restrictions (n=2), receiving only palliative care (n=13) and having a documented weight loss goal (n=2). Data were excluded for two participants receiving enteral nutrition in addition to oral diet.

Ten participants were withdrawn during the pilot study period as they no longer met the eligibility criteria due to a change in their condition. Withdrawal occurred on average 29 (22) (mean (SD)) days following admission (min 7; max 72). Fourteen participants changed between the intervention and control group during the study period due to room changes occurring for clinical reasons. Group change occurred on average 14 (9) (mean (SD)) days following admission (min 3; max 33). Data provided until the point of withdrawal or group change were included in analyses. Those who were withdrawn or changed group were included in intention to treat analyses.

Outcome data were collected at regular intervals for the duration of inpatient stay, which was 79 days at maximum (i.e. longest LOS) (note data collection ceased on day 70 of inpatient stay). The availability of data at each time point diminished due to natural attrition as participants were discharged from subacute care. At day 14 of inpatient stay, the main time point for outcome data collection, data were available for 71 (58.2%) participants. Data were not available due to: discharged (n=39), withdrawn (n=4) or group change (n=8). Figure 4:4 shows recruitment and retention between admission and day 14 of inpatient stay. The number of participants remaining at each time point for the study duration is shown in Figure 4:5.

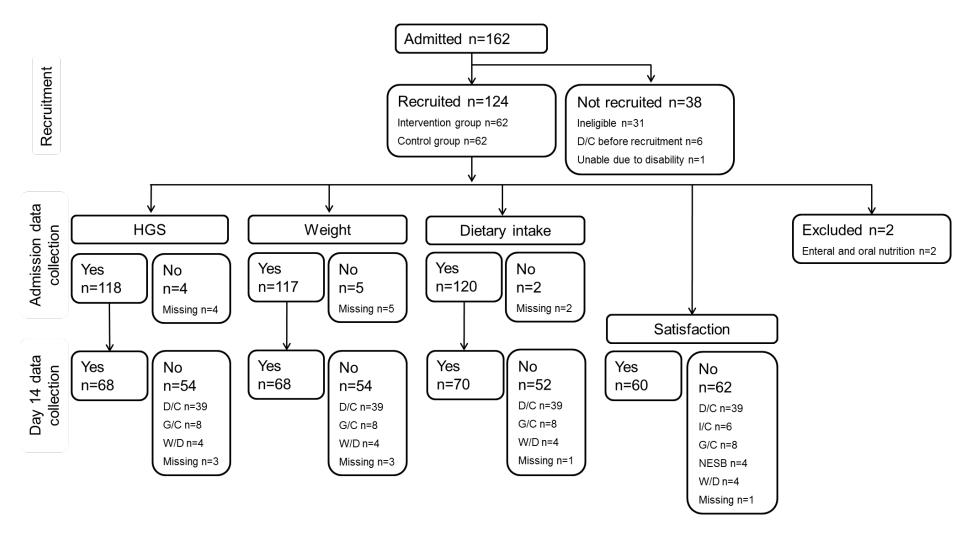


Figure 4:4 Recruitment and retention of study participants from admission to day 14 of inpatient stay.

D/C, discharged; G/C, group change; W/D withdrawn due to no longer meeting inclusion criteria; I/C, impaired cognition; NESB, non-English speaking background

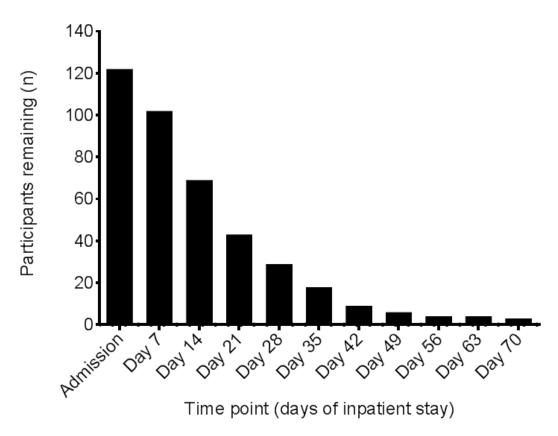


Figure 4:5 Number of participants remaining at each data collection time point (n=122 at study commencement)

4.5.2 Participant characteristics

Among all participants recruited into the study (n=122), the median (IQR) age was 83 (75 - 87) years, LOS was 19 (11-32) days (min1, max 79) and orthopaedic related diagnoses were most common (n=38, 31.1%). On admission, the MST classified 47.9% (n=58) participants as not at risk of malnutrition and a further 13.9% (n=17) were assessed as well nourished using the SGA. A third (n=47, 38.5%) of participants were identified as malnourished on admission according to the SGA.

There was no difference between groups in demographic characteristics or nutritional status at admission (Table 4:4). At admission (i.e. baseline) HGS was the same in the intervention and control groups. Median weight was significantly higher in the control group (Table 4:4). Participants (n=51) unable to provide data at day 14 of inpatient stay (i.e. discharged, changed group or withdrawn) were significantly younger than those who remained (Table 4:5). Of those who were discharged before day 14, half (n=26) returned to their usual residence, a quarter (n=11) were readmitted to acute hospital and the remainder were discharged to higher level care (n=6, 12%) or other care (n=7, 14%).

Table 4:4 Comparison between groups of demographic characteristics and outcome data at
admission (n=122)

Characteristic		Control	Intervention	р
		n=61	n=61	value
Age (years), median	80 (75 – 87)	84 (75 – 88)	0.255	
Male, n (%)	32 (52.5)	29 (47.5)	0.587	
Cognitive impairment	, n (%)	27 (44.3)	29 (47.5)	0.716
Birthplace, n (%)	Australia	37 (60.7)	36 (59.0)	0.853
	Other	24 (39.3)	25 (41.0)	
Language, n (%)	English	54 (88.5)	57 (93.4)	0.343
	Other	7 (11.5)	4 (6.6)	
Primary diagnosis, n	Stroke/neurology	2 (3.3)	1 (1.6)	-
(%)	Orthopaedic	20 (32.8)	18 (29.5)	
	Functional/cognitive decline	10 (16.4)	17 (27.8)	
	Oncology	0	2 (3.3)	
	Amputation	2 (3.3)	0	
	Respiratory	7 (11.5)	5 (8.2)	
	Cardiology	4 (6.6)	3 (4.9)	
Gastrointestinal/Hepatic		7 (11.5)	6 (9.8)	
	Other	9 (14.8)	9 (14.8)	
Diet code, n (%)	Full ward diet	33 (54.1)	43 (70.5)	-
	Soft	6 (9.8)	5 (8.2)	
	Diabetic	21 (34.4)	13 (21.3)	
	Vegetarian	1 (1.6)	0	
Nutritional status	Well nourished	37 (60.7)	38 (62.3)	0.448
n (%)	Mild/moderate malnutrition	16 (26.2)	19 (31.1)	
	Severe malnutrition	8 (13.1)	4 (6.6)	
BMI (kg/m²), mean (SD)		23.9 (4.6)	23.5 (5.8)	0.740
FIM score, mean (SD)		74 (20)	72 (18)	0.484
HGS (kg), mean (SD)		38.7 (17.2)	36.9 (16.2)	0.572
Weight (kg), median	(IQR)	67.70 (55.70	59.80 (49.90	0.032
		- 77.60)	- 69.65)	

Well nourished, SGA=A or MST<2; mild/moderate malnutrition, SGA=B; severe malnutrition, SGA=C; FIM, Functional Independence Measure; HGS, hand grip strength

Table 4:5 Comparison of demographic characteristics and outcome data at admission of participants lost to follow up prior to day 14 of inpatient stay and participants remaining in the study (n=122)

Characteristic		Participants	Participants	р
		not remaining	remaining at	value
		at day 14	day 14	
		n=51	n=71	
Group, n (%)	Control	22 (43.1)	39 (54.9)	0.271
	Intervention	29 (56.9)	32 (45.1)	
Age (years), media	n (IQR)	79 (68 – 85)	84 (79 – 88)	0.005
Male, n (%)		25 (49.0)	36 (50.7)	0.854
Cognitive impairme	ent, n (%)	20 (39.2)	36 (50.7)	0.284
Birthplace, n (%)	Australia	32 (62.7)	41 (57.7)	0.713
	Other	19 (37.3)	30 (42.3)	
Language, n (%)	English	46 (90.2)	65 (91.5)	-
	Other	5 (9.8)	6 (8.5)	
Primary diagnosis	Stroke/neurology	1 (2.0)	2 (2.4)	-
	Orthopaedic	13 (25.5)	25 (35.2)	
	Functional/cognitive	10 (19.6)	17 (23.9)	
	decline	1 (2.0)	1 (1.4)	
	Amputation	5 (9.8)	7 (9.9)	
	Respiratory	3 (5.9)	4 (5.6)	
	Cardiology	7 (13.7)	6 (8.5)	
	Gastrointestinal/Hepatic	11 (21.6)	7 (9.9)	
Diet code, n (%)	Full ward diet	30 (58.8)	46 (64.8)	-
	Soft	7 (13.7)	4 (5.6)	
	Diabetic	13 (25.5)	21 (29.6)	
	Vegetarian	1 (2.0)	0	
Nutritional status	Well nourished	32 (62.7)	43 (60.6)	0.716
n (%)	Mild/moderate malnutrition	13 (25.5)	22 (31.0)	
	Severe malnutrition	6 (11.8)	6 (8.5)	
BMI (kg/m ²), mean	(SD)	23.5 (5.4)	23.8 (5.1)	0.775
FIM score, mean (SD)		76 (21)	71 (17)	0.099

Well nourished, SGA=A or MST<2; mild/moderate malnutrition, SGA=B; severe malnutrition, SGA=C; FIM, Functional Independence Measure

4.5.3 Handgrip strength

Initial HGS data were collected on average two (1) (mean (SD)) days following admission (min 0, max 5) for 118 participants and 14 (1) (mean (SD)) days following admission (min 12, max 14) for 68 participants (missing data is described in Figure 4:4, page 142). Handgrip strength data obtained after day 28 are reported in Appendix 12.

Hand grip strength and nutritional status

Mean HGS (raw and adjusted for age and gender, i.e. percent of normal HGS) at admission was not different among those who were well nourished, mildly/moderately malnourished or severely malnourished (Figure 4:6).

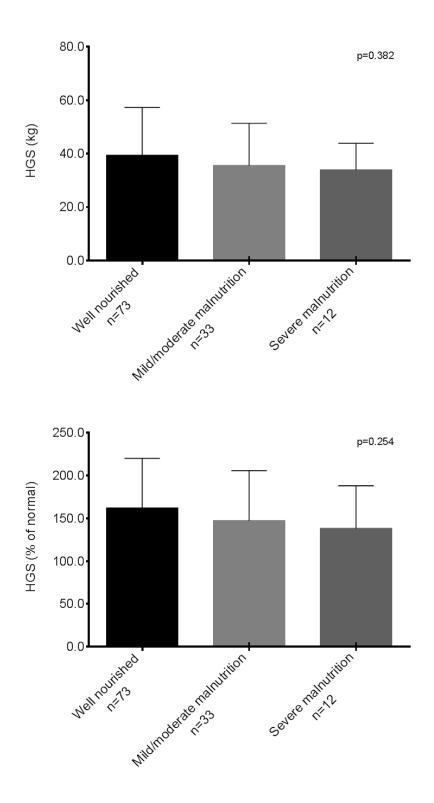


Figure 4:6 Comparison of hand grip strength and nutritional status at admission

Well nourished, SGA=A or MST<2; mild/moderate malnutrition, SGA=B; severe malnutrition, SGA=C; HGS, hand grip strength

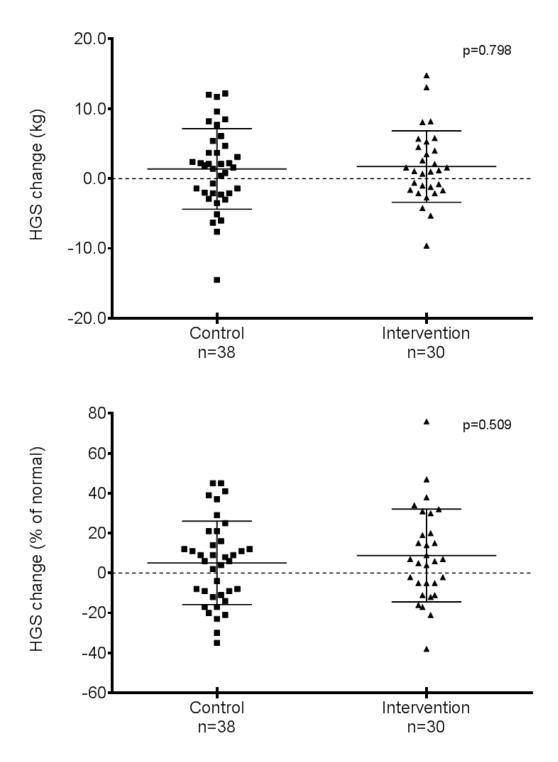
Data analysed using ANOVA

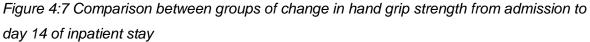
Bars indicate mean and standard deviation

Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)

Hand grip strength change

Change in HGS between admission and day 14 of inpatient stay was calculated for 68 participants. From admission to day 14 of inpatient stay there was no change within each group in raw HGS (mean (SD), control admission 37.1 (17.4) kg, day 14 38.4 (18.3) kg, p=0.146; intervention admission 35.9 (14.1) kg, day 14 37.7 (12.7) kg, p=0.074) or percent of normal HGS (mean (SD), control admission 150 (56) %, day 14 155 (59) %, p=0.143; intervention admission 167 (56) %, day 14 176 (50) %, p=0.051). Between groups, there was no difference in the mean change in HGS from admission to day 14, 21 or 28 of inpatient stay (Figure 4:7, Figure 4:8, Figure 4:9).

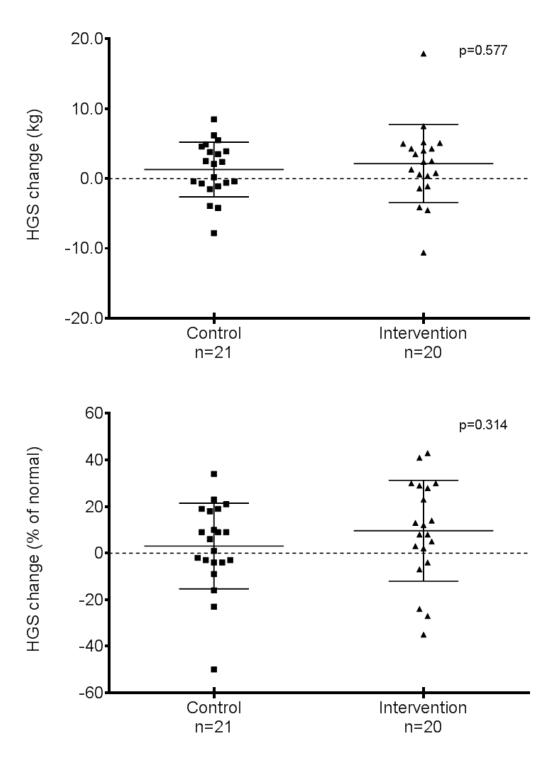


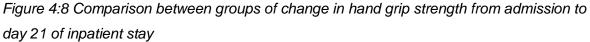


HGS, hand grip strength

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) indicate each participant's HGS change, solid horizontal lines indicate mean (longer line) and standard deviation (two shorter lines) Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)

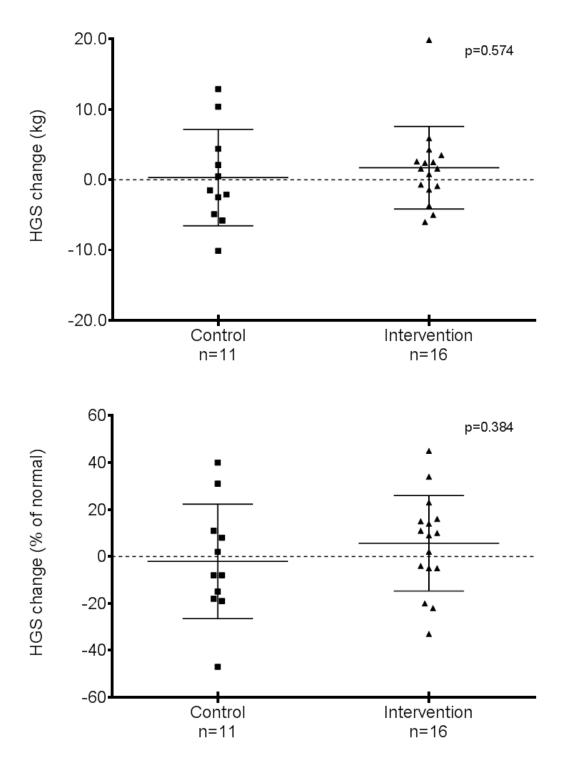


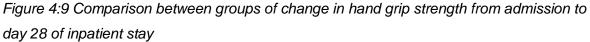


HGS, hand grip strength

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) indicate each participant's HGS change, solid horizontal lines indicate mean (longer line) and standard deviation (two shorter lines) Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)





HGS, hand grip strength

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) represent each participant's HGS change, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines) Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)

Hand grip strength change continued

Change in HGS between admission and last data collection point was calculated for 94 participants. Note that of the 39 participants who were discharged prior to day 14, HGS data were obtained prior to discharge for 25. Change in HGS from admission to last data collection point was compared between groups using ANCOVA, controlling for length of study participation (days), nutritional status, FIM score, age and gender (raw HGS only) (Table 4:6). The models explained over half of the variance associated with change in raw HGS (R^2 = 0.674) or percent of normal HGS (R^2 = 0.567). There was no difference in HGS change between the intervention and control groups and the interaction between group and length of participation was not significant. Age was the only significant factor associated with change in HGS and had a large effect size (Partial Eta Squared=0.195, refer to section 4.4.8 for interpretation of effect size).

Table 4:6 One way analysis of covariance (ANCOVA) model of change in hand grip strength from admission to end of study participation adjusted for length of participation (n=94)

	Model 1 Raw HGS (kg)			Model 2 Percent of normal HGS		
	F	р	Partial	F	р	Partial
		value	Eta		value	Eta
			Squared			Squared
Age (years)	8.210	0.007	0.195	-	-	-
Gender	0.532	0.471	0.015	-	-	-
Nutritional status at admission ^a	0.585	0.563	0.033	0.614	0.547	0.033
FIM score at admission	0.185	0.670	0.005	0.578	0.452	0.016
Group (intervention/control)	2.516	0.122	0.069	1.019	0.320	0.028
Length of participation (days)	0.920	0.603	0.520	0.642	0.913	0.416
Group * length of participation	1.225	0.305	0.319	1.108	0.384	0.286

^aWell nourished, SGA=A or MST<2; malnourished, SGA=B or SGA=C; HGS, hand grip strength; FIM, Functional Independence Measure; Group*length of participation, interaction effect between variables

Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)

4.5.4 Weight

Initial weight data were collected on average one (1) (mean (SD)) day following admission (min 0, max 4) for 117 participants and weekly thereafter until discharge. Data were available for 102 participants on day seven (1) (mean (SD)) of inpatient stay (min 6, max 9) and 68 participants on day 14 (1) (mean (SD)) (min 12, max 15) (missing data are described in Figure 4:4, page 142). Weight data obtained after day 28 are reported in Appendix 13.

Weight and nutritional status

Weight at admission was significantly different among those who were well nourished, mildly/moderately malnourished and severely malnourished at admission (p=0.001). Subsequent analyses between pairs only indicated a significant difference between well-nourished and severely malnourished participants (p=0.001). (Figure 4:10).

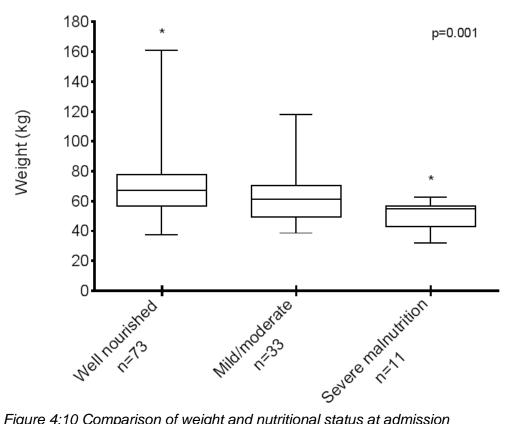


Figure 4:10 Comparison of weight and nutritional status at admission

Well nourished, SGA=A or MST<2; mild/moderate malnutrition, SGA=B; severe malnutrition, SGA=C Data analysed using Kruskall Wallis test and post hoc Mann Whitney U test between pairs Box plots indicate median (middle line in box), IQR (edges of box) and range (shorter lines), * indicates difference p<0.001 in post hoc tests

Weight change

Weight change (kg) was calculated for 100 participants between admission and day seven and 66 participants between admission and day 14. Overall, actual weight was stable within each group from admission to day seven (data not shown) and from admission to day 14 of inpatient stay (mean (SD), control admission 70.85 (16.25) kg, day 14 71.00 (16.45) kg, p=0.644; intervention admission 60.55 (16.90) kg, day 14 60.15 (16.25) kg, p=0.376). Comparisons between groups were made using percentage weight change from admission to day seven, day 14, day 21 and day 28 of inpatient stay to adjust for the significant difference in baseline weight between groups. No difference in percentage weight change from admission was found between the intervention and control groups over four weeks of inpatient stay (Figure 4:11, Figure 4:12, Figure 4:13, Figure 4:14).

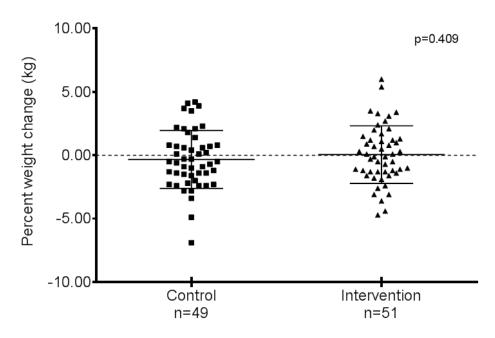


Figure 4:11 Comparison between groups of weight change from admission to day seven of inpatient stay

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) represent each participant's weight change, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)

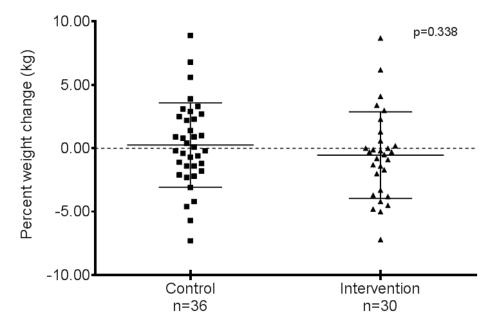


Figure 4:12 Comparison between groups of weight change from admission to day 14 of inpatient stay

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) represent each participant's weight change, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)

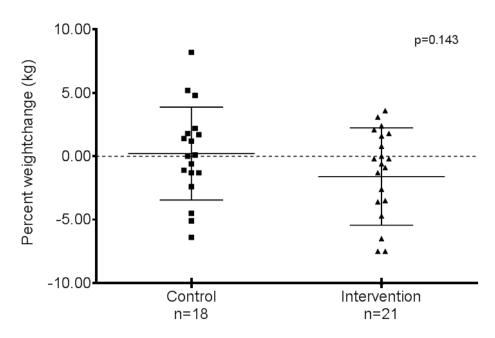
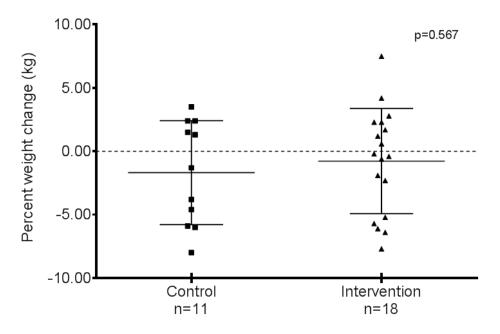
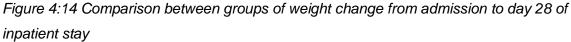


Figure 4:13 Comparison between groups of weight change from admission to day 21 of inpatient stay

Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) represent each participant's weight change, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)





Data analysed using independent samples T-test

Dotted line represents no change, data points (square/triangle) represent each participant's weight change, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)

Weight change continued

Percentage weight change from admission to last data collection point was calculated for 106 participants (including three of nine participants who were discharged prior to day seven). One way analysis of covariance (ANCOVA) was used to compare percentage weight change from admission to last data collection point between groups, controlling for length of study participation, nutritional status, age and gender (Table 4:7). The model explained about 70% of the variance associated with percentage weight change (R^2 = 0.675). There was no difference in percentage weight change between participants in the intervention and control groups and there was no significant interaction between group and length of participation. Length of study participation had a large effect size and was significantly associated with percent weight change.

Table 4:7 One way analysis of covariance (ANCOVA) model of percentage weight change from admission to end of study participation adjusted for length of participation (n=106)

	Model 1			
	Percent change in weight from admission			
	F	p value	Partial Eta Squared	
Age (years)	0.743	0.393	0.016	
Gender	0.567	0.455	0.012	
Nutritional status at admission ^a	1.237	0.299	0.050	
Group (intervention/control)	0.486	0.489	0.010	
Length of participation (days)	1.687	0.044	0.577	
Group * length of participation	1.838	0.057	0.370	

^aWell nourished, SGA=A or MST<2; malnourished, SGA=B or SGA=C; FIM, Functional Independence Measure; Group*length of participation, interaction effect between variables

4.5.5 Clinical outcomes

One participant died during the pilot study. There was no difference in discharge destination, discharge to higher level of care or LOS between participants in the control and intervention group (Table 4:8). Linear regression was used to determine the effect of group on change in FIM score controlling for the effect of LOS and FIM score at admission. Age was not included in the model as univariate analysis indicated a weak and non-significant association with change in FIM score (r=0.061, p=0.560). Group was not statistically significantly associated with change in FIM score and the effect size (a two point greater increase in FIM score in the intervention group) indicated that this change was also not clinically significant (Table 4:9).

		Control	Intervention	р
		n=50	n=48	value
Length of stay, median (IQR)		19 (11 – 25)	18 (10 – 33)	0.853
Discharge destination n (%)	Usual level of care	26 (53.1)	20 (41.7)	0.554
	Higher level of care	16 (32.7)	16 (33.3)	
	Acute hospital	4 (8.2)	7 (14.6)	
	Other	3 (6.1)	5 (10.4)	
Discharged to higher level of care ^a , n (%)		20 (43.5)	23 (53.5)	0.345

Table 4:8 Comparison between groups of clinical outcomes at discharge (n=98)

^aAnalyses exclude participants who were discharged to 'other' destination

Table 4:9 Linear regression model of factors predicting change in FIM score between admission and discharge (n=95)

Independent variables	В	Beta	p value
Group	1.582	0.058	0.566
Length of stay (days)	0.207	0.219	0.034
FIM score at admission	-0.126	-0.168	0.102

Group, intervention (code 1) or control (code 0); FIM, Functional Independence Measure R^2 =0.098, adjusted R^2 =0.068, SEE=13.247

4.5.6 Energy and protein intake

Energy and protein intake and nutritional status

Mean daily energy and protein intake at day 14 of inpatient stay was similar among those who were well nourished, mildly/moderately malnourished and severely malnourished (p=0.747 energy, p=0.585 protein, n=69) (Figure 4:15). The correlations between weight at day 14 and energy intake (r=0.162, p=0.191) and protein intake (r=0.062, p=0.621) at day 14 were weak. Additionally, as weight was significantly different between groups at baseline, energy and protein intake were adjusted for weight in analyses.

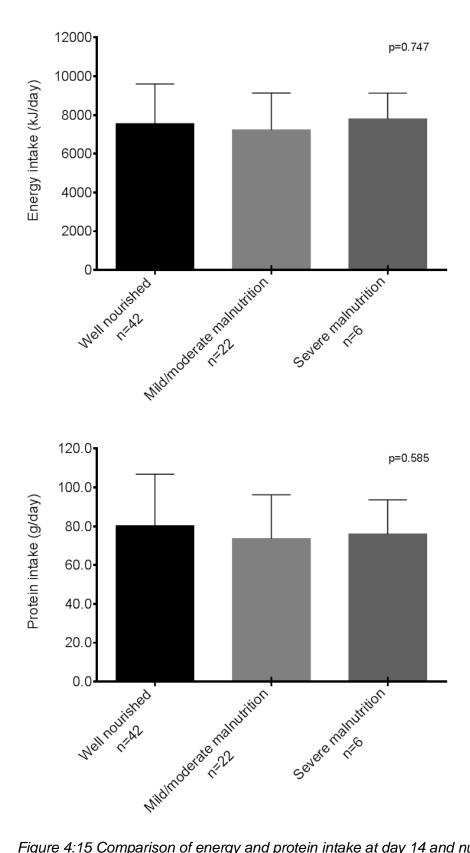


Figure 4:15 Comparison of energy and protein intake at day 14 and nutritional status

Well nourished, SGA=A or MST<2; mild/moderate malnutrition, SGA=B; severe malnutrition, SGA=C Data analysed using ANOVA

Bars indicate mean and standard deviation

Daily energy and protein intake

Comparisons between intervention and control groups were made using data collected on average 14 (1) (mean (SD)) days following admission (min 11, max 16 days) and were available for 70 participants (n=2 missing). There was no difference in actual daily energy and protein intake between groups however, when adjusted for weight, energy and protein intake were significantly higher among the intervention group (mean difference (95% CI), energy 27 (9 – 44) kJ/kg/day; protein 0.3 (0.0 – 0.5) g/kg/day) (Figure 4:16, Figure 4:17). Significant differences remained following intention to treat analysis using admission data carried forward for participants who changed group or were withdrawn prior to day 14 of inpatient stay (Table 4:10).

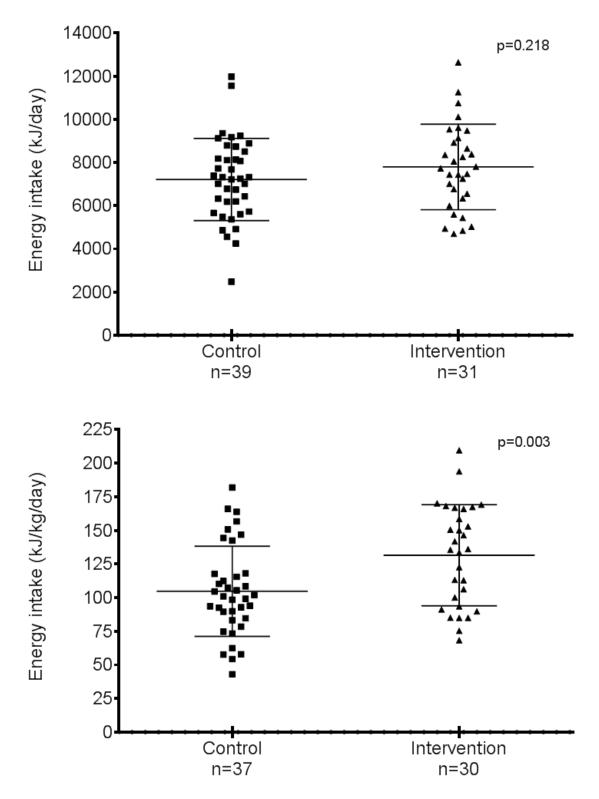


Figure 4:16 Comparison between groups of daily energy intake at day 14 of inpatient stay

Data analysed using independent samples T-test

Data points (square/triangle) represent each participant's intake, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)

Energy intake adjusted using weight (kg) at day 14 of inpatient stay

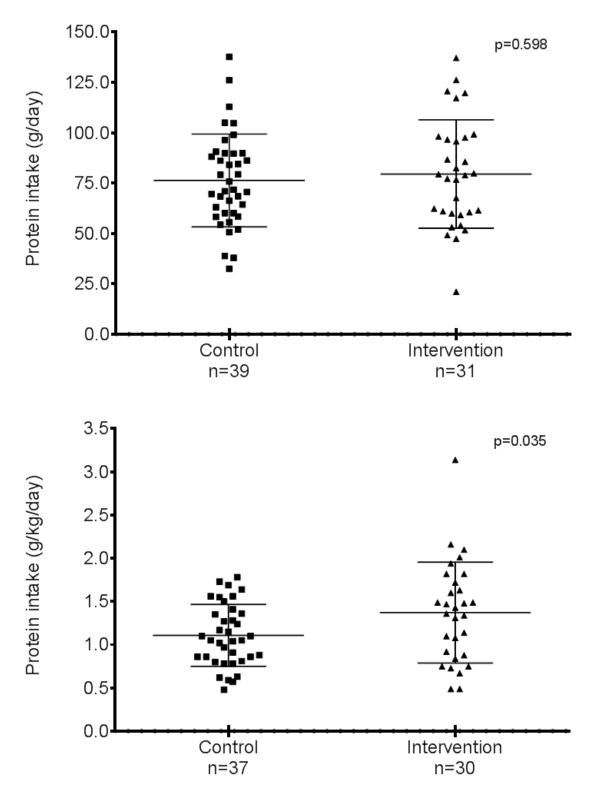


Figure 4:17 Comparison between groups of daily protein intake at day 14 of inpatient stay

Data analysed using independent samples T-test

Data points (square/triangle) represent each participant's intake, solid horizontal lines represent mean (longer line) and standard deviation (two shorter lines)

Protein intake adjusted using weight (kg) at day 14 of inpatient stay

Table 4:10 Intention to treat analyses^a of comparison between groups of energy and protein intake at day 14 of inpatient stay

		Control	Intervention	p value
Energy intake	kJ/day	n=43	n=45	0.073
mean (SD)		7051 (2024)	7928 (2236)	
-	kJ/kg/day	n=39	n=34	0.001
		105 (33)	136 (44)	
Protein intake	g/day	n=43	n=45	0.306
mean (SD)		74.3 (24.2)	80.4 (28.2)	
	g/kg/day	n=39	n=34	0.016
		1.1 (0.4)	1.4 (0.6)	

Data analysed using independent samples T-test

^aAdmission data for energy intake, protein intake and weight carried forward to day 14 for participants who changed groups, were withdrawn or had missing data at day 14

Energy and protein intake adjusted using weight (kg) at day 14 (or admission) of inpatient stay

Energy and protein intake at mid-meals

A comparison of energy and protein intake consumed at mid-meals (morning tea, afternoon tea, supper) on day 14 of inpatient stay showed no difference between the intervention and control groups (Table 4:11).

Table 4:11 Comparison between groups of daily energy and protein intake from mid-meals at day 14 of inpatient stay

		Control	Intervention	p value
Energy intake	kJ/day	n=33	n=29	0.489
median (IQR)		1113 (660 – 1976)	1320 (742 – 2085)	
	kJ/kg/day	n=37	n=30	0.163
		15 (12 – 29)	25 (14 – 36)	
Protein intake	g/day	n=39	n=31	0.507
median (IQR)		9.7 (5.3 – 19.3)	9.8 (5.0 – 15.0)	
	g/kg/day	n=37	n=30	0.940
		0.1 (0.1 – 0.3)	0.2 (0.1 – 0.3)	

Data analysed using Mann Whitney U test

Energy and protein intake adjusted using weight (kg) at day 14 of inpatient day

Oral nutritional supplement intake

The usage and consumption of ONS at day 14 of inpatient stay was considered to determine if this influenced differences in energy and protein intake. Of the 70 participants, 31 consumed ONS (45% intervention group, 44% control group, p=0.895). Daily intake of energy and protein from ONS was significantly higher in the control group compared to the intervention group (median (IQR) energy, control 2011 (1864 – 2080) kJ/day, intervention 1341 (1040 – 2011) kJ/day, p=0.039; protein, control 19.9 (19.1 – 25) g/day, intervention 13.3 (11.9 – 19.9) g/day, p=0.012). Supplements provided on average 30% of daily energy intake in the control group and 21% in the intervention group. The difference between groups for daily and mid-meal energy and protein intake after adjusting for ONS intake remained significant (Appendix 14).

4.5.7 Subgroup analyses

Subgroup analyses were undertaken to explore the interaction between nutrition status (well nourished or malnourished on admission) and group (intervention or control) on HGS change, weight change and energy and protein intake at day 14. There was no interaction between group and nutritional status for change in HGS, weight, energy or protein intake (p>0.05 for all) indicating malnourished and well nourished patients did not respond differently to the intervention (Figure 4:18, Figure 4:19, Figure 4:20).

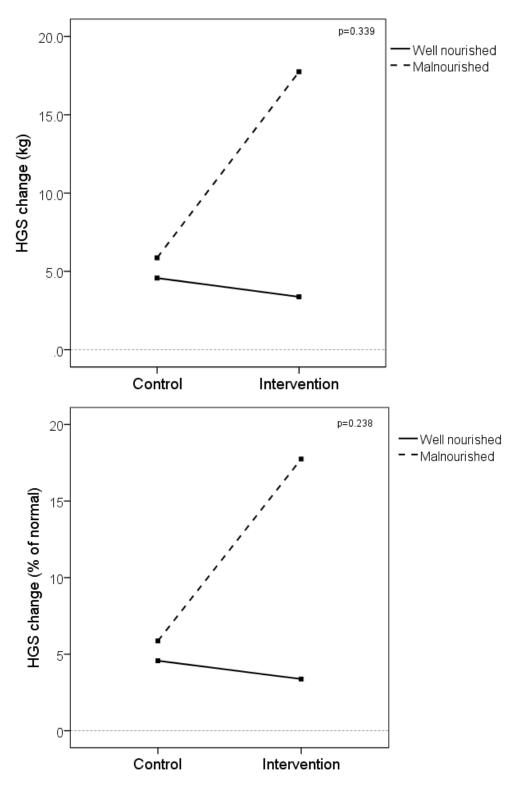


Figure 4:18 Interaction plots of the difference in change in HGS from admission to day 14 of inpatient stay for well nourished (n=42) and malnourished (n=26) participants

HGS, hand grip strength; well nourished, SGA=A or MST<2; malnourished, SGA=B or SGA=C Data analysed using two way ANOVA

Dotted line represents no change, data presented are estimated marginal means

Percent of predicted normal HGS calculated from reference data for age and gender (164, 165)

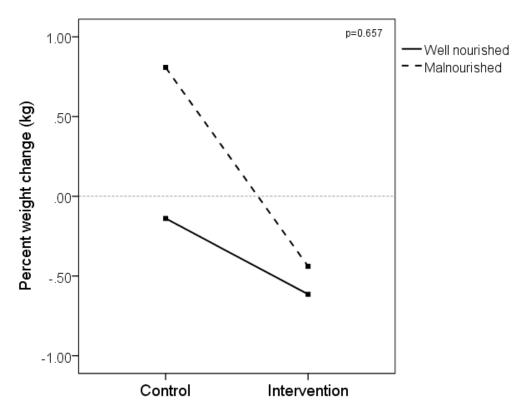


Figure 4:19 Interaction plots of the difference in weight change from admission to day 14 of inpatient stay for well nourished (n=40) and malnourished (n=26) participants

Well nourished, SGA=A or MST<2; malnourished, SGA=B or SGA=C

Data analysed using two way ANOVA

Dotted line represents no change, data presented are estimated marginal means

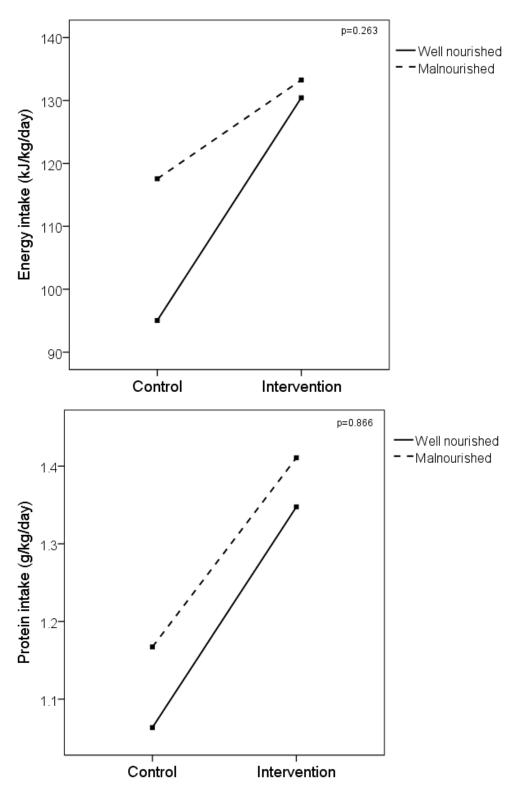


Figure 4:20 Interaction plots of the difference in energy and protein intake at day 14 of inpatient stay for well nourished (n=39) and malnourished (n=28) participants

Well nourished, SGA=A or MST<2; malnourished, SGA=B or SGA=C

Data analysed using two way ANOVA

Data presented are estimated marginal means

Energy and protein intake adjusted using weight (kg) at day 14 of inpatient day

4.5.8 Participant satisfaction with the foodservice

All responding participants (n=32 control, n=28 intervention) (missing data is described in Figure 4:4, page 142) indicated a high level of satisfaction with the foodservice, assessed at day 14 of inpatient stay. Overall satisfaction with the foodservice was rated as good or very good by 75% (n=45) of participants and for all 18 items the majority of responses were for options concomitant with satisfaction (Table 4:12). The greatest variability across response options occurred for items eight (I like the way the way the vegetables are cooked) and 18 (the meat is tough and dry). The most substantial difference between groups appeared to be for item eight (I like the way the way the vegetables are cooked). Uneven numbers in response categories prohibited statistical analyses to compare responses for each item between groups.

Among both groups median scores for foodservice domains were skewed towards one, indicating higher levels of satisfaction (Figure 4:21). There was no difference in median scores for the domains of food quality, meal service or staffing and service between the intervention and control groups. Satisfaction with the physical environment was significantly higher (p=0.013) among the intervention group, with substantially less variability in results. Data collected prior to discharge for 21 of 44 participants with a LOS of less than 14 days are described in Appendix 15. Table 4:12 Comparison between groups of responses to The Acute Care Hospital Foodservice Patient Satisfaction Questionnaire (n=60)

tem	Response	Control	Intervention
		n=32	n=28
1. The hospital food has been as good as I expected	Always/often, n (%)	26 (81.3)	18 (64.3)
	Sometimes, n (%)	3 (9.4)	7 (25.0)
	Rarely/never, n (%)	(9.4)	2 (10.7)
3. The staff who deliver my meals are neat and clean	Always/often, n (%)	32 (100)	27 (96.4)
	Sometimes, n (%)	0	1 (3.6)
5. I am able to choose a healthy meal in hospital	Always/often, n (%)	24 (75.0)	22 (78.6)
	Sometimes, n (%)	4 (12.5)	6 (21.4)
	Rarely/never, n (%)	4 (12.5)	0
7. The cold drinks are always the right temperature	Always/often, n (%)	28 (87.5)	24 (85.7)
	Sometimes, n (%)	3 (9.4)	3 (10.7)
	Rarely/never, n (%)	1 (3.1)	1 (3.6)
8. I like the way the vegetables are cooked	Always/often, n (%)	14 (43.8)	20 (71.4)
	Sometimes, n (%)	8 (25.0)	4 (14.3)
	Rarely/never, n (%)	10 (31.1)	4 (14.3)
9. The meals taste nice	Always/often, n (%)	24 (75.0)	19 (67.9)
	Sometimes, n (%)	4 (12.5)	5 (17.9)
	Rarely/never, n (%)	4 (12.5)	4 (14.3)

10. The hot drinks are just the right temperature	Always/often, n (%)	22 (68.8)	17 (60.7)
	Sometimes, n (%)	4 (12.5)	6 (21.4)
	Rarely/never, n (%)	6 (18.8)	5 (17.9)
11. The staff who take away my finished meal tray are friendly	Always/often, n (%)	28 (87.5)	26 (92.9)
and polite	Sometimes, n (%)	4 (12.5)	2 (7.1)
12. I like to be able to choose different sized meals	Always/often, n (%)	24 (75.0)	17 (60.7)
	Sometimes, n (%)	2 (6.3)	0
	Rarely/never, n (%)	6 (18.8)	11 (39.3)
13. The menu has enough variety for me to choose meals that I	Always/often, n (%)	27 (84.4)	22 (78.6)
want to eat	Sometimes, n (%)	1 (3.1)	3 (10.7)
	Rarely/never, n (%)	4 (12.5)	3 (10.7)
14. The cold foods are the right temperature	Always/often, n (%)	26 (81.3)	26 (92.9)
	Sometimes, n (%)	5 (15.6)	0
	Rarely/never, n (%)	1 (3.1)	2 (7.1)
15. The staff who deliver my menus are helpful	Always/often, n (%)	30 (93.8)	26 (92.9)
	Sometimes, n (%)	1 (3.1)	2 (7.1)
	Rarely/never, n (%)	1 (3.1)	0
16. The meals have excellent and distinct flavours	Always/often, n (%)	22 (68.8)	14 (50.0)
	Sometimes, n (%)	6 (18.8)	10 (35.7)
	Rarely/never, n (%)	4 (12.5)	4 (12.5)
17. The hot foods are just the right temperature	Always/often, n (%)	22 (68.8)	21 (75.0)
	Sometimes, n (%)	6 (18.8)	5 (17.9)
	Rarely/never, n (%)	4 (12.5)	2 (7.1)

2. The crockery and cutlery are chipped and/or stained	Sometimes, n (%)	2 (6.3)	0
	Rarely/never, n (%)	30 (93.8)	28 (100.0)
4. The hospital smells stop me from enjoying my meals	Always/often, n (%)	2 (6.3)	0
	Sometimes, n (%)	4 (12.5)	2 (7.1)
	Rarely/never, n (%)	26 (81.3)	26 (92.9)
6. I am disturbed by the noise of finished meal trays being	Sometimes, n (%)	2 (6.3)	2 (7.1)
removed	Rarely/never, n (%)	30 (93.8)	26 (92.9)
18. The meat is tough and dry	Always/often, n (%)	6 (18.8)	5 (17.9)
	Sometimes, n (%)	8 (25.0)	9 (32.1)
	Rarely/never, n (%)	18 (56.3)	14 (50.0)

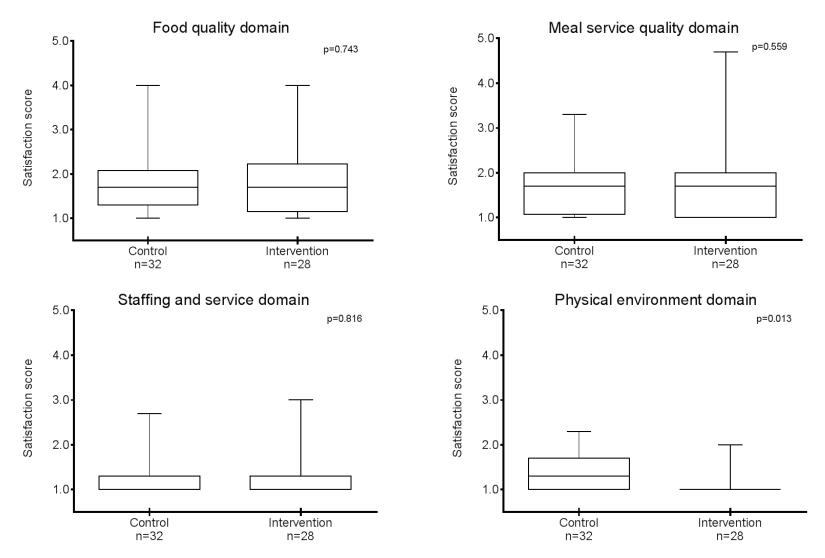


Figure 4:21 Comparison of satisfaction scores for foodservice domains between groups at day 14 of inpatient stay

Box plots indicate median (middle line in box), IQR (edges of box) and range (shorter lines)

4.5.9 Cost

The ongoing additional cost of providing the intervention was estimated to be AU\$7.47/participant/day, consisting of food and drink and labour costs. This estimate was derived from the cost estimates of additional food and drink, labour costs and capital costs as follows. The cost of a default menu (three meals, three mid-meals) (Table 4:2, page 123) was AU\$19.51/participant/day for the higher energy menu and AU\$13.95/participant/day for the standard menu. The cost difference of AU\$5.56/participant/day reflected the additional cost of food and drink associated with the higher energy menu, though not all items were included in the default menu (e.g. excluded omelettes, yoghurt, cheese and biscuits etc.). The additional time taken to complete the main tasks associated with the intervention was estimated to be 0.5 hours/day to prepare the higher energy menu items at breakfast (i.e. pikelets and omelettes) and 0.25 hours/mid-meal (three/day) to deliver the enhanced service. All additional tasks were completed by one foodservice assistant. The total cost of 1.25 hours additional foodservice labour was AU\$30.50/day. The capital costs were AU\$23.22 for production of three visual menus for three mid-meals, incurred once only.

4.5.10 Longitudinal change in energy and protein intake

Longitudinal analyses of change in daily energy and protein intake from admission to day 14 and admission to day 28 were undertaken to support the subsidiary aim of exploring the relationship between LOS and dietary intake. Data were pooled for all participants (intervention and control group) in analyses. Energy and protein intake data for all time points including after day 28 are reported in Appendix 16.

Energy and protein intake increased significantly between admission and the last observation of plate waste prior to discharge, which occurred 15 (13 - 28) (median (IQR)) days following admission (range 3 - 71). The mean (SD) change was 839 (2239) kJ/day for energy (p=0.001) and 12.9 (30.5) g/day for protein (p<0.001) (n=93). The estimated rate of change was 305 kJ energy/week and 4.9 g protein/week, assuming a linear change.

Among those with a LOS of 14 days or longer (n=75) energy and protein intake were significantly higher at day 14 compared to admission (Figure 4:22). For participants with a LOS of at least 28 days, the ANOVA indicated there was a significant effect of time on energy intake (Wilks' Lambda= 0.822, F(2, 32)=3.475, p=0.043; Partial Eta Square=0.178) but pairwise comparisons did not identify significant differences between admission, day 14 and day 28. The effect of time on protein intake between admission, day 14 and day 28 was not significant (Wilks' Lambda= 0.842, F(2, 32)=2.994, p=0.064; Partial Eta Square=0.158) (Figure 4:23).

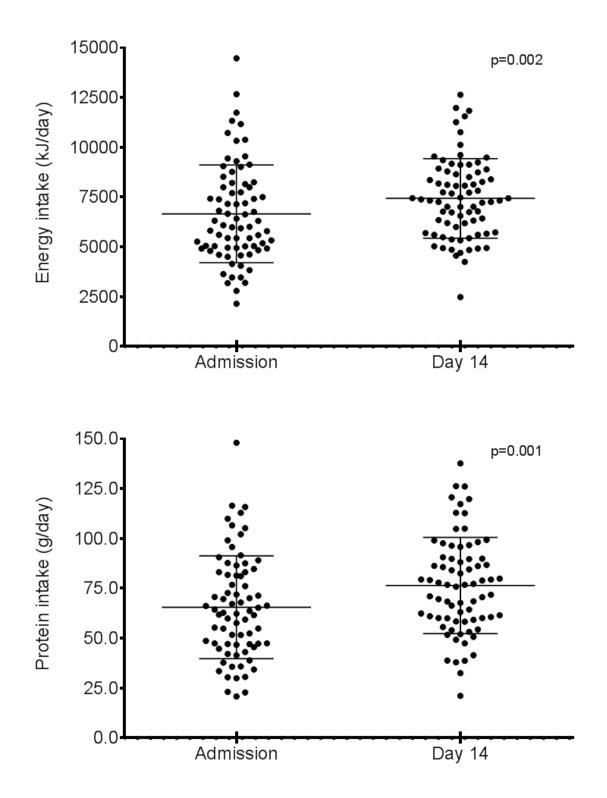


Figure 4:22 Overall change in energy and protein intake between admission and day 14 of inpatient stay (n=75 pooled data from control and intervention)

Data analysed using paired samples T-test

Data points (circle) indicate each participant's intake, solid horizontal lines indicate mean (longer line) and standard deviation (two shorter lines)

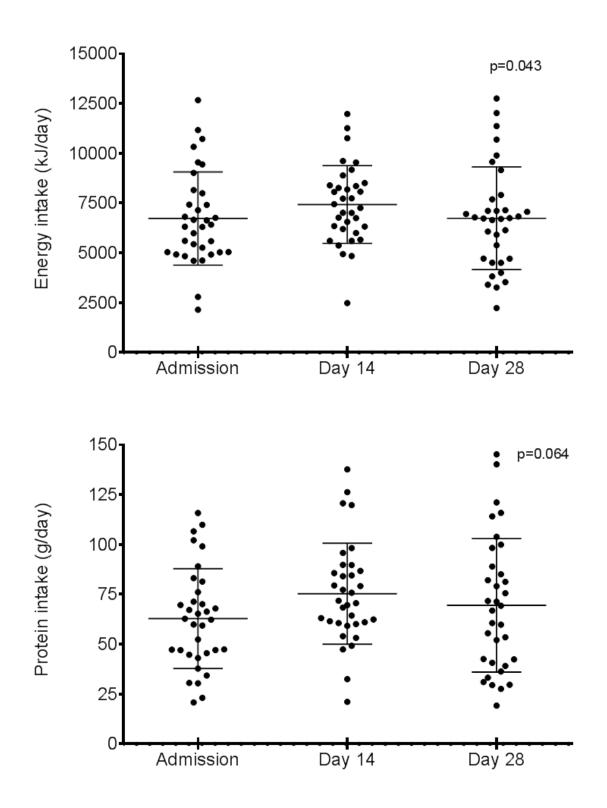


Figure 4:23 Overall change in energy and protein intake between admission, day 14 and day 28 of inpatient stay (n=34 pooled data from control and intervention).

Data analysed using repeated measures ANOVA

Data points (circle) indicate each participant's intake, solid horizontal lines indicate mean (longer line) and standard deviation (two shorter lines)

4.6 Discussion

The provision of adequate, acceptable and effective nutritional care, including culturally appropriate foodservice, is required for all hospitalised patients as the prevalence of malnutrition and inadequate dietary intake is high (25, 52) and nutritional decline occurs (chapter 2). This seeks to improve outcomes for patients and the broader community, reduce pressure on the healthcare system and the costs to government associated with impaired nutritional status. This study developed and tested an innovative concept that operated within the confines of the existing foodservice system to simultaneously enhance the menu and mid-meal delivery service. Importantly, it was undertaken in subacute care where there is a dearth of evidence specifically related to the effect of oral nutrition interventions in this setting (72) (chapter 3). This study makes a valuable contribution to our knowledge of the feasibility, potential clinical effectiveness and estimated additional costs to Foodservice of a combined food and service based strategy to address malnutrition in subacute care.

The finding that the intervention can increase the energy and protein intake (adjusted for weight) of elderly patients at day 14 of subacute inpatient stay, through food independent of ONS, is encouraging. Moreover, patient satisfaction with the foodservice remained high. While this pilot study found that HGS can be measured easily at the bedside in this clinical population, the intervention did not translate into improved HGS, weight or clinical outcomes as it was underpowered to detect differences for these outcomes. Altogether, while these findings provide positive preliminary data, formative evaluation and a fully powered study will afford additional information required to fully understand and inform the potential role of the intervention in practice.

4.6.1 Effect of the intervention on objective indicators of nutritional status and clinical outcomes

Despite greater energy and protein intake (adjusted for weight) among those receiving the intervention, HGS and weight remained stable over LOS for both groups. There was no association between HGS and nutritional status assessed using the SGA. There was also no difference between groups for clinical outcomes

including LOS, change in FIM score or discharge to a higher level of care. In this study the intervention group were heterogeneous in their nutritional status at admission. It was deemed appropriate to deliver the nutrition intervention as a blanket approach for all (eligible) patients regardless of nutritional status, as the findings of chapter 2 indicated that the majority of patients could benefit from greater support of the their nutritional status. Not all patients at malnutrition risk or declining nutritional status received dietetic intervention under usual care conditions. Hospital foodservice is by nature, a systematic operation generally for the nutritional care of all patients. Subgroup analyses did not show a selective effect of the intervention on either the malnourished or well nourished participants, *albeit* sample sizes were small. The conversion of nutrient intake to anthropometric or functional change may be slower in well nourished patients compared with malnourished patients and partially explain the lack of difference in these outcomes observed in this pilot.

It has been proposed that nutrition intervention may have greater effects when selectively targeted to malnourished patients as their depleted physiological state is primed and presents greater capacity for response (2). Indeed, pooled data from clinical trials of nutrition interventions undertaken with a predominately malnourished or at risk sample shows more favourable results. Meta-analyses of protein and energy supplementation (predominately via ONS) in elderly people demonstrate significant improvements in mortality risk among subgroups of malnourished patients in hospital (234) or in a variety of settings (189) not seen overall. Supplementation among mixed samples of elderly people generated improvement in weight or attenuated weight loss among in short or long term healthcare settings (2, 189, 234) and improvement in upper arm anthropometry in various settings (189). There is also evidence of an effect of dietary counselling with or without ONS among patients who are malnourished or at risk on body composition and weight, but not specifically among elderly patients (n=131) (200).

A review of HGS describes a number of studies demonstrating an improvement in HGS for malnourished patients receiving nutrition intervention (56). However, metaanalyses with a heterogeneous sample of elderly subjects found no positive effect of ONS on HGS (189, 234). A range of other functional outcome measures have been used in studies of supplementation and dietary counselling with or without ONS, indicating variable effects (189, 200). Meta analyses with elderly populations indicate that supplementation does not reduce LOS but reduces complications and mortality among those in various settings who receive at least 1674 kJ/day (189, 234). Overall, there are variable, and sometimes contradictory, findings of the effect of dietetic strategies among elderly populations.

As outlined in chapter 3, there is a lack of studies of oral nutrition interventions conducted in the subacute setting specifically reporting on anthropometric, functional or clinical outcomes. More broadly, only a handful of studies (123, 126-129, 132) evaluating food based strategies with heterogeneous samples of elderly patients in various healthcare settings have included these outcomes, most commonly reporting on weight. Further evaluation of this intervention and other food and service based strategies is required to generate sufficient homogenous data for pooled analyses in order to confirm their overall effect on a range of clinically relevant outcomes.

Using hand grip strength to derive a sample size estimate

This pilot study was not powered *a priori* to detect a significant change in any outcome as there was an absence of data available to perform a sample size calculation. The sample size was based on recruitment over a defined time period. Thus an important aspect of this study was to generate these pilot data to identify the sample size required for a fully powered study. HGS is a robust, dynamic, and objective indicator of change in nutritional status, and data was collected with high participation by a single researcher (JC). In contrast, potential error was introduced to weight data as weight was measured by a number of individuals or self-reported and is sensitive to changes in hydration status. HGS data obtained at admission and day 14 were deemed suitable to derive a power estimate.

Retrospective *post hoc* analyses using handgrip strength data collected during this pilot revealed this study was underpowered. Only 5% power to detect a 0.05 kg difference in change in raw HGS or 11% power to detect a 0.2% difference in change in percent of normal HGS between groups was achieved. This effect size is unlikely to be large enough to be clinically meaningful. For example, a minimally important clinical difference in HGS for stroke rehabilitation patients is reported to be 5 - 6kg (235). All participants appeared to have good HGS on admission, as HGS

was above predicted levels when adjusted for age and gender (percent of predicted normal HGS) (Figure 4:6, page 148) which may have limited the capacity for improvement.

Larger sample sizes are required for adequate power. However given the unavoidability of high attrition rates of participants due to discharge this presents a challenge. Increasing the duration of intervention or providing adjunct therapy may be necessary to induce changes in HGS. Muscle function responds earlier to changes in nutritional status compared to body composition, but the minimum time required to detect change in HGS is unclear. A recent study found no improvement in patients' HGS after three days of receiving a high protein menu (236). In comparison, at least eight weeks of ONS has demonstrated benefits in HGS among malnourished patients (237, 238). As such, development of nutrition interventions that commence in the hospital and are able to be continued beyond discharge require exploration.

Recent recommendations focus on the role of resistance exercise and adequate protein intake as essential aspects for maintaining muscle mass and function in the elderly (239). Although energy content was the main consideration when developing the intervention menu, some food items introduced were good sources of protein (e.g. omelette, cheese and biscuits, yoghurt) and overall, the default menu provided more protein than the standard menu. While participants' protein intake was in line with recommendations, consideration of daily physical activity and resistance training may also be important in any future evaluation of this intervention. Alternatively, targeting malnourished patients may be required to observe improvements in HGS as they appear more responsive.

4.6.2 Effect of the intervention on energy and protein intake

The nutrition intervention was provided in conjunction with usual dietetic care when dietetic referral was clinically indicated. Usual dietetic intervention demonstrated a heavy reliance on ONS, with almost half of patients consuming ONS. Other Australian data support this, indicating 43% of rehabilitation patients received supplements that contributed 21.5% to energy intake (1). The participants recruited

to this pilot study included those who were well nourished, at risk of malnutrition and malnourished.

Subgroup analyses of energy and protein intake at day 14 did not appear to indicate that the benefits of the intervention differed between well nourished and malnourished participants. This interpretation is limited by the small sample size of subgroups and the potential for misclassification of nutritional status at day 14 through the use of MST and SGA results from admission. While this food and service based strategy may have a role in supporting the nutritional status of all patients, it does not eliminate the need for individualised dietetic intervention for malnourished or at risk patients.

What does the increase in energy and protein intake mean in a clinical sense? The significance of these findings can be explored in the context of evidence based estimates of energy (elderly no hyper-metabolism, 100 – 125 kJ/kg/day; elderly moderate hyper-metabolism, 125 – 145 kJ/kg/day (240)) and protein requirements (elderly malnourished or at risk of malnutrition, 1.2 – 1.5 g/kg/day (239)) appropriate for this population group. When compared to these recommendations, the average intake of participants receiving the intervention (132 kJ/kg/day, 1.4 g protein/kg/day) was adequate, while under usual care conditions participants' average intake was below or at the lower end of these ranges (105 kJ/kg/day, 1.1 g protein/kg/day). While these crudes estimates do not take into account age, gender, weight, disease or activity state that will vary between patients and influence estimated requirements (85), this comparison illustrates that the effect of the intervention on food intake may be clinically meaningful.

From food alone (i.e. excluding energy from ONS), the intervention group consumed 29 kJ/kg/day more than the control group. This difference is statistically and clinically significant. Based on the mean weight of all participants at admission (65.7 kg), this equates to an additional 1905 kJ/day consumed from food alone. This is on par with the additional energy intake that is achieved from ONS among heterogeneous malnourished patients, as reported in a systematic review (1854 kJ/day, n=642 patients) (241). A key consideration is that compared to ONS, food may be more accepted by patients and a more cost efficient way to deliver additional energy (128, 129).

Interestingly, there was no significant difference in energy and protein intake at midmeals between groups. This was unexpected as it was hypothesised that in combination, the enhanced mid-meal service and higher energy menu would improve food consumption. However, mid-meal intake (~1200 kJ/day from food alone in the intervention group) was comparable to that in other intervention studies that provided high energy mid-meals without the enhanced service component (~1200 – 1300 kJ/day) (128, 129). This raises the question of whether the enhanced mid-meal delivery was implemented sufficiently, and if so, whether it is beneficial. During the study period, contamination of the control group and non-compliance among foodservice staff with the enhanced mid-meal delivery protocol and the higher energy menu was observed. Also observed was resistance among patients to choose the higher energy items. This may have limited the effectiveness of the intervention.

The findings of this study concur with the literature that shows that interventions that modify the food or service regularly throughout the day, compared with targeting only mid-meals (or breakfast), have a cumulative effect on increasing total daily food intake (Appendix 1, (117)). Food fortification is one such strategy that has been explored, with positive findings that it can significantly increase daily energy intake ranging from 1.0 - 2.9 MJ/day in comparison to usual food (121-124, 126). It is perceived by foodservice staff, dietitians and nurse unit managers to be more feasible and a higher priority compared to mid-meals (113). However in this study barriers to food fortification included: labour time, limited ability to intervene in the food production process as meals were prepared offsite and the potential for variability in nutrition content and quality of the product. Instead, choosing alternative items with a higher nutrient content (e.g. substituting toast for pikelets, tea/coffee for hot chocolate) was considered more practical.

Although a default higher energy menu had the capacity to provide 11.1 MJ/day and 109 g protein, this target was not met by the majority of participants. The projected energy intake relied on participants selecting a food and drink item at each mid-meal, and consuming 100% of all items served. However, this scenario is uncommon, with up to 95% of patients not eating all of the food served (26). A similar proportion of

participants in both groups consumed ONS, yet energy and protein from ONS were significantly lower (and therefore more potentially wasted) in the intervention group.

There are a number of reasons for plate waste and inadequate intake in hospitals which include clinical, food, service and environmental issues (38, 218). In particular, poor appetite is a key factor (28, 242). Age of patients, variety of flavours and the energy density of ONS can influence compliance to ONS (241). Analyses were not undertaken to compare between groups the amount of food or ONS provided to participants in total or the amount wasted, which is a limitation of this study. Exploring this may provide insight into patterns of dietitian prescription of ONS or participants' selection of high energy menu items and the way in which this nutrition intervention integrates with ONS use as part of usual dietetic practice.

Longitudinal energy and protein intake

While the literature generally indicates there is a negative relationship between LOS (where LOS ranges from four to up to 89 days) and food intake as observed in heterogeneous samples of acute or subacute patients, data are limited (25, 26, 39, 243). One prospective study conducted repeat assessments of dietary intake for four weeks or until discharge and found the proportion of elderly hospital patients with inadequate intake fluctuated between assessment one (n=100) and assessment nine (n=10) (244). However the authors did not statistically analyse this change, possibly due to attrition, which prevented analysis of these pilot data for very long stay participants. In contrast to the literature, the findings from these longitudinal analyses indicated a significant and modest improvement in intake (equivalent to half a hot meal) observed over two weeks of inpatient stay, which was just under the average LOS. Improvements in appetite and function associated with convalescence are likely to play a role. On this basis, menus (and nutrition intervention) should aim to meet estimated requirements at admission when intake is lowest.

Analysis of change in intake for participants with a LOS of a month or longer suggested an effect of time on energy intake, but further investigation is required to understand the pattern of change. A longer LOS in hospital is associated with greater illness severity, poorer nutritional status, impaired cognition and function all of which can independently reduce food intake (245). Further investigation into

approaches to nutrition care and nutrition intervention in subacute care that acknowledge the vulnerability of longer stay patients is warranted.

4.6.3 Cost

Cost is a driver of operations in foodservice. Managers are required to compete for funds, reduce costs and account for expenditures. It was anticipated that there would be a reduction in ONS usage in the intervention group in preference for the higher energy menu. This would offset the additional cost of the intervention and be a factor for consideration in cost effectiveness and cost benefit analyses. Although energy intake from ONS was less in the intervention group, the source of this difference is unknown as data on wastage of ONS were not explored. It is unclear if the volume of ONS prescribed was less, or the volume was the same but less was consumed (and therefore more wasted). Moreover, food waste overall was not explored in this study even though it is an important aspect of sustainability due to its environmental implications and cost inefficiencies. The ongoing cost incurred by Foodservice of AU\$7.47/patient/day may be prohibitive to a wider roll out or long term implementation. Nevertheless, it is important to consider the big picture of health economics. Improved nutritional status is known to reduce LOS, complications and readmissions, all of which have a meaningful impact on healthcare expenditure. A cost analysis of ONS concluded for every dollar spent on supplements 2.5 times more was saved through reduced LOS, admission costs and 30 day readmissions (246).

4.6.4 Strengths and limitations

This pilot study was designed to be scientifically robust, yet pragmatic to manage the challenges of the clinical environment as a research setting. The evaluation phase was conducted via a parallel controlled trial on a single ward and there are limitations to this study design that have influenced the outcomes (or lack thereof). Blinding was not possible due to the nature of the intervention, however participants were not informed of research aims or hypotheses. While a RCT conveys the highest level of evidence, this was not possible due to the logistical challenges of providing alternating food and services to individual patients within one space. The lack of

randomisation may have introduced bias and led to groups having a different mean weight at baseline, although this was statistically adjusted for.

The risk of contamination was high due to the intervention and control occurring simultaneously on one ward. Indeed, contamination and protocol deviation due to bed changes did occur. Foodservice staff appeared to be another source of contamination and protocol deviation, with non-adherence to the provision of the intervention to this group only. This bias introduced by foodservice staff was an unexpected social construct. Alternate study designs that would circumvent the bias associated to this quasi-experimental design were not feasible or were limited in other ways. A case series (i.e. before and after) with non-concurrent controls conveys a lower level of evidence in comparison to concurrent controls (186). A cluster RCT with allocation of the intervention or control at a ward level was not possible due to insufficient equivalent subacute wards at Eastern Health and personnel to undertake data collection across multiple sites.

A major challenge was attrition occurring due to discharge, withdrawal or group change. Forty two percent of the recruited sample were unable to provide data at day 14 of inpatient stay. This was higher than anticipated and resulted in a smaller sample size (and reduced power), though the sample was still larger than similar studies (121, 122, 129). While evaluating outcomes sooner during inpatient stay would have attenuated this issue, this may not have been worthwhile if this provides insufficient time for changes in outcomes to occur. Limited understanding about the responsiveness of nutrition assessment tools and measurements is a barrier.

A strength of the study design was the waiver of consent which enabled recruitment of all eligible patients, therefore eliminating selection bias. Importantly, patients with impaired cognition and those from non-English speaking backgrounds were recruited. As these individuals may be at higher risk of inadequate intake due to feeding independence, communication barriers or cultural food preferences, their inclusion in nutrition intervention studies is important. Due to the waiver of consent additional data collection for relevant outcomes such as nutritional biochemistry or quality of life were not permissible. While visual estimation of plate waste is not considered the 'gold standard' method of dietary intake assessment, there were some advantages to its use in this study. In particular it was less time intensive compared to weighed plate waste and did not rely on patients' recall, as is required for a diet history.

The findings of this study are likely generalisable to subacute care facilities where foodservice, dietetic care and patient characteristics are similar. The cook chill, centralised plating system used at this healthcare service is the most common system used in large hospitals in Australia (114, 247). Anecdotally, mid-meals are usually provided in hospital via a bedside trolley as they were here. The average LOS in GEM in Australian public hospitals is 19.2 days which is comparable to the LOS in this study (13). It is unclear whether the same outcomes occur among patients with a LOS of less than 14 days as data were not collected for most outcomes before this time point. Subacute patients with a short LOS are likely quite heterogeneous in relation to their illness severity, either being discharged home following a guick recovery or readmitted to acute care after becoming unwell. As data were collected for the entire LOS, long stay patients are represented in the study. However, the sample size of long stay participants was small which is a limitation. Analyses were conducted for all participants with available data reflecting real life clinical practice. Adjustments were made in statistical analyses to account for the potential data skew caused by long stay outliers.

4.6.5 Future directions

Further information is required to understand the feasibility of long term and/or hospital-wide changes to the menu and delivery service. Resources, including staff capacity and money, are key considerations for sustainability of this intervention. The benefits experienced by patients need to be weighed up against the implications and practicalities for healthcare staff and departments.

Foodservice staff are central and crucial actors in nutrition care strategies as they are the gatekeepers of food for patients. Observation of foodservice staff's implementation of the intervention indicated variability in their compliance with the research protocol. There appeared to be inconsistencies in the use of the visual menu and persuasion strategies at mid-meals. Additionally, the higher energy and standard menus were not contained in the respective groups, with many participants in the intervention group being provided with items that were not part of their menu (e.g. tea, coffee, toast). The factors influencing these behaviours of foodservice staff are unclear and are explored in chapter 5.

Results of the pilot study need further consideration in the context of their implications for foodservice staff. The cost analysis indicated the intervention took foodservice staff an additional 1.25 hours/day to undertake. This time burden has the potential to have negative consequences on staff's morale and the efficiency of the department. In contrast, the opportunity for the foodservice staff to engage more with patients at mid-meals to support patient's food choices may in fact improve morale and efficiency. Exploring the impact of the intervention on the foodservice staff is worthwhile to gain insight into barriers and enablers and improve implementation processes in the future.

4.7 Conclusion

This novel, multifactorial nutrition intervention consisting of a higher energy menu and an enhanced mid-meal point of service delivery was developed by making relatively modest changes to the existing foodservice. In addition to usual dietetic care (upon referral), the intervention resulted in a significantly greater intake of energy and protein, adjusted for body weight, in comparison to the standard menu and usual foodservice. This occurred without compromising participants' satisfaction with the foodservice. Increasing the energy density of hospital food and enhancing service may be an effective adjunct strategy to combat inadequate dietary intake among patients with an average LOS in subacute care. The broader implications for cost-benefit, the effect on patients' functional and clinical outcomes and the foodservice staff at the centre of the intervention need investigation. This will strengthen the evidence base for the role of feasible, effective food and service based nutrition interventions to improve dietary intake and nutritional status of patients in subacute care.

Chapter 5

What else is going on here? Exploring factors that influence hospital foodservice staff's capacity to deliver a nutrition intervention This chapter relates to:

The prepared manuscript;

 Collins J, Huggins CE, Porter J & Palermo C. What factors influence hospital foodservice staff's capacity to deliver a nutrition intervention? For submission to J Acad Nutr Diet.

The presentations;

- Collins J, Huggins CE, Porter J & Palermo C. What's going on here? Factors influencing the implementation of a hospital nutrition intervention. Health Services Research Association Australia and New Zealand (HSRAANZ) Conference, Melbourne, Australia. 2015. Oral presentation.
- Collins J. Working with Foodservice Staff An opportunity. Dietitians Association of Australia, Victorian branch and foodservice interest group seminar, Melbourne, Australia. 2015. Invited oral presentation.

5.1 Abstract

Background Translating research into practice is complex. Implementation of an intervention can result in a discrepancy between what was planned and what is delivered, affecting outcomes for recipients. The aim was to explore from the perspective of foodservice staff, their experiences delivering the nutrition intervention to address inadequate intake of patients in subacute care that was described in chapter 4.

Methods A process evaluation of the nutrition intervention using qualitative description was undertaken. A purposive sample of hospital foodservice supervisors and foodservice assistants (n=15) responsible for delivering the nutrition intervention to patients participated in focus groups and semi structured interviews. Content analysis using theoretical frameworks of behaviour was undertaken to describe factors (sub-themes) influencing foodservice staff's capability, opportunity and motivation to provide the nutrition intervention. Thematic analysis (by two independent researchers) was also undertaken to further understand (themes) foodservice staff's experiences.

Results Five key themes (and 15 sub-themes) explained factors affecting the implementation of the nutrition intervention. Aspects of the foodservice environment and patients' resistance were barriers to implementation of the intervention as prescribed and perceived sustainability; while teamwork, problem solving, leadership and job satisfaction were enablers. It emerged that there was opportunity to optimise training and feedback. Characteristics of the foodservice staff including: their knowledge, beliefs and perceptions of diet, health and their job role had the potential to influence their behaviours and decision making.

Conclusions Addressing the challenges of time, the foodservice structure, patients' resistance, gaps in knowledge and misconceptions among foodservice staff may enhance similar nutrition interventions in the future. More broadly, these findings illustrate there are a number of interacting factors that influence healthcare staff's delivery of an intervention as planned that need to be considered for clinical practice or research to enhance fidelity, feasibility and sustainability.

5.2 Introduction

5.2.1 Background

Efforts to address inadequate dietary intake among hospital patients are paramount to address malnutrition and nutritional risk and improve health outcomes. Chapter 4 describes a pilot study of a novel food and service intervention with this intention, and there are many other oral nutrition interventions reported in the literature (208). The traditional research methods used to evaluate these interventions fail to provide insight into how or why outcomes are (or are not) achieved. Hence, little is known about the experience of providing these interventions, or factors influencing their success. Failure of policies, programs and clinical practices to achieve desired outcomes for patients has been observed widely across healthcare disciplines and is not restricted to nutrition interventions.

In many cases, nutrition interventions rely on volunteers or healthcare staff such as foodservice or catering staff, nurses or allied health assistants for implementation. The success of these interventions may, in part, be dependent on the extent to which they are implemented by these individuals. Although it is anticipated that nutrition interventions will be implemented according to plan and demonstrate hypothesised outcomes, this is not always the case. Greenshalgh *et al.* (248) (page 598) describe how individuals responsible for providing or delivering interventions have agency and as such, interact and respond in predictable and unpredictable ways:

"People are not passive recipients of innovations. Rather (and to a greater or lesser extent in different persons), they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, 'work around' them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them—often through dialogue with other users."

Exploring this phenomenon is essential to ensure that interventions, such as the food and service intervention, translate into improved patient outcomes. Theories of behaviour/behaviour change such as the Capability-Opportunity-Motivation Behaviour (COM-B) System and the Theoretical Domains Framework (TDF) help to understand and interpret the process of transforming intentions into effects (249-251). They illustrate that behaviour change is complex and is influenced by a number of personal (internal) and organizational (external) factors. Importantly, the healthcare environment introduces specific social, cultural, economic and physical considerations that can challenge intervention implementation (252, 253).

5.2.2 Aims

The aim of this research was to understand the experiences of those responsible for providing the nutrition intervention (described in chapter 4) to patients. Specifically the objectives were to explore from the perspectives of foodservice staff, in the context of behaviour/behaviour change theories:

- 1. The strengths and limitations of the intervention.
- 2. The barriers and enablers to its implementation.
- 3. The way in which foodservice staff engaged with and responded to the intervention.

The purpose of this analysis was to answer critical questions about how the nutrition intervention was delivered to patients and why it occurred (or did not occur) in this way. Subsequently, this enabled the development of recommendations regarding the key considerations (inherent to the individuals, setting, process or intervention) to inform future implementation of this nutrition intervention or similar efforts in the hospital setting. This may improve the research-to-practice translation, sustainability and feasibility of service delivery

5.2.3 Hypotheses

This exploratory inquiry was not driven by hypotheses to be tested, as is appropriate for this research method (254).

5.3 Methods

5.3.1 The nutrition intervention

Chapter 4 describes in detail the method and results of the parallel controlled pilot study undertaken to test a food and service based nutrition intervention that aimed to increase dietary intake of subacute patients. Briefly, this intervention consisted of a higher energy menu and an enhanced mid-meal (morning tea, afternoon tea and supper) delivery service that required foodservice staff to change their usual job tasks. Specifically their tasks were to: [1] prepare and plate non-standard food and drink items at breakfast and mid-meals and; [2] use a visual menu and 'up selling' strategies at the bedside to encourage patients' food intake at mid-meals. Collaboration between stakeholders including, patients, foodservice supervisors, allied health staff and the researcher (JC) enabled the development of the nutrition intervention.

5.3.2 Study design

A process evaluation of the pilot using qualitative description was undertaken with hospital foodservice staff. This focussed on potential and actual influences on the progress and effectiveness of implementation of the nutrition intervention. Process evaluation is a "rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts" (254) (page S1) and fills a niche in health research to answer questions not addressed through traditional research methods. The method of qualitative description offers "a comprehensive summary of an event in the everyday terms of those events" (255) (page 336) and is useful for interpretive evaluation. It is a basic, yet in no way less valuable or scientific, form of inquiry that elicits findings of "the who, what and where of events or experiences" (255) (page 338). The Human Research and Ethics Committee at the Healthcare Network approved this study protocol and all participants provided written informed consent (LR23/1314) (Appendix 9a). Funding was provided by Monash University Nutrition and Dietetics Department.

Researcher reflexivity

The need for this evaluation was recognised following reflections throughout the pilot study by the researcher (JC) who identified a discrepancy between the planned and actual provision of the nutrition intervention by foodservice staff and between the anticipated and actual uptake of the higher intervention menu by patients. During the pilot study, prior to completion, it was proposed that an in-depth exploration to understand the experience of those involved in the intervention may be important when evaluating the findings of the pilot study and expose the realities of implementing change to foodservice. The researcher's (JC) practical experience, knowledge and connectedness to the nutrition intervention, research methods, patients, foodservice staff and clinical setting influenced her position in this evaluation, however the focus groups were undertaken before the outcome analysis of the nutrition intervention commenced.

5.3.3 Subjects and setting

The sample

The target sample were foodservice staff employed at the public hospital in Melbourne, Australia where the pilot study was undertaken. Foodservice supervisors (i.e. staff who complete administrative duties and supervise the department) and foodservice assistants (i.e. staff responsible for cleaning kitchen areas, equipment and utensils, serving and delivering meals) were identified as having the most extensive and powerful experiences with the intervention and therefore best positioned to provide qualitative description. Other foodservice staff (i.e. chefs, cooks and menu monitors) in addition to nurses, dietitians and other health professionals were not targeted for recruitment as they did not play a key role in the implementation of the nutrition intervention. Eligible staff were casual, part time or full time employees who had been involved with the implementation of the intervention from a managerial role or on the ward at the coalface.

Recruitment

Participants were recruited via purposive sampling. Advertising flyers were displayed in the hospital kitchen and personalised copies were provided to potential participants. To increase response, a department store gift card (AU\$20) was provided to participants.

5.3.4 Data collection

Data were collected in June 2014 once the pilot study had been completed, but before primary outcome data were known. Foodservice assistants (n=12, 35% eligible participants) participated in three focus groups (n=4 in each). Focus groups were the method chosen to obtain perspectives from a range of viewpoints and to encourage discourse of opinion about the nutrition intervention. This method provided opportunities for interaction and dynamics to stimulate discussion about attitudes, experiences and beliefs (256). Data were collected separately from foodservice supervisors and assistants to avoid the effect of potential hierarchical influences on dialogue. It was not possible to schedule a focus group with all foodservice supervisors (n=3, 100% eligible participants) completed an individual semi structured interview.

Interviews and focus groups ran for approximately 20 – 30 minutes and 40 minutes, respectively. They were conducted at the hospital following the work shift for participants' convenience. Data collection was facilitated by a researcher (CEH) who received training in qualitative methods. The facilitator was not involved in the pilot study or known to foodservice staff or employed by the hospital, to encourage participants to speak openly and honestly about their experiences.

Theoretical frameworks

The inquiry and subsequent analyses were informed by behaviour theories; the COM-B System and TDF. The COM-B System proposes that capability (physical or psychological), opportunity (physical or social) and motivation (emotional or reflective) interact to influence behaviour (251). This behaviour system was designed to represent the minimum number of factors required to generate a desired behaviour. The TDF integrates with the COM-B System to describe 14 domains, that are proposed to contribute to capability, motivation and opportunity (250) (Figure 5:1). It was developed by synthesising existing evidence based practice

theories and theoretical constructs to generate a single, simplified theory for use in implementation research in healthcare (249).

COM-B System component		TDF domain	
Capability	Psychological	Knowledge	
		Skills	
		Memory, attention and decision processes	
		Behavioural regulation	
	Physical	Skills	
Opportunity	Social	Social influences	
	Physical	Environmental context and resources	
Motivation	Reflective	Social/professional role and identity	
		Beliefs about capabilities	
		Optimism	
		Beliefs about consequences	
		Intentions	
		Goals	
	Automatic	Social/professional role and identity	
		Optimism	
		Reinforcement	
		Emotion	

Figure 5:1 Influences and sources of behaviour defined by theory

COM-B; Capability-Opportunity-Motivation Behaviour system (251); TDF, Theoretic Domains Framework (250)

Figure reproduced from Table 3 in Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. 2012;7(1):37.

5.3.5 Procedure

The facilitator obtained participant consent, collected demographic data (via questionnaire) and described the purpose and procedure, reiterating anonymity and confidentiality. An interview guide was used as the basis for all interviews and focus groups with questions and prompts specifically developed to elicit responses relating to aspects of the COM-B System (which could be mapped to the domains of the TDF) (Box 5:1). It included two general open-ended questions and a series of prompts, including one prompt added during data collection when participant discussion revealed a further aspect relevant to the COM-B system. Discussions were audio recorded and transcribed verbatim.

Box 5:1 Interview guide used for focus groups and semi-structured interviews with foodservice staff

Questions

- 1. What did you think of the new food items and the new way of delivering mid-meals to the patients participating in the pilot study?
- 2. Were there any other things that made it easier or difficult to provide the new food items and deliver the mid-meals in the new way?

Prompts

- Tell me about the training, support and instructions that were provided COM
- What was the purpose of providing these new foods and delivering the mid-meals in a new way? ^c
- What were the patients' responses to the new menu items and the new way of delivering the mid-meals? ^{O M}
- How did it make you/the foodservice staff feel about your/their job and the work you/they do in the hospital?^M
- How did it affect the usual work tasks that had to be done by the foodservice department? ^o
- What did you think of the nutritional value of the new foods that were offered?^{a C O}

^aPrompt added during data collection process for subsequent focus groups and interviews

C, capability; O, opportunity; M, motivation

Prompts address aspects of the Capability-Opportunity-Motivation Behaviour (COM-B) System (251)

5.3.6 Data analysis

Discussions were audio recorded and transcribed verbatim. Data immersion occurred prior to analyses by repeatedly reading transcripts. Content and thematic analyses were used to construct a qualitative description of the nutrition intervention from the point of view of foodservice staff. Data from interviews and focus groups were analysed together. An overview of the analysis process is provided in Figure 5:2.

Deductive, directed content analysis (257) was completed using the COM-B System and the TDF as theoretical framework to code data. Codes were assigned to interpret and give meaning to sections of data and subsequently adjusted as necessary in light of insights gained during the process in an approach known as focused coding (258). Inductive thematic analysis (259) was then undertaken whereby codes were grouped together to form sub-themes independent of theory. The sub-themes described factors that influenced behaviours of foodservice staff or had the potential to do so; the distinction was not always evident in the data. An independent qualitative researcher (CP) independently coded the transcripts and thematically analysed the data to verify the sub-themes. The sub-themes were grouped together to form themes through consensus between the researcher (JC) and the independent researcher (CP) and using a new theoretical framework; the Consolidated Framework for Implementation Research (CFIR) (260). Concept maps were used in this process to visualise the relationships between codes, sub-themes and themes.

Direct quotes were sourced from transcripts to provide evidence and explanation. The participant supplying the quote was identified by a number and their role as a foodservice supervisor (FSS) or foodservice assistant (FSA). Round brackets () were used to indicate that text was added for clarification and an ellipsis ... illustrated that text had been removed for conciseness.

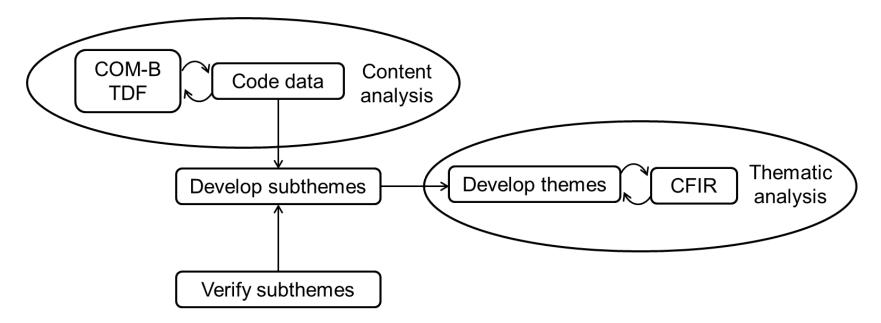


Figure 5:2 Overview of analysis of qualitative data obtained through focus groups and interviews with foodservice staff

COM-B; Capability-Opportunity-Motivation Behaviour System (251); TDF, Theoretic Domains Framework (250); CFIR, Consolidated Framework for Implementation Research (260)

Verification was completed by an independent researcher

5.4 Results

5.4.1 Participant characteristics

In general, participants (n=15) were middle aged, English speaking and worked 3-5 shifts each week (Table 5:1). All participants were female, as there were no male staff employed in the foodservice department.

Table 5:1 Demographic characteristics of foodservice staff participating in focus groups and interviews (n=15)

Demographic characteristic		Response, n (%)
Age (years)	18-30	1 (7)
	30-40	0
	40-50	6 (40)
	50-60	8 (53)
Duration of employment in general hospital foodservice (years)		7 (47)
	5-10	2 (13)
	10-20	4 (27)
	> 20	2 (13)
Duration of employment at the hospital (years)	< 2	3 (20)
	2-5	4 (27)
	5-10	3 (20)
	10-20	3 (20)
	>20	2 (13)
Language spoken at home	English	15 (93)
	Other	1 (7)
Number of shifts worked during an average week		2 (13)
	3-4	5 (33)
	5	5 (33)
	6-7	3 (20)

5.4.2 Themes

Five themes and 15 subthemes were identified that provide a rich qualitative description of the critical events, responses and implications of the nutrition intervention from the perspective of the foodservice staff (Figure 5:3).

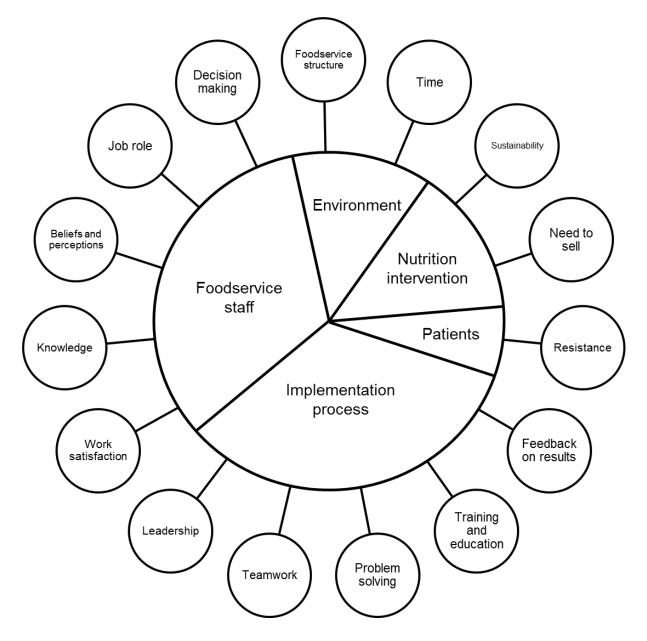


Figure 5:3 Five themes (wedges) and 15 sub-themes (outer circles) describing the key aspects of the nutrition intervention from the perspective of foodservice staff

Theme 1 – Environmental factors

The foodservice system was portrayed to be linear and rigid, with the department operating on a strict time schedule and all staff having allocated jobs to complete. While the participants reported that this structured approach ensured optimal operation of the foodservice system, the downside was the system was inflexible to change. This challenged the implementation of the nutrition intervention. Variations or disruptions to 'business as usual' sent the system into turmoil and was felt to ultimately have a negative impact on patients across the whole hospital who were reliant on the foodservice.

"Everything is timing with us in the kitchen. We're on a time; there is always a job after a job." [Participant 12, FSA].

The participants reported that the additional tasks associated with the nutrition intervention took extra time to complete. It was felt that the foodservice department was already operating at full capacity and it was reported there was no time or labour workforce available to manage the nutrition intervention. There was a strong feeling described of being pressured for time, as more had to fit into their already busy schedules. Consequently, the intervention caused staff to run late and fall behind in their tasks which had a snowball effect that lasted the whole day. Participants described feeling guilty when they were late as they believed they were letting their colleagues down.

"They liked doing it but they were put under a lot of pressure because we were already running on a tight schedule in the kitchen so they were under the pump a lot, the girls. So some of them got a bit stressed if they were running a bit late." [Participant 3, FSS]

"Some of them didn't enjoy it at all because it was more work. They felt (that) we've got enough work and we don't need this added (job)." [Participant 1, FSS]

To overcome these challenges, processes were altered. Changes included: extending the work hours of one staff member at the breakfast shift, reordering the timing of meal plating for the ward and instigating greater teamwork among foodservice staff. However, these changes took time and there was a lag between identifying and rectifying problems. Additionally, participants explained that despite initiating these strategies more support was still required to better cope with the nutrition intervention.

Theme 2 - Characteristics of the nutrition intervention

The nutrition intervention was felt to be unsustainable to adopt across the whole hospital as it was ill-fitting with the current foodservice structure and labour capacity. It was reported that significant restructuring of processes and expanding the workforce would be required to ensure smooth operation of the foodservice if the nutrition intervention was adopted as usual practice. The cost this would incur were acknowledged to be a barrier to a wider roll out of the nutrition intervention given the limitations of healthcare funding (note this was without the knowledge of the analyses presented in chapter 4). The perceived higher amount of plate waste occurring due to the nutrition intervention was also felt to be cost prohibitive.

"If we were offering that type of menu to all patients I just don't know how the kitchen would cope time wise with that. I don't think it would be viable." [Participant 2, FSS]

"I think if you would just generalise this to the whole hospital setting, with the financial situation that we have at the moment I think it's not really a sustainable idea and I think it would be a waste of money personally." [Participant 10, FSA]

Participants recounted their role was to promote the higher energy menu items to patients to facilitate greater food intake. To achieve this they described employing a range of techniques including encouraging, prompting, upselling, tailoring suggestions to food preferences and suggesting alternatives. Informal competition among foodservice staff to see who could 'sell' the most items from the higher energy menu at mid-meals acted as an incentive for staff to do their best.

Theme 3 – Responses of the patients

Despite their attempts, most participants explained that patients were resistant to engaging with them during the enhanced mid-meal delivery and declined food and drink items. This was reported to occur particularly among longer stay patients because they tired of the menu repetition. Patients' lack of receptiveness was perceived to be associated with the large amount of food they received that made them feel overwhelmed.

"I know with the elderly, you put (down) this whopping tray of food and they've just gone "Oh God no, take it away." It was just so overpowering, so much food in one hit." [Participant 7, FSA]

Participants reported patients disliked wasting food and this contributed to their resistance, as they preferred to have nothing to eat rather than generate waste. Food waste was described to occur due to the provision of too much food, and possibly food that did not match patients' preferences. There was variability in perceptions that the higher energy menu met patients' food preferences and the popularity of food items. Together, patients' resistance and food waste appeared to be a source of negative feedback for foodservice staff and may have generated a perception that the nutrition intervention, or aspects of it, were futile.

"I felt the supper run, that was just a complete waste of time. No one really wanted us to come back (and offer food)." [Participant 12, FSA]

Theme 4 – Implementation process factors

Participants were eager to know whether the nutrition intervention had achieved its aims and took the opportunity to ask the facilitator about the outcomes among patients. Interestingly, some participants perceived that the nutrition intervention had been effective despite the results being unknown at the time of the qualitative data collection. This perception was based on their observations of patients during the pilot study.

"...If you were trying to put weight on patients, visually to me it worked. Because visually, I saw that they had put on weight." [Participant 2, FSS]

Participants reported they received face to face training, instruction and demonstration by the researcher (JC) and foodservice supervisors in regards to the nutrition intervention, but it was unclear the extent to which they gained new knowledge and skills. They perceived the content of the training sessions and the

support from the researcher (JC) to be adequate. However, the casual and shift-work nature of their employment was reported as a barrier to access training. Foodservice assistants reported taking on the responsibility to show and tell their colleagues who did not receive formal training

"It's very awkward because there are so many girls working in the kitchen and if (the trainer) only comes down, say, twice in that week she's still going to miss people. So unless she's there every shift (at) the beginning of every shift to make sure everyone knows, it's very hard." [Participant 5, FSA]

Managing the additional tasks associated with the nutrition intervention when time and workforce capacity were limited was expressed as the biggest barrier. The researcher (JC) and foodservice staff worked together to find solutions to overcome these challenges and effective communication was described to be advantageous for problem solving. Teamwork and camaraderie within the foodservice department were reported as essential to minimise the disruption to patients. There was variability in foodservice assistants' perceived support; some reported feeling well supported by their colleagues and supervisors and these participants took the time they needed to do their job properly. Conversely, it was also reported that not all foodservice assistants were willing to help each other out, not limited to the intervention, and changes in work culture were required for effective teamwork.

"We all helped out in different areas to compensate for (the nutrition intervention) because it was a big job doing all those extra things that we had to do up there." [Participant 15, FSA]

"I know it's hard out there because not everyone is so forthcoming [with assistance] and that is very hard because you can be very intimidated out there....it's a big issue actually." [Participant 12, FSA]

The foodservice supervisors championed the nutrition intervention within the department. They explained they were highly motivated to carry out the nutrition intervention to the best of their ability because it was their responsibility to do so. The foodservice supervisors described that they led by example by providing assistance on the floor with tasks when required. Foodservice assistants reported supervisors

were influential in culturing teamwork among the department to overcome the time burden.

Theme 5 - Characteristics of the foodservice staff

Participants described that the enhanced mid-meal delivery service enabled them to be more involved with patients. This was perceived to have a range of benefits for patients: they enjoyed the friendly service and greater interaction with staff, they had a wider choice of food and communication barriers were overcome. Involvement with patients was also reported by some participants to improve their work satisfaction. Communicating more with patients and having the challenge of implementing the intervention were rewarding and enabled them to do their job the way they would like it to be done. Conversely, feelings of guilt, time pressure and lack of support from colleagues were reported by some participants and caused them to be resistant toward the nutrition intervention.

"The other part as well is you were using your brain a little bit more. You weren't just walking in and checking the name, you were actually communicating with them and you had to make sure they got the right things. So I found it great." [Participant 13, FSA]

"It was lovely to be able to talk to the patients and have that communication with them because we don't get that (usually). ...That was a nice feeling." [Participant 12, FSA]

The data revealed gaps in participants' knowledge of the intervention procedure and general nutrition. There was no discernible difference between the knowledge of foodservice supervisors and foodservice assistants. Despite this, participants reported confidence in their skills and knowledge and perceived their knowledge to be appropriate for their role. The majority of participants did not feel that additional education was warranted. Some participants indicated that it was not their responsibility to be more knowledgeable about nutrition as this was the dietitians' role. Participants appeared to have limited understanding about the rationale for the nutrition intervention and specifically the higher energy menu. They stated they knew the purpose of the nutrition intervention and described it was related to nutrition, weight status and "*building patients up*" but their responses lacked detail and their

language indicated uncertainty suggesting a gap between their perceived and actual knowledge.

Facilitator: "Do you understand what the purpose of providing the new foods was and why they (the foodservice staff) were delivering them in the new way?"

Participant: "Yeah. They didn't have the nutrition and we were building them up and what have you." [Participant 1, FSS]

Participants referred to nutrition care practices that they believed were aspects of the nutrition intervention that were not in fact part of the protocol. For example, they believed there was no limit to the number of items patients could order from the higher energy menu. There also appeared to be confusion between usual dietetic care practices and the 'rules' of the intervention.

There was a strong negative perception towards the amount and type of food included in the higher energy menu and its inappropriateness for patients. The high frequency, volume and portion size of food items led to the perception that patients were provided with more food than they were capable of consuming. This was perceived to be evidenced by the greater amount of plate waste felt to be observed among the intervention group. This belief also appeared to be shaped by the participants' observations of what was 'normal' food intake for patients, and their perceptions of the nutritional needs of the sick and elderly. For example, some participants reported that *"skinny"* patients did not need to receive the higher energy menu and since patients were sedentary they did not need to eat much food.

Many participants reported that the higher energy menu was unhealthy and unsuitable for patients. This was based on their health beliefs that were consistent with general public health nutrition messages (e.g. reduce saturated fat and sugar intake). There was a lack of recognition by participants that sick and elderly patients have different nutritional needs and priorities to the overall population. Sugar and saturated fat were perceived not to be nutritious. Consequently, there was concern and confusion about providing the higher energy menu (e.g. cakes, muffins, chocolate biscuits) to patients, particularly those with diabetes. "We understood it to be for nutritional purposes and that's why I don't understand why I was offering you (the patient) four lots of sugary things." [Participant 4, FSA]

"We were just concerned... that they wanted the patients to put on weight but everything, like, the mid-meal muffins and cakes and the Tim Tams (chocolate covered biscuits) and all that, we class that as has got...the wrong kind of fat in it." [Participant 3, FSS]

Participants described their role as gate keepers of food and providers of nutrition care, playing an important role in patients' recovery. Foodservice supervisors and some assistants were more connected to this professional identity than others. Supervisors reported feeling frustration when staff didn't appreciate this role, and a responsibility to change these attitudes. They explained their department was obliged to participate in nutrition research as it can benefit patients. There was a firm trust that the research team knew what they were doing and belief that the nutrition intervention must have a purpose for patients. Because the intervention was for research purposes it was respected and held in high regard.

"You want to make things better and if by making things better we do studies, it's great." [Participant 2, FSS]

"I must say, I didn't feel pressured when I was up there because you knew you had to do it. It was part of a research thing so you can't rush around like a mad fool, you've got to actually speak to them and do each one." [Participant 13, FSA]

Participants expressed that their role was to respect patients' wants and wishes in regard to food. When patients did not want food, participants had to manage their beliefs about their job role against the expectation that they would aim to convince patients to have something to eat. This meant finding the balance between forcing and encouraging intake.

"If they didn't want it, they didn't want it. But you would try and encourage them as much as you could and say "Have you tried this? Really, it's the best."." [Participant 1, FSS] Participants acknowledged nutritional care was a team effort, with foodservice staff, nursing staff and dietitians needing to work together. They described that the nurses' role was to continue the provision of assistance and encouragement at the bedside that they initiated when they delivered the meal trays. Participants viewed dietitians as more senior and reported they were obliged to do as the dietitians (including the researcher (JC)) instructed.

Situations where participants intentionally deviated from the nutrition intervention protocol were described. Some foodservice assistants with strong beliefs that the higher energy menu was inappropriate for patients refused to provide food items to particular patients (e.g. hot chocolate for diabetic patients). This was not supported by other participants who indicated it was not foodservice staff's role to make such decisions.

"I would never offer them (diabetic patients) hot chocolate; any diabetic, never ever. I don't want to give them (hot chocolate) because that's sugar, that's very high." [Participant 9, FSA]

"I think she (the researcher (JC)) set it out quite well in we sort of knew what we had to do so long as we really followed the instructions. And really, at the end of the day that's what our role is. It's not to provide nutritional education to patients." [Participant 10, FSA]

Some participants described providing patients with smaller serves of higher energy menu items although the portion sizes were set and at times offering toast, tea and coffee although these had been removed from the higher energy menu. This was perceived to be acceptable because participants believed it was better for the patients to have something to eat rather than nothing. Participants also described that they provided higher energy menu items to patients in the control group because they did not feel it was fair they missed out on the 'better' food, especially if it was tray waste.

5.5 Discussion

This process evaluation using qualitative description provides insight into the factors that impact on foodservice staff's capability, opportunity and motivation to provide a food and service based nutrition intervention to subacute patients. It found that the foodservice structure, time pressure and patients' resistance to the higher energy menu were barriers to successful implementation and sustainability of the nutrition intervention. Teamwork, leadership of foodservice supervisors, collaborative problem solving between the researcher (JC) and foodservice supervisors and improved work satisfaction were enablers. There was opportunity to optimise the provision of timely feedback and access to training to further support implementation processes. Characteristics of the foodservice staff, including their knowledge, beliefs and perceptions of diet, health and their job role, had the potential to influence their behaviours and decision making. Collectively these factors may have, in part, influenced the outcomes of the nutrition intervention among patients.

5.5.1 Environmental factors

The opportunity to provide the nutrition intervention as planned was limited by the environmental systems and availability of resources and time. Previous research has established that healthcare staff experience a lack of time and competing priorities at meal times, which impede the provision of nutritional care (261, 262). The nutrition intervention introduced a patient-centred approach to meal delivery as interaction at the staff-patient interface offers benefits for patients (220). Additionally, the results indicate this also had the potential to increase work satisfaction of staff. However the rigidity of the foodservice operations appeared to hamper this innovative intervention. Inflexibility is a recognised limitation of foodservice systems (113, 114, 263, 264). The current cook chill, centrally plated foodservice system did not cater for the enhanced mid-meal service in particular, which necessitated more time spent at the bedside. This generated time pressure, with foodservice staff experiencing increased work stress.

5.5.2 Implementation process factors

Successful implementation processes require individuals who will promote the intervention and provide social influence to support its adoption into practice. The

role of opinion leaders and champions is recognised in implementation theory (248, 260). In this pilot study, the foodservice supervisors were such individuals - problem solvers, teachers, owners and leaders. Permitting and empowering foodservice supervisors to participate in the process maximised their position as 'insiders'. Importantly, they fostered a culture among their staff of valuing their role in patient care and believing in the intervention. Previous studies of nutrition care practices also recognise the pivotal role of champions, suggesting they are a key facilitator of change in healthcare settings (265-267).

5.5.3 Patient factors

The behaviours of patients' receiving a nutrition intervention are equally as important as behaviours of those facilitating or providing the intervention. Patients' resistance toward the higher energy menu was reported by foodservice staff as a key barrier to implementation. A recent study of the efficacy of an oral nutritional supplement (ONS) dose feeding program (i.e. med pass program) also reported nurses' challenges in convincing patients to consume products to support their nutritional status (268). Foodservice staff speculated that resistance may have been due to poor appetite, large portion sizes, fear of food waste or food not meeting patients' preferences. This concurs with findings reported in the literature (43, 144, 264, 269). Elderly Meals on Wheels clients' lack of receptiveness towards food snacks has also been attributed to their misconceptions about the nutritional value of these items and a lack of awareness of malnutrition and its implications (270).

5.5.4 Foodservice staff factors

Foodservice staff's capability to carry out the nutrition intervention was largely influenced by their knowledge, rather than skills or psychological processes. Their level of knowledge was below what was anticipated, given the education and training they had received. Poor knowledge of nutrition among non-dietetic healthcare staff and lack of knowledge have been identified in other studies as barriers to implementation of nutrition care practices (266, 268, 271). Participants' views and appreciation of the nutrition intervention appeared to be influenced by their: misconceptions about diet, nutritional needs and disease (e.g. malnutrition, diabetes); lack of knowledge about the links between these concepts and; disinterest

in further education. Importantly, this appeared to result in the selective provision of higher energy menu items to patients by some foodservice staff. Lambert *et al.* (268) also describe similar situations, reporting that nursing staff questioned why patients who did not appear malnourished or underweight were receiving ONS and would exercise their own agency and alter ONS prescriptions ordered by dietetic and medical staff. Pre-ordered and/or pre-plated mid-meals may be an alternate approach to reduce the freedom of foodservice staff to interfere in the research protocol. However, this would eliminate patients' choice and the use of upselling strategies at the point of service.

5.5.5 Degree of implementation of the intervention

Data gathered during the process evaluation enable judgements to be made about degree of implementation of the intervention during the pilot study. Berkel *et al.* (272) propose four dimensions of implementation that may be sources of disconnect between the planned and actual implementation of an intervention. These are considered in the context of the nutrition intervention:

1. Participant responsiveness

This describes enthusiasm and participation of intervention recipients (272). Patients' resistance to the nutrition intervention was a sub-theme in itself that has been discussed in section 5.4.2.

2. Fidelity

Fidelity is the extent to which the core components of the intervention were delivered as prescribed (272). Participants' omissions provided evidence of intentional deviation from the nutrition intervention. It appeared this was dependent on foodservice staff's subjective opinions of who they believed would benefit (or not benefit) from the higher energy menu and whether they felt they had the time to provide the enhanced mid-meal service. The maintenance of usual care among the control group was also spoilt, with group contamination evident. The parallel controlled study design with control and intervention conditions occurring simultaneously on one ward was a contributing factor. Despite these examples of non-adherence, favourable effects of the intervention on patients' energy and

protein intake adjusted for weight were achieved (chapter 4) suggesting sufficient fidelity of the intervention. It is possible that a greater effect of the intervention would have been demonstrated under ideal circumstances. A review of the effect of implementation on outcomes found that positive results were achieved in studies where there was at least 60% compliance with the intervention (273). This suggests there is some capacity for non-adherence before the integrity of the intervention is adversely affected.

3. Adaptation

Intervention provider adaptations are changes to the content or processes associated with the intervention (272). It is accepted that modifications are necessary to ensure a 'borrowed' intervention is suitable for the context and recipients where it will be implemented. As the nutrition intervention was designed specifically for the subjects and setting (section 5.3.3) in mind, theoretically adaptations should not have been necessary. Nevertheless, the theme 'Problem solving' described in section 5.4.2, identified that changes to foodservice structure and processes did occur during the roll out of implementation. Foodservice staff also described that the boundaries of the intervention were extended to include additional components (e.g. completing menus for patients, providing patients with multiple menu items). It was unclear if these changes to the intervention occurred unintentionally because of misunderstanding of the boundaries of the intervention or intentionally due the belief that they would be beneficial for patients.

4. Quality of delivery

The quality of delivery relates to the processes the intervention providers use to deliver the intervention to recipients (272). Such processes may include interaction, enthusiasm and clear presentation of the intervention (272). This dimension is redundant in the case of this nutrition intervention, as these components were built in to the enhanced mid-meal service. Evaluating the quality of delivery would in essence be determining fidelity of the enhanced mid-meal service.

5.5.6 Strengths and limitations

Effort was made to establish credibility (internal validity), dependability (reliability), confirmability (objectivity) and transferability (generalisability) to enhance trustworthiness of the data (274). Triangulation between data gathered from different types of participants (foodservice assistants and foodservice supervisors), overlapping methods (focus groups and interviews) and analysed by two independent researchers (inter-coder agreement) showed consistency and reproducible tendencies. To minimise the researcher's (JC) position influencing analyses, theories were used to provide a framework for accountability and sub-themes were validated to verify the honesty and accuracy of data.

To encourage accuracy and completeness of participants' contributions an independent facilitator and iterative questioning were employed. However, the objectivity created through the semi-structured inquiry mode may have limited the depth of exploration of some aspects of the discussion. In particular, further probing to explore participants' beliefs and reasons for these beliefs may have provided fascinating data to strengthen analyses. The occurrence of participation bias is unknown; foodservice staff who did not participate may have had different perspectives and experiences to participants that were not captured, although the use of an incentive sought to attenuate this. The findings of this evaluation are likely to be transferrable where there are sufficient parallels between foodservice staff and the subacute setting.

5.5.7 Implications

Recommendations for future research

A number of theories and frameworks exist that provide recommendations to guide intervention development and implementation in the healthcare setting (e.g. CFIR (260), The Behaviour Change Wheel (251), The Diffusion of Service Innovations (248)). Consulting and utilising theory and key literature is encouraged for future research to ensure research design reflects the evidence base rather than researchers' intuition of what 'works'. Process evaluation is recommended to complement and support summative outcome data (254, 275). Research methods that are particularly suited to exploring questions of 'what, 'how' and 'why' during implementation research have been proposed (253). Mixed methods studies and participatory action research are among those suggested. While these methods were not formally used here, elements were adopted (i.e. the use of qualitative data to supplement quantitative findings; engaging foodservice staff in the pilot study process) and proved extremely valuable. Participatory action research has been used in previous studies and appears to be an effective approach for successfully changing nutrition care processes in the healthcare setting (140, 262, 271).

This study captured the experiences of foodservice staff, the providers of the nutrition intervention. Equally as important are the views and experiences of recipients of the intervention. Directly engaging with patients to gain insight into their receptiveness of nutrition interventions would add to understanding of what did and did not work.

Recommendations for changing nutrition care practices

Findings from previous qualitative exploration of hospital eating environments (261, 262, 271) and nutrition related quality improvement efforts (265, 266, 268, 270) indicate congruence with these data, suggesting there may be a number of barriers or enablers to changing nutrition care practices experienced consistently in the healthcare setting. There is an opportunity to address a number of internal and external barriers to optimise the capability, opportunity and motivation of healthcare professionals providing nutrition interventions in a healthcare setting. Box 5:2 lists suggestions based on key learnings from this study that may inform the use of this nutrition intervention or similar strategies in research or clinical practice in the future.

Box 5:2 Recommendations to support the implementation of nutrition interventions designed to improve dietary intake of patients in healthcare settings

- 1. Identify champions that will support the intervention among the social network.
- 2. Empower intervention providers to participate, contribute to, and evaluate the process.
- 3. Ensure regular communication between researchers and intervention providers.
- 4. Emphasise the role of the intervention providers in nutrition care and how their role fits into the multi-disciplinary team approach to nutrition care.
- 5. Educate intervention providers on basic nutrition, diet and disease relationships; differentiate between the nutritional requirements of the general population and the study sample.
- 6. Ensure the education and training schedule is flexible so it can be accessed by all intervention providers.
- 7. Provide intervention providers with timely feedback on progress and outcomes.
- 8. Ensure sufficient staff and time are allocated to enable the provision of the intervention.
- 9. Re-organise environmental structures, systems and processes to support the intervention.

5.6 Conclusion

These data afford insight into the complexities of undertaking nutrition clinical trials in the healthcare setting. Future nutrition interventions within foodservice systems should consider how the ability of healthcare staff to deliver the intervention as planned may be influenced by: the 'human element', the implementation process, resources and the environment. There is an opportunity to address a number of internal and external barriers to optimise the capability, opportunity and motivation of staff providing nutrition interventions in a healthcare setting.

Chapter 6

General discussion

6.1 Contribution of this thesis

This thesis makes a substantial contribution to knowledge and understanding of malnutrition in subacute care. Malnutrition in healthcare settings is a 'wicked' problem, a term coined to describe a societal problem that is "malignant (in contrast to benign) or vicious (like a circle) or tricky (like a leprechaun) or aggressive (like a lion, in contrast to the docility of a lamb)" (276) (page 160). The observation of malnutrition and recognition of the role of nutritional care are not new, documented by Florence Nightingale over a century ago. There have been decades of research to establish understanding of: physiological processes of malnutrition; the adverse effects of malnutrition; factors contributing to inadequate intake and; the clinical and cost effectiveness of potential solutions. Nevertheless, malnutrition persists and ongoing inquiry and is warranted in order to improve health, quality of life and longevity of patients and efficiency in health service delivery.

The focus of this thesis specifically on subacute care aimed to address some of the evidence gap due to previous limited research in this setting (72). This is timely given the current and future expansion of subacute services in recognition of the important role they play in supporting the needs of an ageing population. The clinical research trials undertaken were conducted pragmatically in a real-world hospital setting to reflect actual subacute practice, facilitating the capacity for translation. All eligible patients were recruited regardless of disease condition to enhance the generalisability of results. It is an achievement that this research was completed with large sample sizes and well-designed studies, given the challenges inherent when undertaking nutrition research in the healthcare setting.

In culmination, this thesis provides a comprehensive picture of the nutritional status of subacute patients, how this changes during inpatient stay and the evidence for a number of nutrition interventions that aimed to prevent and treat malnutrition in this setting. The salient conclusion this body of research makes about malnutrition in subacute care is that adequate, appropriate nutritional care for all patients must be a pillar of health service delivery. Figure 6:1 depicts a multifactorial, multidisciplinary model of nutrition intervention. This model brings together the multiple components of nutrition care and dietetic intervention described in the literature (19, 208, 277), practice guidelines (12, 72, 74, 83, 111, 278) and observed by the researcher (JC) in

practice. The contribution of this thesis to our understanding of malnutrition in subacute care centres on two aspects of nutrition care, contextualised in Figure 6:1:[1] monitoring of nutritional status and; [2] the foodservice system and workforce.The implications of the findings are discussed further in section 6.2.

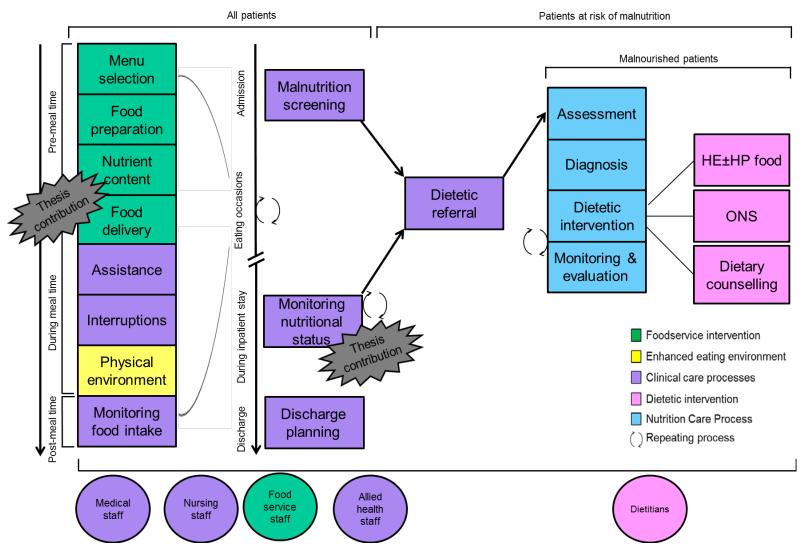


Figure 6:1 Multifaceted, multidisciplinary action plan to address malnutrition in subacute care

ONS, oral nutritional supplements; HE±HP, high energy ± high protein

6.1.1 Synthesis and major findings of the research investigations

The series of associated research studies presented in this thesis were each informed by the results and reflections of prior chapters. Table 6:1 revisits the four research questions addressed in the thesis and the key findings in relation to these. The way in which the line of inquiry evolved throughout the chapters of this thesis is described below.

The first investigation (chapter 2) aimed to observe the nutritional status of patients at admission and discharge from subacute care.

Finding1: Standard multidisciplinary care, including dietetic intervention, had the capacity to enable improvement in nutritional status, particularly of participants who were malnourished on admission.

The size of the problem of impaired nutritional status was emphasised, as was the need to address nutritional decline and the high prevalence of nutritional risk through evidence based nutrition care. This led to a systematic literature review to collate the findings of existing studies of oral nutrition interventions on nutritional and functional outcomes specifically among subacute patients (chapter 3).

Finding 2: There is little evidence to guide nutrition intervention in the subacute setting.

The gaps in the evidence identified by the review provided the impetus to develop and test a novel nutrition intervention in a pilot study (chapter 4). The focus of the intervention was narrowed to foodservice since it was determined that modified meals can increase dietary intake and the systematic nature of foodservice provides a means to reach all patients. This is the first time an intervention that integrated improvements to both food and service into an existing foodservice model has been developed, implemented and evaluated in subacute care.

Finding 3: The nutrition intervention increased dietary intake (adjusted for weight) of all participants.

Finally, a process evaluation using qualitative description (chapter 5) added the details of 'how' and 'why' the quantitative findings of the pilot study were achieved. To the researcher's knowledge this is the first in depth, theoretical based exploration of the social phenomenon underpinning the provision of nutrition care by foodservice staff.

Finding 4: The staff, environment, implementation process, intervention and the patients are interrelated factors that must be considered to support changes to health professionals' behaviours and maintain a research protocol in the clinical setting

Evaluating the food and service based nutrition intervention

Together the pilot study (chapter 4) and qualitative process evaluation (chapter 5) provide complementary data that can be used to inform the future direction of the food and service based intervention. The finding that the nutrition intervention increased energy and protein intake (adjusted for weight) provided evidence that this strategy can work, however questions remain:

 What is the effect of the nutrition intervention on weight, hand grip strength (HGS) and clinical outcomes?

The pilot study was underpowered to find a difference in HGS (and likely weight and clinical outcomes). A fully powered study is required to further evaluate the effects of the food and service based intervention. The most suitable approach would be a collaborative effort between local healthcare networks to achieve the large target sample size required. A step wedged cluster design (279) or a cluster RCT involving multiple subacute wards would minimise the risk of bias while overcoming the limitations of the quasi-experimental design of the pilot study. This would require funding for research assistants to manage data collection across a number of locations. A focus must be optimising the implementation and delivery of the intervention by foodservice staff, including intensive and ongoing training. Including multiple sites would introduce variability in environmental factors (e.g. multidisciplinary care, foodservices) which may influence the effect of the intervention and this would need to be accounted for in analyses. 2. Would the food and service based nutrition intervention be successful outside the context of a research study?

The responses of the foodservice staff largely indicated that they perceived the intervention was unfeasible and unsustainable in its current form, in the current setting. Adaptations, including those outlined in chapter 5, would be required to improve fidelity and sustainability for the nutrition intervention to be adopted into current foodservice operations.

3. Is a more targeted approach to the provision of the food and service based nutrition intervention preferable?

The appeal of the food and service based nutrition intervention was that it was available to all patients regardless of nutritional status at admission, and independent of dietetic intervention. However, due to the heterogeneity of the subacute population, participants' response to the nutrition intervention evaluated in the pilot study was highly variable. It is possible that a graded version of the nutrition intervention provided to patients 'in need' may produce less variable results and be a more efficient use of resources. The challenge then, would be to determine who the intervention should target and how they should be identified.

Research question	Key findings	
How does patients'	 Change in nutritional status under usual conditions was 	
nutritional status	variable.	
change during	 Malnutrition prevalence declined and half of malnourished 	
subacute inpatient	participants' nutritional status improved.	
stay?	 Over half of participants were at risk of malnutrition at 	
(chapter 2, chapter 4)	admission and discharge.	
	 One in ten participants at risk of malnutrition or well 	
	nourished had a decline in nutritional status, which was	
	associated with discharge to a higher level of care.	
	 Dietary intake increased from admission to day 14 of inpatient 	
	stay.	
	 Methods of nutritional assessment did not identify change in 	
	nutritional status consistently.	
What is the state of the	 Few studies (n=10) have been undertaken exploring oral 	
evidence describing	nutrition interventions in the subacute setting.	
oral nutrition	 Compared to standard care, ONS and energy dense meals 	
interventions that aim	may improve energy and protein intake consistent with findings	
to increase dietary	from other settings.	
intake among patients	 The effect on anthropometry, function and nutrition related 	
in subacute care?	biochemistry of ONS and energy dense meals is unclear or	
(chapter 3)	unknown, respectively.	
What is the effect of a	 There was a variable response to the nutrition intervention. 	
novel oral nutrition	 Dietary intake (adjusted for weight) was higher among both 	
intervention to improve	malnourished and well nourished patients receiving the	
dietary intake of	intervention compared to the control condition.	
patients in subacute	 There was no benefit in HGS, weight or clinical outcomes 	
care on patient-related	compared to standard care, however the pilot was	
outcomes and cost?	underpowered to find a difference in these outcomes.	
(chapter 4)	 A financial and time cost were incurred by Foodservice. 	

Table 6:1 Summary of the research questions addressed and the key findings of the thesis

What are the	•	Foodservice staff perceived the nutrition intervention to be a
experiences of		valuable strategy with worthwhile aims to evaluate.
healthcare staff	-	Organisational (i.e. external) and personal (i.e. internal) factors
involved in the		challenged foodservice staff's ability to deliver the nutrition
implementation of the		intervention, affecting their perception of its feasibility.
novel oral nutrition	-	Foodservice staff had the capacity to contribute positively to
intervention in		enhanced nutrition care and nutrition research.
subacute care?		
(chapter 5)		

ONS, oral nutritional supplements; HGS, hand grip strength

6.2 Implications for practice, policy and research

The implications described below are relevant to the practice of healthcare professionals in subacute care, policies instigated by healthcare organisations and clinical nutrition researchers. In the longer term, as further research is undertaken considering malnutrition in subacute care, these findings presented in this thesis will contribute to evidence for translation to clinical practice, to improve and support the nutritional status of patients and ultimately, their health, quality of life and the utility of the healthcare system.

6.2.1 Implications for monitoring subacute patients' nutrition status

Include new objective indicators of nutritional status in the dietitian's toolbox

HGS and bioelectrical impedance analysis (BIA) to derive fat free mass (FFM) (in particular populations) are valuable additions to the clinicians' toolbox. These are objective and reliable measures of nutritional status (or change in nutritional status) obtained easily at the bedside with limited ongoing expense. Both were completed with high participation rate in the clinical studies reported in chapters 2 and 4 indicating feasibility in practice. Anecdotally, HGS and FFM estimated from BIA are used infrequently, if ever, by clinicians in healthcare settings. There are strong calls for clinicians to utilise objective, diagnostic criteria for malnutrition and its sub-classifications including FFM and HGS, which should motivate uptake of these less familiar methods of nutrition assessment (3, 4, 7, 8). A recent review concluded that HGS measurement should be "a routine part of nutrition assessment by a registered dietitian" (92) (page 216).

In addition to being used to diagnose malnutrition, HGS can provide feedback on short term changes in muscle function and nutrition status, as it can be repeated sooner than anthropometry or nutrition assessment tools (55, 56). The use of BIA may also allow changes in body composition to be monitored. Further research is required to determine the utility of BIA in the heterogeneous subacute population including patients where BIA is less reliable (e.g. obese or those with altered fluid status) (88, 90). There is a role for researchers to provide practical support to encourage clinicians to use HGS and BIA in practice, for example advising on evidence based measurement protocols or predictive equations.

Identify meaningful, responsive tools or measurements to capture change in nutritional status during subacute inpatient stay

While the use of objective indicators and nutrition assessment tools for evaluating nutrition status at a single point in time has been well established, the best method to assess change in nutritional status over time is unclear. Chapter 2 identified disconnect between repeated measures of objective and subjective outcome measures. There is opportunity for future research to explore the responsiveness of nutrition assessment tools (e.g. full Mini Nutritional Assessment (MNA®), MNA®, Subjective Global Assessment, Scored Patient Generated Subjective Global Assessment) and objective nutritional indices (e.g. HGS, FFM derived from BIA). Identifying suitable methods to capture change in nutritional status is necessary so this can be undertaken by researchers and clinicians with accuracy and validity. Importantly, it is necessary to understand what change is real (i.e. not due to error or confounding factors) and meaningful (i.e. minimal clinically important difference).

Strengthen processes for identifying nutritional decline during subacute inpatient stay

Greater attention needs to be given to monitoring the nutritional status of all patients, regardless of nutritional status, during subacute inpatient stay. The findings of chapter 2 and other studies (174, 176, 177) suggest that nutritional decline is associated with worse outcomes for patients and increased costs incurred by healthcare. Identifying nutritional decline relies on the active processes of monitoring and re-evaluating nutritional status. According to Figure 6:1 this should be undertaken by dietitians as part of the NCP (18) and by members of the multi-disciplinary team as part of ward based nutrition care.

Usual care practices may be overlooking patients experiencing nutritional decline. Repeating malnutrition screening weekly and monitoring weight frequently throughout inpatient stay are recommended (4, 12, 72). Yet, recent data from a large sample of Australian and New Zealand acute hospitals indicate that in practice, rescreening and regular weighing of patients after admission occur infrequently (280). Additionally, not all malnourished or at risk patients who were seen by the dietitian received dietetic review during inpatient stay (chapter 2). Weekly re-screening and re-weighing of all subacute patients as per existing guidelines is recommended. Priority should be given to cognitively impaired patients who are less likely to experience improvement in nutritional status (chapter 2). Identifying additional patient factors (e.g. sub-classification of nutritional status, section 6.2.3) that are predictive of trajectories of nutritional change will assist to develop priority criteria for monitoring of nutritional status. Re-screening and re-weighing should be undertaken by nursing staff or allied health assistants as they are responsible for these processes on admission and familiar with protocols. Importantly, if malnutrition risk or weight loss are identified throughout inpatient stay, patients should be referred to the dietitian for further assessment (Figure 6:1).

6.2.2 Implications for the foodservice system and workforce

Utilise the foodservice workforce to provide nutrition care to patients

While a multidisciplinary approach to nutrition care is advocated, the potential impact that the foodservice workforce can have on patients' nutrition does not appear to have been recognised. A recent call to action for multidisciplinary nutrition care did not recognise foodservice staff as key stakeholders (104). The majority of hospital foodservice operations in Australia use foodservice staff to deliver meals to patients (113), which puts foodservice staff in a unique dual position in the kitchen and at the bedside. There appears to be an opportunity to upskill and empower foodservice staff to capitalise on the contribution they can make to patients' nutrition care. The dedicated qualitative inquiry into foodservice staff's experience undertaking nutrition care processes had positive findings, suggesting this workforce recognise and appreciate their role as purveyors of nutrition care for patients.

Dietitians, as experts in nutrition, are recommended to "serve as primary authority on all things nutrition" (104) (page 488). This includes creating learning opportunities for the multidisciplinary care team, including foodservice staff. There is a need for dietitians to provide regular, accessible training to foodservice staff on the topics of food and nutrition. Lack of nutrition-related knowledge of foodservice staff, and poor insight into this, were clearly identified in chapter 5. Observation of and consultation with foodservice staff are recommended to identify areas for improvement in knowledge and skills. In large organisations training sessions may need to be

repeated and delivered via alternate mediums (i.e. face to face and online) to capture all staff.

There may also be potential to extend the duties of foodservice staff to include additional nutrition care tasks at the bedside (e.g. provide encouragement or assistance with menu selection, monitor meal intake). Clear role boundaries and further education would be required to ensure the competence of this largely unskilled workforce. Mandating training, formally evaluating learning or setting minimum qualifications for foodservice staff may be potential solutions.

Elevate the role of hospital foodservice

Healthcare management, clinicians and patients need to give due credit to the impact hospital food (and the foodservice system more broadly) can have on patients' nutritional status, satisfaction with the hospital experience and quality of life. This is particularly important in subacute care where the longer length of stay, relative to acute care, gives patients greater exposure to foodservice. Undoubtedly, a range of nutrition interventions (e.g. dietetic counselling, ONS, clinical care process and enhanced eating environments) are required to suit patients' needs and preferences. It is, however, contended that foodservice forms the back bone to supporting the nutritional status of patients.

Improving the image and function of hospital foodservice has been a priority for many decades (106). In Australia and Britain, there has been a commendable effort to elevate the nutritional quality of hospital meals and menus through the introduction of standards that encourage healthcare services to take a patient-focussed approach to foodservice (108-111). There is a role for policy and governance at a local level within healthcare organisations to demonstrate a formal commitment to provide and invest in excellent food and service for patients. It is recommended that healthcare organisations have a policy outlining the organisation's vision of the contribution that foodservice will make to patients' nutrition care and specific objectives on how this will be achieved. A committee representing key stakeholders (i.e. management, foodservice, dietetics, nursing, consumers and finance etc.) dedicated to reviewing foodservice performance and direction is also recommended. Securing and maintaining budgets, workforces and foodservice systems that have the capacity and flexibility to deliver on relevant standards and policies are important responsibilities now, and will remain so in the future.

Further studies that focus on the effect of food, service or both in combination, on a range of outcomes relevant to the patient and the health service are required. In particular, functional, anthropometric, clinical and cost outcomes must be included to fill the gap in the literature. Foodservice systems and operations evolve over time. Developing a strong evidence base for the nutritional, clinical and cost implications will help foodservice and hospital managers to make decisions regarding changes.

6.2.3 Malnutrition in Subacute care – future considerations

Cachexia, sarcopenia and starvation: Delineated approaches to malnutrition?

Previously in this thesis the sub-classifications of malnutrition were introduced (chapter 1) and the relationship between inflammation and change in nutritional status under usual conditions (chapter 2) or in response to nutrition intervention (chapter 4) were considered. The recognition of the contribution and effects of disease-related inflammation has changed the recommendations for identification and treatment of malnutrition. Distinguishing between acute or chronic disease related malnutrition (inflammation present), and starvation malnutrition (inflammation not present) is now advocated for the diagnosis of malnutrition (4). Alternate physical and pharmacological therapies have been proposed instead of traditional higher energy diets for sarcopenia (e.g. resistance exercise) and cachexia (e.g. steroids, hormonal agents) (9).

It is anticipated that ongoing developments will occur in this space, with relevance to how malnutrition is identified, documented and treated in subacute care in the future. Dietetic practice currently lags behind recommendations, with poor understanding and use of terminology and appropriate treatment strategies reported among Australian dietitians (11). Translational research is required to support the dietetic profession to make practice changes. Further research is also required to establish universal definitions (7, 281), develop screening tools (282) and data collection protocols (4) for accurate identification and documentation of starvation, sarcopenia and cachexia. There is a need to confirm the role a concomitant high energy diet

plays alongside non-dietary treatment options and to update existing guidelines for the management of malnutrition (72, 83).

Is it worth it? Focussing on the cost of nutrition interventions

Throughout this thesis the cost implications of malnutrition and decline in nutritional status have been acknowledged. Any intervention to address malnutrition comes at a cost, and it is necessary that this cost is outweighed by the financial benefits of the intervention (i.e. cost effective). Public healthcare funding is tenuous therefore consideration of the cost, cost effectiveness and cost benefit of nutrition interventions is imperative as it enables clinicians, managers and policymakers to determine if it is 'worth it'. Cost analyses are rarely undertaken in studies of nutrition interventions to address malnutrition in healthcare (283). There is an opportunity for further research focussing on economic considerations. At minimum, future studies should report the costs (including labour cost) associated with nutrition interventions.

6.3 Conclusion

"The very first requirement in a hospital is that it should do the sick no harm."

Florence Nightingale, 1860 (1) (page 63)

Through nutrition care and dietetic intervention, healthcare facilities can support patients' nutritional status to improve their hospital experience, health and quality of life and in turn minimise healthcare costs. It is worth investing in further clinical and translational research to extend understanding of malnutrition in subacute care and effective ways to address this issue.

Chapter 7

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Chapter 8

Appendices

Appendix 1

Compilation of nutritional outcomes reported in studies of food-based nutrition interventions

	Setting	Intervention	Outcomes	Control	Outcomes	Comparison between groups
1.	Rehabilitation	Mid-meal snacks	Mid-meals: 1198	ONS between	ONS: 1265 kJ/day,	Significantly less daily energy and
			kJ/day, 9 g	meals	11 g protein/day	protein among intervention
			protein/day		Total: 121.0	
			Total: 103.3 kJ/day,		kJ/day, 1.29 g	
			1.03 g protein/day		protein/day	
2.	Paediatric	Mid-meal snacks	84% consumed	Unclear, ?	50% consumed	No statistical comparison
	hospital		snacks received	standard mid-	snacks received	
				meals		
3.	Nursing	Mid-meal snacks	Mid-meals: 1277	Unclear, ?	Mid-meals: 307	No change in daily energy intake
	home		kJ/day	standard mid-	kJ/day	within the intervention or control
			Total: 5372 kJ/day	meals	Total: 4612 kJ/day	group
4.	Oncology	Hot breakfast	6165 kJ/day, 68 g	Continental	5416 kJ/day, 54 g	No difference in daily energy or
	(onc) and		protein/day (onc);	breakfast	protein/day (onc);	protein intake, no difference in
	obstetrics		8071 kJ/day, 96 g		8328 kJ/day, 93 g	energy at breakfast. Higher
	(obst)		protein/day (obst)		protein/day (obst)	protein intake with intervention
						among obs group
5.	Rehabilitation	Hot breakfast	7324 kJ/day, 57.4 g	Continental	5985 kJ/day, 47.4	Significantly higher energy and
			protein/day	breakfast	g protein/day	protein intake with intervention

5.	Rehabilitation	Reduced portion,	7186 kJ/day, 48.7	Standard meals	5985 kJ/day, 47.4	Significantly higher energy intake
		fortified meals	g protein/day		g protein/day	with intervention. No difference in
						protein intake
6.	Rehabilitation	Reduced portion,	10760 kJ/day, 90 g	Standard meals	7829 kJ/day, 73 g	Significantly higher energy and
		fortified meals	protein/day		protein/day	protein intake with intervention
7.	Long stay	Fortified meals,	7665 kJ/day	Standard meals	5657 kJ/day	Significantly higher energy intake
	facility	high energy snacks		and snacks		with intervention. Decrease in
						energy intake from snacks (no
						data)
8.	Acute hospital	Fortified meals,	6930 kJ/day, 55.4	Standard meals	5897 kJ/day, 51.2	Significantly higher energy intake
		high energy snacks	g protein/day	and no snacks	g protein/day	with intervention. No difference in
						protein intake
9.	Nursing home	Fortified breakfast	no data	Standard meals	no data	Significantly higher energy intake
		and lunch				among big and small eaters with
						the intervention. No difference in
						protein intake
10.	Nursing home	Fortified meals,	7009 kJ/day, 74.3	Standard meals	7484 kJ/day, 62.6	No difference in energy intake.
	(malnourished/	high energy snacks	g protein/day	and no snacks	g protein/day	Significantly higher protein intake
	nutrition risk)					with intervention
11.	Nursing home	Fortified meals	7728 kJ/day, 57.9	Standard meals	6035 kJ/day, 54.7	Significantly higher energy intake
			g protein/day		g protein/day	with intervention. No difference in
						protein intake

Appendix 1

12.	Nursing home	Fortified meals	no data	Standard meals	no data	No significant difference in
	(underweight)					change in energy or protein intake

ONS, oral nutritritional supplements

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Appendix 2 Mini Nutritional Assessment MNA®

Nestlé Nutrition[nstitute

Last name:		First name:		
Sex:	Age:	Weight, kg:	Height, cm:	Date:

Complete the screen by filling in the boxes with the appropriate numbers.

Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening	J How many full meals does the patient eat daily? 0 = 1 meal
A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?	1 = 2 meals 2 = 3 meals
0 = severe decrease in food intake 1 = moderate decrease in food intake 2 = no decrease in food intake	 K Selected consumption markers for protein intake At least one serving of dairy products (milk, cheese, yoghurt) per day yes □ no □ Two or more servings of legumes
B Weight loss during the last 3 months 0 = weight loss greater than 3kg (6.6lbs) 1 = does not know 2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs) 3 = no weight loss	• Two of more servings of regulates yes $\ $ no $\ $ • Meat, fish or poultry every day yes $\ $ no $\ $ • 0.0 = if 0 or 1 yes 0.5 = if 2 yes 1.0 = if 3 yes
C Mobility 0 = bed or chair bound	L Consumes two or more servings of fruit or vegetables per day? 0 = no 1 = yes
1 = able to get out of bed / chair but does not go out 2 = goes out	M How much fluid (water, juice, coffee, tea, milk) is
D Has suffered psychological stress or acute disease in the past 3 months? 0 = yes 2 = no	consumed per day? $0.0 = less$ than 3 cups $0.5 = 3$ to 5 cups $1.0 = more$ than 5 cups
E Neuropsychological problems 0 = severe dementia or depression 1 = mild dementia 2 = no psychological problems	N Mode of feeding 0 = unable to eat without assistance 1 = self-fed with some difficulty 2 = self-fed without any problem
 F Body Mass Index (BMI) = weight in kg / (height in m)² 0 = BMI less than 19 1 = BMI 19 to less than 21 2 = BMI 21 to less than 23 3 = BMI 23 or greater 	O Self view of nutritional status 0 = views self as being malnourished 1 = is uncertain of nutritional state 2 = views self as having no nutritional problem
Screening score (subtotal max. 14 points) Image: Constraint of the status 12-14 points: Normal nutritional status 8-11 points: At risk of malnutrition 0-7 points: Malnourished For a more in-depth assessment, continue with questions G-R	 P In comparison with other people of the same age, how does the patient consider his / her health status? 0.0 = not as good 0.5 = does not know 1.0 = as good 2.0 = better
Assessment	Q Mid-arm circumference (MAC) in cm 0.0 = MAC less than 21 0.5 = MAC 21 to 22
G Lives independently (not in nursing home or hospital)	1.0 = MAC greater than 22
1 = yes 0 = no	R Calf circumference (CC) in cm
H Takes more than 3 prescription drugs per day 0 = yes 1 = no	0 = CC less than 31 1 = CC 31 or greater
I Pressure sores or skin ulcers	Assessment (max. 16 points)
0 = yes $1 = no$	Screening score
	Total Assessment (max. 30 points)
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Nutritional Assessment (MNA-SF). J. Geront. 2001; 56A : M366-377 3. Guigoz Y. The Mini-Nutritional Assessment (MNA [®]) Review of the Literature - What	17 to 23.5 points At risk of malnutrition Less than 17 points Malnourished

Guigoz Y. The Mini-Nutritional Assessment (MNA[®]) Review of the Literature - What does it tell us? *J Nutr Health Aging*. 2006; **10**:466-487.
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For more information: www.mna-elderly.com



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Human Research Ethics Committee - Scientific and Ethical Review

Ethical Approval – Granted

Commencement of Research at Eastern Health has been authorised

27 September 2012

Dr Judi Porter Dietetics Manager, Peter James Centre/ Wantirna Health/Angliss Hospital Eastern Health Eastern Health Research and Ethics Committee Ph: 03 9895 3398 Fax: 03 9094 9610 Email: ethics@easternhealth.org.au Website: www.easternhealth.org.au/ethics

Dear Dr Porter

E08/1213 Mapping nutritional status of patients admitted to subacute care

Principal Investigator: Dr Judi Porter

<u>Associate Investigator/s</u>: Prof Helen Truby, Dr Catherine Huggins, Ms Jorja Collins (student researcher)

Other Approved Personnel: Nil

Eastern Health Site/s: Peter James Centre: east, west and centre wards (subacute and rehabilitation units)

The above study was considered by the Eastern Health Research and Ethics Committee at its meeting on 16 August 2012.

<u>Approval Period</u>: On-going - subject to a satisfactory progress report being submitted annually.

The above study was considered by the Eastern Health Research and Ethics Committee at its meeting on 16 August 2012 and was approved subject to amendments and clarifications. Following receipt of amended documents and additional information (received on 4 September 2012), **final approval** can now be given for the study to proceed.

List of documents approved:

- Modules 1 revised sections 1.12 and 1.13.
- Victorian Specific Module
- Participant Information and Consent Form version 1 dated 14 June 2012

N:\02-03¤t\Ethics - Eastern Health\All Correspondence\1213 studies\E08-1213\E08-1213 Correspondence from EH\E08-1213 Final Approval 27 September 2012.docx Page 1 of 3

Angliss Hospital	Box Hill Hospital	Healesville & District	Maroondah Hospital	Peter James Centre	Wantirna Health	Yarra Ranges Health	Yarra Valley

Members of Fastern Health

Appendix 3a



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- Nestle Mini Nutritional Assessment MNA[®]
- Flyer 'Nutrition research at PJC'

Additionally the following documents have been submitted:

• Confidentiality agreement signed by Ms Jorja Collins

Reporting Requirements:

Please note, **an annual progress report is due <u>September</u> 2013** – continuing approval is subject to the timely submission of a satisfactory progress report. Progress report template can be downloaded from our web-page: <u>http://www.easternhealth.org.au/research/ethics/progressreports.aspx</u>

Please ensure you notify the Ethics Committee of all personnel changes and any serious adverse events that may affect study conduct. Any changes to the approved Protocol or other approved documents must be submitted for ethical review and approval <u>prior to use</u>.

Eastern Health Research and Ethics Committee

The Eastern Health Research and Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council Guidelines (National Statement on Ethical Conduct in Human Research 2007). No member of the Committee adjudicates on research in which that member has any conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.

Please refer to the National Statement on Ethical Conduct in Human Research (2007) <u>http://www.nhmrc.gov.au/publications/synopses/e35syn.htm</u> and Module 1.38 for researchers' obligations. **Continuing approval is subject to the adherence of these** guidelines and the fulfilment of researchers' obligations.

Please quote our reference number E08/1213 in all future correspondence.



N:\02-03¤t\Ethics - Eastern Health\All Correspondence\1213 studies\E08-1213\E08-1213 Correspondence from EH\E08-1213 Final Approval 27 September 2012.docx Page 2 of 3

				Eastern Health	Members of			- age 2 or o
	Yarra Valley	Yarra Ranges Health	Wantirna Health	Peter James Centre	Maroondah Hospital	Healesville & District	Box Hill Hospital	Angliss Hospital
1	Yarra Valley	Yarra Ranges Health	Wantirna Health	Peter James Centre	Maroondah Hospital	Healesville & District	Box Hill Hospital	Angliss Hospital



Monash University Human Research Ethics Committee (MUHREC) Research Office

Human Ethics Certificate of Approval

Date:	4 October 2012	
Project Number:	CF12/2630 - 2012001428	
Project Title:	Mapping the nutritional statu	s of patients admitted to subacute care
Chief Investigator:	Dr Judi Porter	
Approved:	From: 4 October 2012	To: 4 October 2017

Terms of approval

- 1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.
- Approval is only valid whilst you hold a position at Monash University.
 It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
- You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
- 5. **Complaints:** The researchers are required to inform MUHREC promptly of any complaints made about the project, whether the complaint was made directly to a member of the research team or to the primary HREC.
- 6. Amendments to the approved project (including changes in personnel): Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
- 7. Future correspondence: Please quote the project number and project title above in any further correspondence.
- 8. Annual reports: Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
- 9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
- 10. Monitoring: Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
- 11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny Chair, MUHREC

cc: Prof Helen Truby, Dr Catherine Huggins, Ms Jorja Collins

Postal – Monash University, Vic 3800, Australia Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton

www.monash.edu/research/ethics/human/index/html ABN 12 377 614 012 CRICOS Provider #00008C Formula for relative risk calculation

 $RR = A/(A+B) \div C/(C+D)$

		Outcom	е	
		Yes	No	Total
Exposure	Yes	А	В	A+B
	No	С	D	C+D
	Total	A+C	B+D	A+B+C+D

95% CI of RR = $log_e(RR) \pm (1.96 \times SE log_e(RR))$

Where: SE $\log_e(RR) = \sqrt{(1/A) + (1/C) - (1/A+B) - (1/C+D)}$

Then take the exponential of 95% CI limits

<u>Calculation of relative risk of inpatient mortality during readmissions one year</u> <u>following discharge from subacute care associated with change in nutritional status</u>

		Inpatient mor follow up (out		
		Yes	No	Total
Improvement in full MNA®	Yes	2 (A)	21 (B)	23 (A+B)
classification (exposure)	No	11 (C)	43 (D)	54 (C+D)
	Total	13 (A+C)	64 (B+D)	77 (A+B+C+D)

RR = (2/23) ÷ (11/54) = 0.4269

 $log_{e}(RR) = -0.8512$

SE $\log_{e}(RR) = \sqrt{(1/2) + (1/11) - (1/23) - (1/54)} = 0.7273$

LL 95% CI = $-0.8512 - (1.96 \times 0.7273) = -2.277 = e^{-2.277} = 0.1026$

UL 95% CI = $-0.8512 + (1.96 \times 0.7273) = 0.574 = e^{0.574} = 1.775$

RR, relative risk; 95% CI, 95% confidence interval; log_e, natural logarithm; SE, standard error

Hackshaw A. Statistical formulae for calculating some 95% confidence intervals. A Concise Guide to Clinical Trials [internet]. Oxford, UK: Wiley-Blackwell; 2009 [cited 2015 Mar 1]. Available from: http://onlinelibrary.wiley.com/book/10.1002/9781444311723 DOI: 10.1002/9781444311723

Albumin at admission and discharge from subacute care (n=13)

	Admission	Discharge	p value
Albumin (g/L), median (IQR)	33.0 (23.0 – 34.5)	30.0 (25.5 – 35.0)	0.581

Data analysed using Wilcoxon Signed Rank test

Linear regression model (Model 1a) of admission characteristics predictive of a change in full MNA® score during subacute inpatient stay (n=210)

Variable	В	Standard	Beta	p value
		Error		
Age (years)	-0.037	0.020	-0.135	0.066
Gender (female=1)	0.521	0.457	0.080	0.256
Impaired cognition (yes=1)	-0.566	0.555	-0.076	0.309
FIM score admission	-0.009	0.013	-0.055	0.483
LOS acute admission (days)	-0.007	0.020	-0.027	0.707
Admissions in previous 12 months (n)	0.145	0.154	0.067	0.346

Full MNA®, 18 item Mini Nutritional Assessment; FIM, Functional Independence Measure; LOS, length of stay

Standard error of the estimate=3.15; R^2 =0.032



Journal of Human Nutrition and Dietetics

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CLINICAL NUTRITION

The effect of interventions to prevent and treat malnutrition in patients admitted for rehabilitation: a systematic review with meta-analysis

J. Collins¹ & J. Porter^{1,2}

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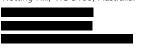
Keywords

dietary intervention, food service, malnutrition, oral nutritional supplements, rehabilitation.

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doi: 10.1111/jhn.12230

Abstract

Background: Malnutrition occurs frequently among patients in rehabilitation, leading to poorer outcomes. Evidence of the effects of interventions to prevent or treat malnutrition is required to guide clinical practice in this setting. This systematic review aimed to determine the effect of oral nutrition interventions implemented in rehabilitation on nutritional and functional outcomes.

Methods: Five databases were searched to identify relevant publications; intervention trials of oral nutrition interventions (such as oral nutrition supplements, foodservice interventions, clinical care processes, enhanced eating environments) conducted with patients admitted for rehabilitation, reporting dietary intake, anthropometric, biochemical or functional outcomes. The reviewers determined study eligibility and assessed the included studies for risk of bias. Outcome data were combined narratively and by meta-analyses.

Results: From 1765 publications, 10 studies trialling oral nutrition supplements, foodservice interventions and clinical care processes (of neutral or positive quality) were identified. Compared to meals alone, oral nutritional supplements significantly improved energy and protein intake, with some evidence for improvements in anthropometry and length of stay. There was little evidence that speciality supplements were beneficial compared to standard versions. Meta-analyses demonstrated significantly greater energy [weighted mean difference (WMD) = 324 kcal, 212–436 kcal 95% confidence interval (CI)] and protein (WMD = 9.1 g, 0.2–17.9 g 95% CI) intake with energy dense meals. Opposing results were reported in studies investigating enhanced clinical care processes.

Conclusions: The provision of oral nutrition supplements and energy dense meals improved energy and protein intake and therefore may comprise effective strategies for addressing malnutrition in rehabilitation. The effect of these strategies on other nutritional and functional outcomes should be explored further.

Introduction

Malnutrition research has largely focussed on acute hospitals and, more recently, on residential aged care facilities, with little attention given to the rehabilitation setting despite growing demand for this type of health care. Rehabilitation 'is care in which the primary clinical purpose or treatment goal is improvement in the functioning of a patient with an impairment, activity limitation or participation restriction due to a health condition'

Oral nutrition interventions in rehabilitation

(AIHW, 2013). Data from the UK and Australia indicate that admissions to rehabilitation facilities increased by over 20% between 2007/2008 to 2011/2012 and 2006/2007 to 2010/2011, respectively (HSCIC, 2009; HSCIC, 2012; AIHW, 2013).

A recent review found that malnourished patients have worse function and quality of life following discharge from rehabilitation to the community, and are more likely to be discharged to higher level care or an acute hospital (Marshall *et al.*, 2014). Malnutrition among rehabilitation patients is also associated with longer length of stay and inpatient mortality (Compan *et al.*, 1999; Charlton *et al.*, 2012). As a result of its adverse effects, interventions that are clinically, nutritionally and cost effective are required to prevent and treat malnutrition.

A range of interventions to prevent and treat malnutrition exist. Strategies that promote adequate intake of nutrition via an oral route include oral nutritional supplements (ONS), foodservice interventions, clinical care processes and an enhanced eating environment. Oral nutritional supplements are whole protein enteral products, usually in drink or pudding form, specifically designed for clinical use to manage malnutrition (Baldwin & Weekes, 2011). Foodservice interventions are based on manipulation to the food production, preparation, selection or provision system. Clinical care processes are systems or policies implemented by clinicians, or to support clinicians, with the aim of identifying, preventing, treating or monitoring malnutrition and its risk factors, and may be considered under the scope of 'nutritional care' defined by Weekes et al. (2009). Enhanced eating environments can be considered as settings that have been modified to make the eating experience more enjoyable.

Malnutrition guidelines report no evidence underpinning the efficacy of many interventions implemented in rehabilitation because of a lack of studies in this setting (Watterson *et al.*, 2009). The findings of nutrition research conducted in the hospital environment with J. Collins and J. Porter

acutely unwell patients or in aged care settings with residents with functional or psychological deficits may be translatable to rehabilitation patients but should be confirmed through evaluative studies specifically recruiting these patients. As such, currently, there is a lack of evidence on which to base nutrition-related clinical care and multidisciplinary practice within the rehabilitation setting.

The present review examined the evidence to determine whether oral nutrition interventions that aim to enhance dietary intake improve nutritional and functional outcomes in patients admitted for rehabilitation compared to alternate interventions or standard/usual care.

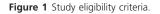
Methods

This review was registered on the Prospero international prospective register of systematic reviews (CRD42013003937 http://www.crd.york.ac.uk/PROSPERO/).

Eligibility criteria

Criteria for study inclusion were developed using the Participant - Intervention - Comparator - Outcomes -Study design (PICOS) format (Fig. 1) (Liberati et al., 2009). Studies conducted with adult inpatients in rehabilitation, Geriatric Evaluation Medicine wards or similar were considered. Research conducted in residential aged care facilities, acute hospital wards, mental health facilities or drug and alcohol rehabilitation were excluded, in addition to those recruiting participants living in the community, receiving palliative care, or outpatient or ambulatory rehabilitation. Studies describing interventions initiated in the acute setting with follow-up occurring following discharge to rehabilitation were also excluded. Studies that tested an oral nutrition intervention (e.g. ONS, food service procedures, therapeutic diets, meal environment, ward support or education etc.) and compared this with an alternate intervention or standard/usual care were eligible for inclusion. Interventions designed to optimise

Population	Adults, inpatients, rehabilitation
Intervention	Oral nutrition related intervention
Comparator	Alternate intervention, standard/usual care
Outcomes	Dietary intake, anthropometry, biochemistry, nutrition assessment, function, length of stay
Study design	Intervention study, level of evidence of IV or above (based on NHMRC (2009) Additional levels of evidence and grades for recommendations for developers of guidelines)



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nutritional status via enteral or parenteral nutrition, vitamin and mineral supplements, chemical additives (e.g. monosodium glutamate) or medications (e.g. steroids to stimulate appetite) were not considered because the focus was on oral nutrition approaches to preventing or treating malnutrition. Similarly, multifactorial interventions with only a single component relating to nutrition were also excluded.

The primary outcome measures were dietary intake (energy intake, protein intake), anthropometry [weight, body mass index (BMI), fat free mass (FFM), triceps skin fold, mid arm circumference (MAC), mid arm muscle circumference (MAMC)], nutrition-related biochemistry (albumin, prealbumin) or structured nutritional assessment score or classification (e.g. Subjective Global Assessment, Mini Nutritional Assessment). The secondary outcomes were function, including measures capturing the need for assistance, physical capacity or strength [e.g. functional independence measure (FIM), Barthel Index, lung function test, 6-min walk test, grip strength] and length of stay (LOS). Outcomes measured during the rehabilitation inpatient stay only were considered. Studies with a level of evidence of II [randomised controlled trials (RCT)], III-1 (pseudo RCT), III-2 (comparative study with concurrent controls), III-3 (comparative study with nonconcurrent controls) or IV (case series) were eligible to be included [National Health and Medical Research Council (NHMRC), 2009]. These levels of evidence rank the strength of the evidence based on the study design and its appropriateness in addressing the research question, ranging from level I (strongest) to IV (weakest). Observational studies and cross-sectional studies were excluded because no intervention was tested. Publications in a language other than English were ineligible.

Search strategy

Ovid Medline (from 1946), PsycINFO (from 1806), CINAHL (from 1937), Embase (from 1947) and the Cochrane Central Register of Controlled Trials (from 1991) were searched in March 2013 to identify relevant publications. Reference lists of included publications and review articles related to nutrition interventions retrieved from the database search were hand searched to identify additional studies for inclusion (Akner & Cederholm, 2001; Cederholm, 2002; Milne *et al.*, 2009; Avenell & Handoll, 2010).

The search terms were determined through exploration of key words used in the relevant literature and refined after consultation with a librarian with health science expertise. The subject heading and phrases were searched to ensure maximum retrievals. Details of the search strategy are available as online supporting information.

Study selection

Studies were selected using a process of identification, screening and eligibility assessment recommended in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Liberati et al., 2009). After removing the duplicates, two authors independently screened titles and abstracts to exclude those not meeting the inclusion criteria, and then reviewed full texts of the remaining publications to identify the studies to be included in the review. Conflicting opinions were resolved through consensus. Because there were a range of terms used internationally to describe non-acute care facilities (e.g. continuing care, long-term geriatric care, geriatric rehabilitation, subacute care), the authors referred to the description of the patient group, including the average LOS, functional and clinical status, treatment provided and researchers' affiliations, to determine whether the study was conducted in an eligible setting.

Data extraction and assessment

A standard template was used to collate data relating to study method (e.g. level of evidence, intervention), results (e.g. outcome, clinical relevance), internal validity (e.g. randomisation, compliance) and external validity (e.g. generalisability, applicability). Both authors independently rated study quality using the Quality Criteria Checklist for Primary Research and came to consensus through discussion to assign a rating of negative (weak quality; does not adequately address inclusion/exclusion, bias, generalisability, data collection and analysis), neutral (neither exceptionally strong nor exceptionally weak quality) or positive (strong quality; adequately addresses inclusion/ exclusion, bias, generalisability, data collection and analysis) (ADA, 2010). A negative rating was assigned if six or more validity items were not adequately addressed and a positive rating was provided if validity items two, three, six, seven and one other were adequately addressed (Table 1) (ADA, 2010). This tool includes criteria that are associated with decreased bias and improved validity in primary research and is specific for studies in the field of nutrition and dietetics.

Analysis

Eligible studies were grouped according to the type of intervention and results were described narratively, with a greater emphasis placed on findings from studies achieving high-quality ratings. The mean and standard deviation (SD) or standard error of the mean (SEM) were reported for energy and protein intake in each group (or before and after for case series). The change in mean and

Oral nutrition interventions in rehabilitation

SD (or SEM) were reported for other outcomes, including anthropometry, biochemistry and functional measures for each group. Units were converted to a consistent format (e.g. kcal, kg, $g L^{-1}$). Data were determined from graphs or sought from authors when necessary. Metaanalyses were undertaken using STATA, version 11 (Stata-Corp, College Station, TX, USA) where there were at least three studies testing the same type of intervention and reporting the same outcome. The unstandardised weighted mean difference (WMD) and 95% confidence interval (95% CI) between groups was calculated using a random effects model. This model was selected a priori because independent studies were assumed not to be functionally equivalent as a result of different protocols and participant groups, and therefore lacking a common effect size. The I^2 statistic was calculated to indicate heterogeneity between studies, with 25%, 50% and 75% classified as low, medium and high variance, respectively (Higgins et al., 2003).

Results

Ten studies out of 1468 retrieved publications fulfilled the inclusion criteria for the present review (Fig. 2). Eight studies were identified from the database search, one study was identified via hand searching references lists of reviews, and one study known to the authors was also included. No additional relevant studies were located from the reference lists of included publications. The majority of studies were excluded at the final stage because the study population was recruited from an ineligible setting. One study with a multi-arm design was referred to as the 'sub-study' and considered separately in the analyses (Barton *et al.*, 2000). One study recorded

outcomes at two time points that have also been considered separately (Hankey *et al.*, 1993).

The included studies were conducted with elderly patients with a mean age ranging from 65 to 83 years with nonspecific and specific clinical conditions including hip fracture (Neumann *et al.*, 2004; Myint *et al.*, 2013), stroke (Rabadi *et al.*, 2008) and chronic obstructive pulmonary disease (COPD) (Creutzberg *et al.*, 2003) (Table 2). The participants in most studies were frail, malnourished or at risk of malnutrition. Studies trialled a range of interventions: ONS (n = 3), ONS with a modified nutrient content or delivery schedule (speciality ONS) (n = 3), food service interventions (n = 4) and clinical care processes (n = 2).

Study quality

A quality rating of positive, neutral or negative was assigned to all studies based on performance against set criteria (Table 1). Five studies were rated as positive, suggesting a low risk of bias (Creutzberg *et al.*, 2003; Neumann *et al.*, 2004; Poulsen *et al.*, 2007; Rabadi *et al.*, 2008; Myint *et al.*, 2013). Of these, three were RCTs and therefore conveyed both high quality and a strong level of evidence (Neumann *et al.*, 2004; Rabadi *et al.*, 2008; My-int *et al.*, 2013). The majority of the studies (six of 11) were assessed as being of neutral quality and were considered to be at risk of bias.

Outcomes

Oral nutritional supplements versus food

Three studies compared the provision of ONS plus usual meals with usual meals only as the control (Hankey *et al.*,

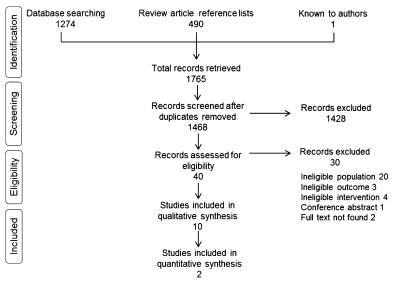


Figure 2 Study selection process.

		l evel of	Ouality	Valio	Validity items †	ns⁺								
Study	Study design	evidence*	rating [*]	-	2	Μ	4	ы	9	7	œ	6	10	Comments
Myint <i>et al.</i> (2013)	RCT	=	Positive	7	7	7	7	NA	7	7	7	7	7	Dietary intake methodology not described
Neumann <i>et al.</i> (2004)	RCT	=	Positive	7	7	7	7	7	7	7	7	×	×	Limitations not described; supported by nutrition company
Rabadi <i>et al.</i> (2008)	RCT	=	Positive	7	7	7	7	7	7	7	7	7	7	
Creutzberg <i>et al.</i> (2003)	Historical control study, case series	III-3 to IV	Positive	7	7	7	7	NA	7	7	7	7	7	Concurrent controls not used
Lorefalt et al. (2005)	Case series	≥	Positive	7	7	AN	7	AN	7	7	7	7	7	
Hankey <i>et al.</i> (1993)	RCT	=	Neutral	7	×	7	7	NA	7	7	7	7	×	Inclusion or exclusion criteria not described; funding sources not described
Barton <i>et al.</i> (2000) (main study)	Randomised cross over trial	=	Neutral	7	×	NA	×	AN	7	7	7	×	7	Inclusion or exclusion criteria not described; limitations not described
Barton <i>et al.</i> , (2000) (sub study)	Non randomised controlled study	III-2	Neutral	7	×	×	×	NA	7	7	7	×	7	Inclusion or exclusion criteria not described; comparability of groups not described; limitations not described
Campbell et al. (2013)	Non randomised controlled study with three arms	III-2	Neutral	7	7	×	7	NA	7	7	7	7	7	Groups not comparable at baseline; Concurrent controls not used
Poulsen <i>et al.</i> (2007)	Quasi experimental controlled trial	III-2	Neutral	×	7	7	7	NA	×	AA	7	7	7	Intervention not described sufficiently
Babineau <i>et al.</i> (2008)	Case series	≥	Neutral	×	7	ΝA	7	ΝA	×	7	7	7	7	Intervention not described sufficiently
National Health and Medical Research Council (NHMRC) (2009) Level [] American Dietetic Association (ADA) (2010) Evidence analysis manual. Validity items: (1) research question stated; (2) subject selection free fr (7) outcomes stated, measurements valid and reliable; (8) appropriate applicable; RCT, randomised controlled trial.	dical Research Council ation (ADA) (2010) Evi n question stated; (2) s isurements valid and ri sed controlled trial.	(NHMRC) (200 dence analysis subject selectic eliable; (8) ap	(2009) Levels of evidence and grades for recommendations for developers of guidelines. ysis manual. sction free from bias; (3) comparable study groups; (4) method for withdrawals describe appropriate statistical analysis; (9) appropriate conclusions, limitations described; (10)	f evide bias; atistica	ence a (3) cc al anal	nd gra mpara ysis; (9	des foi Ible stu	r recon udy gro	nmend sups; (4	ations (1) metl usions,	for dev nod fo limita	velope r with	rs of ç drawa descrik	*National Health and Medical Research Council (NHMRC) (2009) Levels of evidence and grades for recommendations for developers of guidelines. [†] American Dietetic Association (ADA) (2010) Evidence analysis manual. Validity items: (1) research question stated; (2) subject selection free from bias; (3) comparable study groups; (4) method for withdrawals described; (5) blinding used; (6) interventions described; (7) outcomes stated, measurements valid and reliable; (8) appropriate statistical analysis; (9) appropriate conclusions, limitations described; (10) funding and sponsorship free from bias.NA, not applicable; RCT, randomised controlled trial.

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Study	Population	Intervention	Comparator	Ancillary treatments	Sample size <i>n</i> (% retained)	Duration	Outcomes
Oral nutritional supplements	supplements						
Creutzberg et al. (2003)	Malnourished elderly with COPD. Mean age 65 years. Eligibility included malnutrition (based on BMI, FFM or BMI plus weight loss)	Standard meals plus ONS	Standard meals	8-week inpatient pulmonary rehabilitation programme	64 (l) 28 (C) Retention not reported	8 weeks (1 or C)	Energy intake; protein intake; weight; albumin; FFM; maximum inspiratory mouth pressure; 12-min walk distance
Myint et al. (2013)	Elderly patients with hip fracture. Mean age 81–82 years. Eligibility included BMI <25 kg m ⁻²	Standard meals plus ONS	Standard meals	Inpatient rehabilitation therapy; vitamin D supplement; oral calcium supplement	n = 65 (94%) (l) n = 61 (98%) (C)	Maximum 4 weeks (I or C)	Energy intake; protein intake, BMI; albumin; MAC; TSF; FIM; elderly mobility scale; handgrip strength; LOS strength; LOS
Hankey <i>et al.</i> (1993)	Frail elderly. Mean age 81 years	Standard meals plus ONS plus beverages with glucose polymer	Standard meals	None reported	n = 10 (70) (l) n = 10 (70) (C)	8 weeks (I or C)	Energy intake; protein intake; weight; albumin; MAC; AMC
peciality oral n Neumann <i>et al.</i> (2004)	Speciality oral nutritional supplements Neumann Elderly patients with hip fracture. <i>et al.</i> (2004) Mean age 83 years. Eligibility included BMI <30 kg/m ²	High protein ONS	Standard ONS	None reported	n = 22 (82) (l) n = 24 (83) (C)	Maximum 4 weeks (I or C)	Albumin; prealbumin; FIM (mobility subscale); LOS
Rabadi et al. (2008)	Elderly patients post stroke. Mean age 74–75 years Eligibility 2.5% recent loss of weight	Energy and protein dense ONS	Standard ONS	Inpatient rehabilitation therapy	n = 58 (88) (l) n = 58 (88) (C)	Entire length of stay [~3.5 weeks (l or C)]	Weight; albumin; prealbumin; FIM; 2-min walk test; 6-min walk test; LOS

Oral nutrition interventions in rehabilitation

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stuay	Population	Intervention	Comparator	Ancillary treatments	Sample size <i>n</i> (% retained)	Duration	Outcomes
Campbell et al. (2013)	Malnourished elderly patients. Mean age 80–81 years. Eligibility included malnutrition (based on SGA category B or C)	ONS delivered during medication round	ONS delivered at mid meals	Education and tailored nutritional advice about improving nutrition	n = 32 (78) (l) n = 33 (76) (C)	2 weeks (I or C)	Energy intake; protein intake; weight; albumin
Food service interventions	erventions						
Campbell et al. (2013)	Malnourished elderly patients. Mean age 76–81 years. Eligibility included malnutrition (based on SGA category B or C)	Food snacks self selected at mid meals	ONS delivered at mid meals	Education and tailored nutritional advice about improving nutrition	n = 33 (73) (l) n = 33 (76) (C)	2 weeks (I or C)	Energy intake; protein intake; weight; albumin
Durton		Cmallor moals fortified with	Ctandard moals	Nono reported	(J/I) 20 - a) wooke (1)	Enoral intolor
et al. (2000)	Mean age 75–77 years.	energy	סומותמות ווונמוס		ri = z / vc.) Retention unclear	 z weeks (i) then 2 weeks (C) then repeated until discharge or 8 weeks 	protein intake,
Barton	Heterogenous elderly,	Cooked breakfast to improve	Standard meals	None reported	n = 8 (l)	8 weeks (I)	Energy intake;
<i>et al.</i> (2000)	Mean age 75–78 years	dietary intake			n = 27 (C) Retention unclear	(C as above)	protein intake
Lorefalt	Heterogeneous elderly.	Smaller meals fortified with	Standard meals	None reported	n = 12 (83) (I/C)	3 days (I then C)	Energy intake;
<i>et al.</i> (2005)	Mean age 82 years	energy and protein					protein intake
Clinical care processes	DCesses						
Poulsen et al. (2007)	Heterogeneous elderly. Mean age 84 years	Enhanced nutrition-related nursing care	Usual nursing care	Occupational therapy for functional eating problems, as required; ONS or extra food, as required; no involvement by dietitians	345 (Total) Retention not reported	Entire length of stay (~5 weeks) (I or C)	Weight; Barthel Index; LOS

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Study	Population	Intervention	Comparator	Ancillary treatments	Sample size <i>n</i> (% retained)	Duration	Outcomes
Babineau et al. (2008)	Elderly patients at risk of malnutrition. Mean age 81 years. Eligibility included being at risk of malnutrition (based on BMI and weight loss or alburnin)	Nutritional assessment and care plan implemented by a dietitian	Standard care	Improved nutritional screening	n = 62 (VC) Retention unclear	Entire length of stay [mean length of stay not reported (I, C at baseline)]	Energy intake; protein intake; weight; albumin; prealbumin; health-related quality of life (physical functioning subscale)

AMC, arm muscle circumference; BMI, body mass index; COPD, chronic obstructive pulmonary disease; FFM, fat free mass; FIM, functional independence measure; LOS, length of stay; MAC, mid arm circumference; ONS, oral nutritional supplements; SGA, Subjective Global Assessment; TSF, triceps skin fold; 1, intervention group; C, control group J. Collins and J. Porter

1993; Creutzberg *et al.*, 2003; Myint *et al.*, 2013). Hankey *et al.* (1993) provided two supplement drinks as part of the medication round at mid-morning and mid-afternoon (652 kcal day⁻¹, protein content not reported) and a glucose polymer prepared as a drink (up to 358 kcal) as the intervention. Myint *et al.* (2013) supplied two 240-mL supplement drinks per day (500 kcal day⁻¹, 18–24 g protein day⁻¹), whereas Creutzberg *et al.* (2003) gave ONS (drinks or puddings) one to three times a day between meals (average 670 kcal day⁻¹, protein content not reported), according to patient preferences.

These studies found that the consumption of ONS led to significantly greater energy and protein intake, although this did not consistently result in improvements in anthropometric or biochemical outcomes (Table 3). There was no difference in weight or BMI change in two studies (Hankey et al., 1993; Myint et al., 2013;); however, a significant increase was demonstrated among COPD patients (Creutzberg et al., 2003). Creutzberg et al. (2003) also used bioelectrical impendence analysis to measure FFM in subjects and showed a significant increase within the supplemented group and between groups. Arm muscle circumference improved in the supplemented group in another study (Hankey et al., 1993). No studies demonstrated a significant change in albumin. Two studies reported the effect of ONS on a range of outcomes relating to function and indicated mixed results (Creutzberg et al., 2003; Myint et al., 2013). The study reporting LOS found that patients in the intervention group had a significantly lower LOS in rehabilitation (Myint et al., 2013).

Speciality oral nutritional supplements versus standard oral nutritional supplements

Three studies tested ONS that had modified nutrition formulations or delivery times. These were deemed speciality ONS for the purpose of this review because they were designed to be superior and hypothesised to offer additional benefits over standard ONS (Neumann *et al.* 2004; Rabadi *et al.* 2008; Campbell *et al.* 2013). In these studies, the intervention group received speciality ONS, whereas the control group received standard ONS, with both groups also receiving regular meals.

One study contrasted two 237-mL high protein drinks (480 kcal day⁻¹, 30 g protein day⁻¹) with standard supplements (500 kcal day⁻¹, 18 g protein day⁻¹) (Neumann *et al.*, 2004). Rabadi *et al.* (2008) provided 120 mL of ONS every 8 h, with the intervention group receiving an energy dense supplement (720 kcal day⁻¹, 33 g protein day⁻¹) and the control group receiving a standard supplement (381 kcal day⁻¹, 15 g protein day⁻¹). One arm of the Campbell *et al.* (2013) study explored a MedPass programme, a dose-feeding strategy where a high energy

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Table 3 Outcome data for studies testing oral nutritional supplements to prevent and treat malnutition in the rehabilitation setting

Outcome	Study	Intervention	Control	P value
Energy intake (kcal day ⁻¹)	Hankey <i>et al.</i> (1993)*	1741 (102)	1143 (116)	<0.01
	Myint <i>et al.</i> (2013)	1480 (208)	1127 (211)	< 0.001
	Creutzberg et al. (2003) (change)	436 (NR)	NA	< 0.001
Protein intake	Hankey <i>et al.</i> (1993) (g day ⁻¹)*	64.0 (6.2)	43.7 (4.1)	< 0.05
	Myint <i>et al.</i> (2013) (g day ⁻¹)	73.6 (10.6)	63.5 (12.3)	< 0.001
	Creutzberg <i>et al.</i> (2003) (change g kg day $^{-1}$)	0.3 (NR)	NA	< 0.001
Weight change (kg)	Hankey <i>et al.</i> (1993) (4 weeks)	2.35 (NR)	0.00 (NR)	NS
	Hankey <i>et al.</i> (1993) (8 weeks)	3.53 (NR)	-1.25 (NR)	NS
	Creutzberg et al. (2003)*	2.15 (0.27)	0.08 (0.19)	< 0.05
BMI change (kg m ⁻²)	Myint <i>et al.</i> (2013)	-0.25 (0.83)	-0.72 (0.91)	0.012
Albumin change (g L ⁻¹)	Hankey <i>et al.</i> (1993) (4 weeks)	0.9 (NR)	-0.7 (NR)	NS
	Hankey <i>et al.</i> (1993) (8 weeks)	0.2 (NR)	-1.3 (NR)	NS
	Myint <i>et al.</i> (2013)	4.28 (3.39)	3.85 (3.12)	NS
	Creutzberg et al. (2003)	0.9 (NR)	NA	NS
MAC change (cm)	Hankey <i>et al.</i> (1993) (4 weeks)	0.59 (NR)	0.00 (NR)	NS
	Hankey <i>et al.</i> (1993) (8 weeks)	0.00 (NR)	-0.62 (NR)	NS
	Myint <i>et al.</i> (2013)	-0.01 (0.99)	-0.09 (0.83)	NS
AMC change (cm)	Hankey <i>et al.</i> (1993) (4 weeks)	1.23 (NR)	-0.63 (NR)	< 0.05
	Hankey <i>et al.</i> (1993) (8 weeks)	3.12 (NR)	-0.62 (NR)	< 0.05
FFM change (kg)	Creutzberg et al. (2003)*	1.00 (0.31)	-0.85 (0.38)	< 0.05
TSF change (mm)	Hankey <i>et al.</i> (1993) (4 weeks)	0.0 (NR)	0.3 (NR)	NS
	Hankey <i>et al.</i> (1993) (8 weeks)	-0.5 (NR)	-1.2 (NR)	< 0.05
	Myint <i>et al.</i> (2013)	-0.13 (1.16)	-0.66 (1.78)	NS
FIM score change	Myint <i>et al.</i> (2013)	13.38 (7.11)	12.00 (7.91)	0.416
Elderly mobility scale	Myint <i>et al.</i> (2013)	8.63 (4.13)	8.50 (4.66)	0.763
Handgrip strength change (kg)	Myint <i>et al.</i> (2013)	-0.14 (1.61)	0.10 (1.71)	0.545
	Creutzberg et al. (2003)	1.2 (NR)	NA	0.004
Quadriceps strength change (unaffected leg) (kg)	Myint <i>et al.</i> (2013)	1.91 (1.44)	1.97 (1.61)	0.663
12-min walk distance change (m)	Creutzberg <i>et al.</i> (2003)	132 (NR)	NA	< 0.001
Maximum inspiratory mouth pressure change (cm H ₂ O)	Creutzberg <i>et al.</i> (2003)*	4.3 (1.3)	2.0 (2.2)	< 0.05
LOS (days)	Myint <i>et al.</i> (2013)	26.2 (8.2)	29.9 (11.2)	0.040

Myint *et al.*, 2013 tested significance for the change in outcomes over three time points including follow up beyond discharge from rehabilitation.

All results are reported as the mean (SD) unless when indicated by an asterisk (*) where the mean (SEM) is reported.

AMC, arm muscle circumference; BMI, body mass index; FFM, fat free mass; FIM, functional independence measure; LOS, length of stay; MAC, mid arm circumference; NA, not applicable as a result of a case series study design; NR, not reported; NS, not significant; TSF, triceps skin fold.

dense supplement (e.g. 2 kcal mL⁻¹) was distributed multiple times per day as part of the medication round. In this study, those allocated to the med-pass intervention group received 60 mL of ONS four times a day with medications (475 kcal day⁻¹, 20 g protein day⁻¹), whereas the control group received two drinks provided at mid-morning and mid-afternoon (500–570 kcal day⁻¹, 18–26 g protein day⁻¹).

Overall, the three studies investigating the effect of speciality ONS demonstrated variable effects (Table 4). Energy intake and weight gain were greater in the intervention group, although this was not a statistically significant difference (Neumann *et al.*, 2004; Campbell *et al.*, 2013). Neumann *et al.* (2004) showed significantly greater intake of protein and increase in albumin levels among those receiving high protein ONS. There were some significant improvements in functional independence and exercise performance among stroke patients receiving speciality ONS but no difference in LOS (Neumann *et al.*, 2004; Rabadi *et al.*, 2008).

Food service interventions

Three studies compared energy dense meals with standard meals. Barton *et al.* (2000) and Lorefalt *et al.* (2005) implemented smaller, fortified meals and the substudy by Barton *et al.* (2000) implemented a cooked breakfast. Comparison of up to two self-selected high energy and/or protein snacks (e.g. nuts, flavoured milk, crisps) and ONS between meals was undertaken by Campbell *et al.* (2013).

There was a significantly higher daily energy and protein intake among patients receiving energy dense

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Table 4 Outcome data for studies testing speciality oral nutritional supplements to prevent and treat malnutrition in the rehabilitation setting

Outcome	Study	Intervention	Control	P value
Energy intake	Neumann <i>et al.</i> (2004) (kcal day ⁻¹)	1437 (NR)	1261 (NR)	0.215
	Campbell <i>et al.</i> (2013) (kcal kg ⁻¹ IBW)	30.0 (7.0)	28.8 (7.7)	NS
Protein intake	Neumann <i>et al.</i> (2004) (g day ⁻¹)	62.6 (NR)	49.5 (NR)	0.048
	Campbell <i>et al.</i> (2013) (g kg ⁻¹ IBW)	1.3 (0.3)	1.3 (0.3)	NS
Weight change	Rabadi <i>et al.</i> (2008) (kg)	1.0 (3.3)	0.3 (3.8)	0.37
	Campbell <i>et al.</i> (2013) (kg %BW)	1.5 (5.8)	0.4 (3.8)	NS
Albumin change (g L^{-1})	Rabadi <i>et al.</i> (2008)	-1.7 (3.5)	-1.6 (3.7)	0.87
	Neumann <i>et al.</i> (2004)	7.0 (4.9)	2.0 (4.9)	0.019
	Campbell et al. (2013)	2.8 (2.6)	2.3 (4.2)	0.960
Pre-albumin change (mg dL^{-1})	Rabadi <i>et al.</i> (2008)	1.2 (5.7)	2.1 (6.1)	0.77
	Neumann <i>et al.</i> (2004)	5.7 (6.7)	4.1 (4.8)	0.316
FIM score change	Rabadi <i>et al.</i> (2008)	31.5 (14.3)	22.9 (11.8)	0.001
FIM (motor subscale) change	Rabadi <i>et al.</i> (2008)	24.3 (11.8)	16.7 (9.6)	0.001
	Neumann <i>et al.</i> (2004)	21.8 (NR)	20.0 (NR)	NS
2-min walk test change (feet)	Rabadi <i>et al.</i> (2008)	101.6 (79.4)	44.0 (62.5)	0.001
6-min walk test change (feet)	Rabadi <i>et al.</i> (2008)	299.3 (201.5)	170.6 (198.6)	0.001
LOS (days)	Rabadi <i>et al.</i> (2008)	26.0 (10.1)	25.5 (7.3)	0.77
	Neumann <i>et al.</i> (2004)	23.2 (1.3)	28.0 (2.6)	0.27

It was assumed that Rabadi *et al.* (2008) reported data as the mean (SD) in the units specified because this was not reported in the original publication. Values for energy and protein intake in the study by Neumann *et al.* (2004) were the average of five diet recalls including two administered post discharge from rehabilitation.

All results are reported as the mean (SD).

BW, body weight; FIM, functional independence measure; IBW, ideal body weight; LOS, length of stay; NR, not reported; NS, not significant.

Table 5 Outcome data for studies testing food service interventions to	o prevent and treat malnutrition in the rehabilitation setting
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Outcome	Study	Intervention	Control	P value
Energy intake	Barton et al. (2000) (kcal day $^{-1}$)	1711 (195)	1425 (136)	0.001
	Barton <i>et al.</i> (2000) (substudy) (kcal day ^{-1})	1744 (176)	1425 (136)	0.001
	Lorefalt <i>et al.</i> (2005) (kcal day ⁻¹)	2562 (490)	1864 (513)	0.01
	Campbell <i>et al.</i> (2013) (kcal kg ⁻¹ IBW)	24.6 (5.9)	28.8 (7.7)	< 0.05
Protein intake	Barton <i>et al.</i> (2000) (g day $^{-1}$)	48.7 (6.3)	47.4 (6.5)	NS
	Barton <i>et al.</i> (2000) (substudy) (g day ^{-1})	57.4 (6.0)	47.4 (6.5)	< 0.05
	Lorefalt <i>et al.</i> (2005) (g day ⁻¹)	90 (7.5)	72.5 (10)	<0.05
	Campbell <i>et al.</i> (2013) (g kg ⁻¹ IBW)	1.0 (0.3)	1.3 (0.3)	< 0.05
Weight change (kg %BW)	Campbell et al. (2013)	1.0 (3.1)	0.4 (3.8)	NS
Albumin change (g L ⁻¹)	Campbell et al. (2013)	1.9 (3.4)	2.3 (4.2)	0.960

All results are reported as the mean (SD).

BW, body weight; IBW, ideal body weight; NS, not significant.

compared to standard meals (Table 5). Meta-analyses demonstrated that, overall, energy dense meals resulted in a significant mean difference of 324 kcal (95% CI = 212–436) and 9.1 g of protein (95% CI = 0.2–17.9) per day, in favour of the intervention (Figs 3 and 4). The heterogeneity between the studies was low–moderate for energy intake ($I^2 = 39.0\%$, P = 0.194) and high for protein intake ($I^2 = 89.1\%$, P = 0.000). Campbell *et al.* (2013) found that patients who received mid meal snacks consumed significantly less energy and protein compared to ONS (Table 5).

Clinical care processes

Interventions involved enhanced clinical care practices implemented by nursing and dietetic staff at the ward level. Babineau *et al.* (2008) implemented a system of nutritional screening followed by nutritional assessment completed by a dietitian and the commencement of an individualised nutritional care plan with ongoing followup and modifications as required. This enhanced care process significantly improved dietary intake, biochemistry and physical function. Alternatively, trained nursing staff completed nutrition assessments and implemented

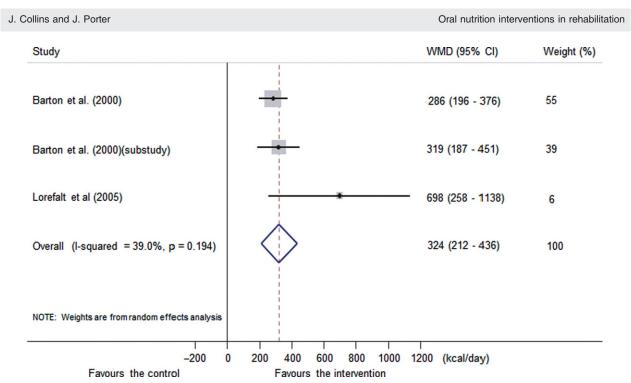


Figure 3 Meta-analysis of the effect of energy dense meals and standard meals on energy intake (kcal/day) among patients admitted for rehabilitation.

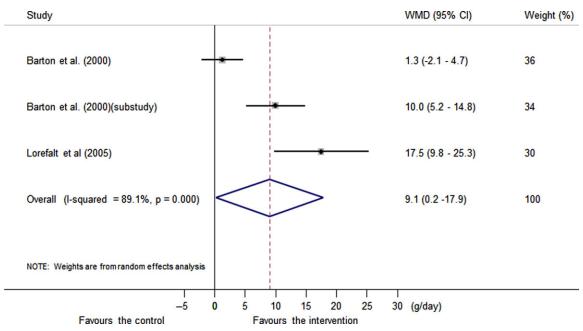


Figure 4 Meta-analysis of the effect of energy dense meals and standard meals on protein intake (g/day) among patients admitted for rehabilitation.

individualised nutrition interventions in the study by Poulsen *et al.* (2007). There was no significant difference in patients' weight or LOS under the control condition compared to the enhanced nurse-led clinical care process (Table 6).

Discussion

The present review aimed to identify and collate the evidence relating to the effect of oral nutrition interventions among patients admitted for rehabilitation on nutritional

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and functional outcomes. There is convincing evidence that malnourished patients experience worse outcomes following discharge from rehabilitation (Marshall *et al.* 2014). Effective, evidence-based strategies to treat and prevent malnutrition during the rehabilitation period are essential for counteracting the course of decline and improving health outcomes for patients. To this end, the findings of this review recommend the use of oral nutrition supplements or energy dense meals compared to standard meals alone, as potential solutions to improve energy and protein intake among patients in rehabilitation.

There was some evidence indicating that the consumption of ONS in addition to regular meals improved energy and protein intake compared to consuming meals only (Hankey et al., 1993; Creutzberg et al., 2003; Myint et al., 2013). The patients who received ONS consumed on average an additional 350-600 kcal day⁻¹ (1.5-2.5 mJ day⁻¹) and exceeded their estimated requirements, which is a clinically important outcome. There were positive changes in anthropometry, biochemistry, function and LOS, although not all outcomes were statistically significant or clinically meaningful. Past reviews and metaanalyses of studies conducted with patients with a range of clinical conditions in a variety of settings appear to show an overall effect in favour of ONS compared to standard care for improving weight, mortality, functionality, morbidity and LOS (Potter et al., 1998; Stratton et al., 2003; Babineau et al., 2008; Milne et al., 2009). It has been suggested that there may be a differential effect of supplements among different patient groups (Baldwin & Weekes, 2012). Indeed, the most favourable results were reported in a single study of nutritionally depleted patients with COPD receiving ONS during inpatient pulmonary rehabilitation (Creutzberg et al., 2003). It was unclear whether beneficial outcomes were a consequence of ONS alone or if other aspects of the pulmonary rehabilitation programme also contributed.

The three studies investigating speciality ONS (i.e. ONS with modified nutrition content or delivery schedule) were vastly different in their outcome measures, study particiJ. Collins and J. Porter

pants and the scope of the intervention. They included hip fracture patients receiving high protein ONS (Neumann et al., 2004), stroke patients trialling high energy ONS (Rabadi et al., 2008) and a Medpass programme implemented with heterogeneous elderly (Campbell et al., 2013), where all participants had compromised nutrition. Participants in the intervention and control groups demonstrated changes in outcomes in the same direction, with those receiving speciality ONS performing significantly better for only some measures. The current state of evidence remains inconclusive on whether speciality formulations or delivery schedules of ONS offer substantial benefits in excess of those achieved with standard or traditional ONS. Clinical guidelines emphasise individualising nutrition support to meet the nutritional needs of the patient in the context of their clinical condition, goals, progress and preferences (Watterson et al., 2009; NICE, 2006; Nutricia, 2009). As such, clinical judgement should be used to determine whether modified supplements are more suitable.

As an alternative to ONS, foodservice interventions including food fortification or mid meal snacks can be used to address malnutrition in healthcare settings. The metaanalyses (Figs 3 and 4) of the three neutral to positive quality studies of energy-dense meals with 113 participants demonstrated greater intake of energy (324 kcal; 1360 kJ) and protein (9.1 g) in favour of the intervention. It remains unknown whether the increase in dietary intake translates into clinically important endpoints as a result of the lack of inclusion of these outcomes. The majority of studies conducted in long-term care settings or acute hospitals have shown consistent findings, although there is scant evidence of additional clinical benefits (Odlund Olin et al., 1996, 2003, 2003; Smoliner et al., 2008; Castellanos et al., 2009). Although food-based interventions are potentially more acceptable to patients than ONS, they may fail to deliver energy and protein in adequate quantities to meet requirements and produce physiological changes.

Two studies relating to clinical care processes focussed on creating supportive environments to facilitate the delivery of nutrition interventions. Educating, training and

Table 6 Outcome data for studies testing	clinical care processes to prevent and t	treat malnutrition in the rehabilitation setting
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Outcome	Study	Intervention	Control	P value
Energy intake (kcal day ⁻¹)	Babineau <i>et al.</i> (2008)	1627 (536)	1455 (456)	0.0001
Protein intake (g day ⁻¹)	Babineau <i>et al.</i> (2008)	64.4 (26.0)	59.0 (22.0)	0.01
Weight change (kg)	Babineau <i>et al.</i> (2008)	0.2 (NR)	NA	0.545
	Poulsen <i>et al.</i> (2007)	0.0 (2.9)	-0.1 (2.8)	0.89
Albumin change (g L ⁻¹)	Babineau <i>et al.</i> (2008)	1.1 (NR)	NA	0.001
Pre-albumin change (mg dL ⁻¹)	Babineau <i>et al.</i> (2008)	2.0 (NR)	NA	0.003
Barthel Index score change	Poulsen <i>et al.</i> (2007)	15.1 (NR)	15.6 (NR)	NS
Health-related quality of life (physical functioning) score change	Babineau <i>et al.</i> (2008)	0.5 (NR)	NA	0.044
LOS (days)	Poulsen <i>et al.</i> (2007)	37.2 (29.8)	32.2 (24.9)	0.13

NA, not applicable; NR, not reported; NS, not significant; LOS, length of stay.

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supervising nurses to provide nutrition care to rehabilitation patients failed to demonstrate any benefits, potentially as a result of limitations of the design and the intensity of the education programme (Poulsen *et al.*, 2007). BAPEN (2010) recommend that dietitians are involved in planning and providing nutrition education to other health professionals, which was not apparent in the study by Poulsen *et al.* (2007). This contrasts with improved outcomes when dietitians commenced a nutrition care pathway, supporting the importance of ensuring they are the members of the multidisciplinary team primarily responsible for leading nutrition care (Babineau *et al.*, 2008).

This review identified a small number of studies, reinforcing the paucity of malnutrition research conducted in the rehabilitation care setting. This contrasts with the plethora of nutrition intervention studies undertaken in other healthcare settings, including acute hospitals and residential facilities. The quality and design of the majority of the studies was determined to be neutral because a number of publications failed to report critical elements of the study protocol, resulting in uncertainty about the risk of bias. Three well designed RCTs were exceptions, indicating that it is possible to carry out robust, highquality studies despite the unpredictability of the clinical environment as a research setting. An additional strength was that function was measured as an outcome, which is of considerable importance in rehabilitation where the primary aim of treatment is to improve functional independence and physical capacity. A number of studies, those testing food service interventions in particular, only measured energy and protein consumption and therefore could not show whether improving dietary intake resulted in clinical or functional benefits.

Despite the range of oral nutrition strategies that aim to enhance dietary intake, the studies included in this review were limited to three types of interventions: ONS, foodservice interventions and clinical care processes. No studies relating to enhanced eating environments in the rehabilitation setting were identified. Creating a social and homely dining environment to improve dietary intake in the acute and aged care settings has yielded inconsistent results (Mathey et al., 2001; Remsburg et al., 2001; Neumann et al., 2004; Nijs et al., 2006). Similarly, no studies relating to the provision of feeding assistance, general nutrition support or dietary counselling in the rehabilitation setting were identified. These clinical care processes have been evaluated in other healthcare settings with positive outcomes noted (Duncan et al., 2006; Baldwin & Weekes, 2011, 2012; Green et al., 2011).

Future studies evaluating these and other new and innovative oral nutrition strategies in the rehabilitation setting are justified. Interventions conducted in acute hospitals and residential aged care facilities should be considered to inform clinical practice in the rehabilitation setting; however, the generalisability and applicability of the results may be limited by fundamental differences in the goals of healthcare, the environment and the characteristics of the patients in rehabilitation. There is an opportunity for further research to determine the translative capacity of findings of nutrition interventions across the continuum of healthcare.

The inclusion of robust clinical (e.g. LOS, morbidity, mortality), functional (e.g. FIM) and cost outcomes in studies evaluating oral nutrition interventions are required to improve the relevance of research in this setting. The role of ONS and energy dense meals as effective strategies for addressing malnutrition in the rehabilitation setting will be strengthened by further evidence of improvements in these outcomes.

Limitations

The range of terms used internationally to describe healthcare settings posed a challenge when assessing whether studies were conducted in a rehabilitation setting and therefore met the inclusion criteria for this review. The authors considered the description of the participants and the facility to determine eligibility. For example, a number of studies conducted in 'long-term care' were excluded because this was defined as catering for 'older, more disabled long-term residents with medically complex conditions' with an average LOS of 835 days (Dorner, 2010). Additionally, the search terms used in the review may not have been sufficiently extensive to retrieve studies conducted in a setting equivalent to rehabilitation but named alternatively. Limitations at the review level include the potential of publication bias and language bias because studies in languages other than English were excluded.

Conclusions

This review found that the provision of ONS or energy dense meals compared to standard meals alone may be effective strategies for preventing or treating malnutrition among patients admitted for rehabilitation. The small number of studies and the quality of the evidence, however, make it difficult to develop firm recommendations for clinical practice.

There was consistent evidence from three studies for the role of ONS to significantly increase energy and protein intake. Additional improvements in anthropometry, function and LOS may be achieved with ONS, although it is unclear whether these benefits are limited to particular patient groups only. Meta-analyses found that

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higher energy meals including a cooked breakfast or smaller, fortified meals increased daily energy and protein intake; however, the subsequent effect on anthropometry, function and LOS is unknown.

Other oral nutrition interventions that aim to enhance dietary intake such as enhanced eating environments and clinical care processes (e.g. feeding assistance) show benefits in other healthcare settings, although their effects among patients admitted for rehabilitation remain unknown in the absence of evaluative studies undertaken in this setting.

Conflict of interest statement, source of funding and authorship

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JC conducted the literature search, collated, analysed and interpreted the data, and wrote the manuscript. JP supervised this process and critically reviewed the manuscript. Both authors contributed to the conception of this review, the study selection and the quality assessment process, and have read and approved the final publication submitted for publication.

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J. Collins and J. Porter

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Supporting information

Additional Supporting Information may be found in the online version of this article: **Data S1.** Full search strategy.

Complete literature search strategy database 1 CINAHL

- 1. "intermediate care"
- 2. "subacute care" or "sub acute care" or "sub acute" or subacute or sub-acute
- 3. (MH "subacute care")
- 4. rehab or rehabilitation or "geriatric N3 rehabilitation"
- 5. (MH "rehabilitation")
- 6. (MH "rehabilitation, geriatric")
- 7. "nutrition* intervention*"
- 8. "nutrition* care"
- 9. (MH "diet therapy")
- 10. "diet* therap*"
- 11. feeding W1 (assistan* or support or behaviour* or behavior*)
- 12. "protected mealtimes" or "protected meal times"
- 13. "red tray"
- 14. "communal dining"
- 15. (eating or meal) W1 environment*
- 16. (MH "eating behavior")
- 17. dining W1 (room* or location*)
- 18. "social eating"
- 19. (dietetic or nutrition) W1 assistan*
- 20. nutrition* N3 education
- 21. (MH "nutrition education")
- 22. "food service" or "hospital food service"
- 23. (MH "food services")
- 24. "hospital catering"
- 25. menu or menu W1 plan*
- 26. (MH "Menu Planning")
- 27. "food provision"
- 28. "food fortification"
- 29. (diet* or nutrition*) W1 advice
- 30. "oral nutrition* support" or "oral nutrition* supplement*"
- 31. (MH "Nutritional support") OR (MH "Dietary Supplementation")
- 32. 1. or 2. or 3. or 4. or 5. or 6.
- 33. 7. or 8. or 9. or 10. or 11. or 12. or 13. or 14. or 15. or 16. or 17. or 18. or 19. or 20. or 21. or 22. or 23. or 24. or 25. or 26. or 27. or 28. or 29. or 30. or 31.
- 34. 32. and 33.

35. 34. limit to English Language; Exclude MEDLINE records; Human; Age Groups: Adult: 19-44 years, Middle Aged: 45-64 years, Aged: 65+ years, Aged, 80 and over

MH, exact subject heading

Complete literature search strategy database 2 EMBASE

- 1. 'subacute care' OR 'sub acute care' OR 'sub acute'
- 2. rehab OR rehabilitation OR geriatric NEAR/3 rehabilitation
- 3. 'geriatric rehabilitation'/de
- 4. 'intermediate care'
- 5. nutrition* NEXT/1 intervention*
- 6. nutrition* NEXT/1 care
- 7. nutrition* NEXT/1 therap*
- 8. 'diet therapy'/de
- 9. diet* NEXT/1 therap*
- 10. 'feeding behavior'/de
- 11. 'protected mealtimes' OR 'protected meal times'
- 12. 'red tray'
- 13. 'communal dining'
- 14. 'social eating'
- 15. nutrition* NEAR/3 education
- 16. 'food service' OR 'hospital food service'
- 17. 'hospital food service'/de
- 18. 'hospital catering'
- 19. 'hospital catering'/de
- 20. menu OR menu NEXT/1 plan*
- 21. 'food provision'
- 22. 'food fortification'
- 23. feeding NEXT/1 (assistan* OR support OR behaviour* OR behavior*)
- 24. (diet* OR nutrition*) NEXT/1 advice
- 25. (dietetic OR nutrition) NEXT/1 assistan*
- 26. dining NEXT/1 (room* OR location*)
- 27. (eating OR meal) NEXT/1 environment*
- 28. 'oral nutritional support' OR 'oral nutrition support' OR 'oral nutrition' NEXT/1 supplement* OR' oral nutritional' NEXT/1 supplement*
- 29. 'nutritional support'/de
- 30. 'diet supplementation'/de

- 31. 1. or 2. or 3. or 4.
- 32. 5. or 6. or 7. or 8. or 9. or 10. or 11. or 12. or 13. or 14. or 15. or 16. or 17. or 18. or 19. or 20. or 21. or 22. or 23. or 24. or 25. or 26. or 27. or 28. or 29. or 30.
- 33. 31. and 32.
- 34. 33. and ([adult]/lim OR [aged]/lim) AND [humans]/lim AND [english]/lim AND [embase]/lim NOT [medline]/lim

/de, Index (Emtree) term

<u>Complete literature search strategy database 3 Cochrane Central Register of</u> Controlled Trials

- 1. ("subacute care" or "sub acute care" or "sub acute" or subacute or sub-acute).mp.
- 2. subacute care/
- 3. (rehab or rehabilitation or "geriatric adj3 rehabilitation").mp.
- 4. Rehabilitation/
- 5. "intermediate care".mp.
- 6. "nutrition* intervention*".mp.
- 7. "nutrition* care".mp.
- 8. Nutrition Therapy/
- 9. "nutrition* therap*".mp.
- 10. Diet Therapy/
- 11. "diet* therap*".mp.
- 12. Feeding Behavior/
- 13. ("protected mealtimes" or "protected meal times").mp.
- 14. "red tray".mp.
- 15. "communal dining".mp.
- 16. "social eating".mp.
- 17. (nutrition* adj3 education).mp.
- 18. ("food service" or "hospital food service").mp.
- 19. Food Services/
- 20. Food Service, Hospital/
- 21. "hospital catering".mp.
- 22. (menu or "menu plan*").mp.
- 23. "food provision".mp.
- 24. "food fortification".mp.
- 25. (feeding adj1 (assistan* or support or behaviour* or behavior*)).mp.
- 26. ((diet* or nutrition*) adj1 advice).mp.

- 27. ((dietetic or nutrition) adj1 assistan*).mp.
- 28. (dining adj1 (room* or location*)).mp.
- 29. ((eating or meal) adj1 environment*).mp.
- 30. ("oral nutrition* support" or "oral nutrition* supplement*").mp.
- 31. Nutritional Support/
- 32. Dietary Supplements/
- 33. Food, Fortified/
- 34. Dietary Services/
- 35. 1. or 2. or 3. or 4. or 5.
- 36. 6. or 7. or 8. or 9. or 10. or 11. or 12. or 13. or 14. or 15. or 16. or 17. or 18. or 19. or 20. or 21. or 22. or 23. or 24. or 25. or 26. or 27. or 28. or 29. or 30. or 31. or 32. or 33. or 34.
- 37. 35. and 36.

.mp, term mapped to subject heading

Complete literature search strategy database 4 PsycINFO

- 1. ("subacute care" or "sub acute care" or "sub acute" or subacute or sub-acute).mp.
- 2. (rehab or rehabilitation or "geriatric adj3 rehabilitation").mp.
- 3. Rehabilitation/
- 4. "intermediate care".mp.
- 5. "nutrition* intervention*".mp.
- 6. "nutrition* care".mp.
- 7. "nutrition* therap*".mp.
- 8. "diet* therap*".mp.
- 9. (feeding adj1 (assistan* or support or behaviour* or behavior*)).mp.
- 10. ("protected mealtimes" or "protected meal times").mp.
- 11. "red tray".mp.
- 12. "communal dining".mp.
- 13. ((eating or meal) adj1 environment*).mp.
- 14. (dining adj1 (room* or location*)).mp.
- 15. "social eating".mp.
- 16. ((dietetic or nutrition) adj1 assistan*).mp.
- 17. (nutrition* adj3 education).mp.
- 18. ("food service" or "hospital food service").mp.
- 19. "hospital catering".mp.
- 20. (menu or "menu plan*").mp.

- 21. "food provision".mp.
- 22. "food fortification".mp.
- 23. ((diet* or nutrition*) adj1 advice).mp.
- 24. ("oral nutrition* support" or "oral nutrition* supplement*").mp.
- 25. Dietary Supplements/
- 26. 1 or 2 or 3 or 4
- 27. 5. or 6. or 7. or 8. or 9. or 10. or 11. or 12. or 13. or 14. or 15. or 16. or 17. or 18. or 19. or 20. or 21. or 22. or 23. or 24. or 25.
- 28.26. and 27.
- 29. limit 28. to (human and English language and ("adulthood <age 18 yrs and older>" or "young adulthood <age 18 to 29 yrs>" or "thirties <age 30 to 39 yrs>" or "middle age <age 40 to 64 yrs>" or "aged <age 65 yrs and older>" or "very old <age 85 yrs and older>"))

.mp, term mapped to subject heading

Complete literature search strategy database 5 Ovid MEDLINE

- 1. ("subacute care" or "sub acute care" or "sub acute" or subacute or sub-acute).mp.
- 2. Subacute Care/
- 3. (rehab or rehabilitation or "geriatric adj3 rehabilitation").mp.
- 4. Rehabilitation/
- 5. "intermediate care".mp.
- 6. "nutrition* intervention*".mp.
- 7. "nutrition* care".mp.
- 8. Nutrition Therapy/
- 9. "nutrition* therap*".mp.
- 10. Diet Therapy/
- 11. "diet* therap*".mp.
- 12. Feeding Behavior/
- 13. ("protected mealtimes" or "protected meal times").mp.
- 14. "red tray".mp.
- 15. "communal dining".mp.
- 16. "social eating".mp.
- 17. (nutrition* adj3 education).mp.
- 18. ("food service" or "hospital food service").mp.
- 19. Food Services/
- 20. Food Service, Hospital/

- 21. "hospital catering".mp.
- 22. (menu or "menu plan*").mp.
- 23. Menu Planning/
- 24. "food provision".mp.
- 25. "food fortification".mp.
- 26. (feeding adj1 (assistan* or support or behaviour* or behavior*)).mp.
- 27. ((diet* or nutrition*) adj1 advice).mp.
- 28. ((dietetic or nutrition) adj1 assistan*).mp.
- 29. (dining adj1 (room* or location*)).mp.
- 30. ((eating or meal) adj1 environment*).mp.
- 31. ("oral nutrition* support" or "oral nutrition* supplement*").mp.
- 32. Nutritional Support/
- 33. Dietary Supplements/
- 34. Food, Fortified/
- 35. Dietary Services/
- 36. 1. or 2. or 3. or 4. or 5.
- 37. 6. or 7. or 8. or 9. or 10. or 11. or 12. or 13. or 14. or 15. or 16. or 17. or 18. or 19. or 20. or 21. or 22. or 23. or 24. or 25. or 26. or 27. or 28. or 29. or 30. or 31. or 32. or 33. or 34. or 35.
- 38. 36. and 37.
- 39. limit 38. to (english language and humans and ("young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)"))

.mp, term mapped to subject heading





ABN 68 223 819 017

www.easternhealth.org.au

Human Research Ethics Committee - Scientific and Ethical Review

Ethical Approval – Granted

Commencement of Research at Eastern Health has been authorised

16 September 2013

Dr Judi Porter Department of Nutrition and Dietetics Monash University Level 1, 264 Ferntree Gully Road Notting Hill VIC 3168 Eastern Health Research and Ethics Committee

www.easternhealth.org.au/ethics

Dear Dr Porter,

LR23/1314 – The menu reGEMeration study.

Principal Investigator: Dr Judi Porter

Associate Investigators: Professor Helen Truby and Dr Catherine Huggins

Student Investigator: Ms Jorja Collins

Other Approved Personnel: Nil

Eastern Health Site: Maroondah Hospital

Approval Period: On-going - subject to a satisfactory progress report being submitted annually

Thank you for the submission of the above project for review. The project has been reviewed by the Eastern Health Research and Ethics Committee. The project is considered of low risk in accordance with definitions given in the National Statement (2007). All queries have now been addressed and the project is accordingly **APPROVED**.

Documents submitted for review:

- Application Form Module 1 incorporating Research Proposal version 2 dated 11 September 2013.
- Malnutrition Screening Tool
- Nutrition Subjective Global Assessment
- Ward Notice version 2 dated 10 September 2013
- Patient Information Brochure version 1 dated 10 September 2013
- Patient Satisfaction Survey
- CVs for Jorja Collins and Catherine Huggins
- Confidentiality Agreements for Helen Truby, Jorja Collins and Catherine Huggins

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- Members of Eastern Health -





www.easternhealth.org.au

Please note: Privacy legislation applies – project will be included in the annual report to the Health Privacy Commissioners and brief details of the project will be posted on our web-page. This is a requirement for all research projects where a waiver of consent has been granted by the Ethics Committee.

IMPORTANT: A final progress report should be submitted on project completion. If the project continues beyond 12 months an annual progress report should be submitted in **September 2014**. Continuing approval is subject to the submission of satisfactory progress reports. The Progress Report template can be downloaded from our web-page:

http://www.easternhealth.org.au/research/ethics/formstemplates.aspx

Please quote our reference number *LR23/1314* in all future correspondence.

Yours sincerely,

Astrid Nordmann

Research Governance Officer Eastern Health Office of Research and Ethics (Signed on behalf of the Eastern Health Research and Ethics Committee)

Copy to:

• Helen Truby, Catherine Huggins and Jorja Collins

Confidentiality, Privacy & Research

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices.

Electronic storage devices must be password protected or encrypted.

The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications

Whilst the Eastern Health Research and Ethics Committee is an independent committee, the committee and Eastern Health management encourage the publication of the results of research in a discipline appropriate manner. Publications provide evidence of the contribution that participants, researchers and funding sources make.

It is very important that the role of Eastern Health is acknowledged in publications.

N:\02-03¤t\Ethics - Eastern Health\All Correspondence\1314 studies\LR23-1314 - AUTHORISED Sep13\LR23-1314 Correspondence from Eastern Health\LR23-1314 Final Authorisation (16Sep13).docx



Monash University Human Research Ethics Committee (MUHREC) Research Office

Human Ethics Certificate of Approval

This is to certify that the project below has been approved by the Monash University Human Research Ethics Committee under the Memorandum of Agreement with Eastern Health.

Project Number:	CF13/2773 - 2013001493
Project Title:	The menu reGEMeration study
Chief Investigator:	Dr Judi Porter
Approved:	From: 25 September 2013 to 25 September 2018

Terms of approval - Failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.

- 1. Approval is only valid whilst you hold a position at Monash University and approval at the primary HREC is current.
- 2. Future correspondence: Please quote the project number and project title above in any further correspondence.
- 3. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
- 4. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Chair, MUHREC

cc: Prof Helen Truby; Dr Catherine Huggins; Ms Jorja Collins

Postal – Monash University, Vic 3800, Australia Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton

THE ACUTE CARE HOSPITAL FOODSERVICE PATIENT SATISFACTION QUESTIONNAIRE

We are improving the hospital foodservice and we need to know your opinions. Please note that participation in this survey is completely voluntary. Thank you.

11. The inspiration of the section of the sectin of the sectin of the section of the section of	1. The hospital food has been as	Always	Often	Sometimes	Rarely	Never	CODING
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			Good	Okay	Poor	-	

Please feel free to make any other comments about the hospital foodservice:

Copyright © Capra, S, Wright O, Sardie M, Buaer J, Askew D (2005) 'The acute hospital foodservice patient satisfaction questionnaire: the development of a valid and reliable tool to measure patient satisfaction with acute care hospital foodservices' *Foodservice Research International*, 16, 1-14.

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Subjective Global Assessment

Name: Date:

Date:					
Medical History			А	В	С
WEIGHT Wt change past 6 months 0-<5% loss 5-10% loss >10% loss	Usual weight Amount weight loss		*	*	*
Weight change past 2 weeks No change; normal weight Increase to within 5% Increase (1 level above) No change, but below usual wt Increase to within 5-10% Decrease		Amount	* *	* * *	*
DIETARY INTAKE No change; adequate No change; inadequate			*	*	
Change Suboptimal diet Full liquid Hypocaloric liquid Starvation	Duration of ch	ange		*	*
Intake borderline; increasing Intake borderline; decreasing Intake poor; no change Intake poor; increasing Intake poor; decreasing			*	* * *	*
GASTROINTESTINAL SYMPTON Frequency (never, dai Nausea Vomiting Diarrhoea Anorexia		Duration (<2wk, >2wk)			
None; intermittent Some (daily >2 week) All (daily >2 week)			*	*	*
FUNCTIONAL CAPACITY No dysfunction Difficulty with ambulation/normal a Bed/chair-ridden		nge	*	*	*
Change past 2 week Improved No change Regressed			*	*	*

 This is a consensus document from Dietitian/ Nutritionists from the Nutrition Education Materials Online, "NEMO", team.

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 Posted: May 2009

 Due for Review: November 2014

Physical examination	A	В	С
SUBCUTANEOUS FAT			
Under the eyes	Slightly bulging area		Hollowed look, depression, dark circles
Triceps	Large space between fingers		Very little space between fingers, or fingers touch
Biceps	Large space between fingers		Very little space between fingers, or fingers touch
MUSCLE WASTING			
Temple	Well-defined muscle/flat	Slight depression	Hollowing, depression
Clavicle	Not visible in Males; may be visible but not prominent in females	Some protrusion; may not be all the way along	Protruding/prominent bone
Shoulder	Rounded	No square look; acromion process may protrude slightly	Square look; bones prominent
Scapula/ribs	Bones not prominent; no significant depressions	Mild depressions or bone may show slightly; not all areas	Bones prominent; significant depressions
Quadriceps	Well rounded; no depressions	Mild depression	Depression; thin
Calf	Well developed		Thin; no muscle definition
Knee	Bones not prominent		Bones prominent
Interosseous muscle between thumb and forefinger	Muscle protrudes; could be flat in females		Flat or depressed area
OEDEMA (related to malnutrition)	No sign	Mild to moderate	Severe
ASCITES (related to malnutrition)	No sign	Mild to moderate	Severe
OVERALL SGA RATING	A	В	С

Adapted from: Detsky et al., 1994⁸; Baxter Healthcare Corporation, 1993; McCann, 1996 (Ferguson, Bauer, Banks, Capra, 1996)©

Time point			2 (1)	14 (1)	21 (1)	28 (1)	41 (1)	56 (1)	68 (3)
(days since admission)									
mea	mean (SD)								
	All	n	118	68	41	27	7	4	4
		mean	37.8	38.1	37.7	35.5	28.2	26.5	27.1
		(SD)	(16.7)	(16.0)	(14.4)	(13.2)	(10.7)	(14.7)	(13.4)
(g)	Control	n	60	38	21	11	1	1	1
HGS (kg)		mean	38.7	38.5	39.3	36.4	29.4	30.7	29.4
ВН		(SD)	(17.2)	(18.3)	(37.8)	(10.6)			
	Intervention	n	58	30	20	16	6	3	3
		mean	36.9	37.7	36.1	34.9	28.0	25.1	26.3
		(SD)	(16.2)	(12.7)	(14.7)	(15.1)	(11.7)	(17.6)	(16.3)
	All	n	118	68	41	27	7	4	4
al)		mean	155	164	167	152	152	139	143
orm		(SD)	(58)	(56)	(56)	(55)	(65)	(82)	(77)
of n	Control	n	60	38	21	11	1	1	1
ent		mean	153	155	164	140	109	114	109
HGS (percent of normal)		(SD)	(57)	(59)	(53)	(47)			
	Intervention	n	58	30	20	16	6	3	3
БН		mean	158	176	169	161	159	148	155
		(SD)	(59)	(50)	(61)	(60)	(68)	(99)	(90)

Hand grip strength data obtained at each data collection point for all participants and control and intervention groups

Percent of predicted normal HGS calculated from reference data for age and gender (1, 2)
Bohannon RW, Peolsson A, Massy-Westropp N, Desrosiers J, Bear-Lehman J. Reference values for adult grip strength measured with a Jamar dynamometer: a descriptive meta-analysis.
Physiotherapy. 2006;92(1):11-5.

2. Bohannon RW, Bear-Lehman J, Desrosiers J, Massy-Westropp N, Mathiowetz V. Average grip strength: A meta-analysis of data obtained with a Jamar dynamometer from individuals 75 years or more of age. J Geriatr Phys Ther. 2007;30(1):28-30.

Weight data obtained at each data collection point for all participants and control and intervention groups

Time point		1 (1)	7 (1)	14 (1)	21 (1)	28 (1)	35 (1)	41 (1)	49 (1)	56 (1)	64 (1)	71 (1)
(days since a mean (SD)	admission)											
All	n	117	102	68	41	31	15	8	3	4	4	2
	Weight (kg)	65.70	65.80	66.60	66.70	67.45	66.55	67.85	68.85	68.20	68.95	53.30
	mean (SD)	(18.50)	(16.20)	(17.35)	(18.65)	(19.70)	(20.90)	(18.60)	(18.60)	(23.60)	(23.50)	(14.90)
Intervention	n	60	52	31	22	19	11	6	3	3	3	2
	Weight (kg)	63.80	63.30	61.40	62.00	63.50	60.25	69.60	68.20	67.95	68.65	53.30
	mean (SD)	(20.60)	(16.55)	(17.40)	(18.10)	(18.85)	(19.10)	(20.80)	(28.95)	(28.90)	(28.75)	(14.90)
Control	n	57	50	37	19	12	4	2	0	1	1	0
	Weight (kg)	67.70	68.35	71.00	72.10	73.70	83.80	62.65		68.95	69.90	
	mean (SD)	(15.90)	(15.60)	(16.25)	(18.25)	(20.25)	(16.80)	(13.55)				

Comparison between groups of energy and protein intake at day 14 of inpatient stay excluding oral nutritional supplement^a intake

		Control	Intervention	p value					
Daily intake									
Energy intake kJ/day		n=39	n=31	0.099					
mean (SD)		6269 (2040)	7089 (2030)						
	kJ/kg/day	n=37	n=30	0.001					
		91 (32)	120 (37)						
Protein intake	g/day	n=39	n=31	0.325					
mean (SD)		66.3 (25.4)	72.5 (27.3)						
	g/kg/day	n=37	n=31	0.019					
		1.0 (0.4)	1.3 (0.6)						
Mid meal intake									
Energy intake	kJ/day	n=31	n=28	0.274					
median (IQR)		985 (637 – 1394)	1184 (649 – 1799)						
	kJ/kg/day	n=29	n=27	0.075					
		14 (10 – 18)	19 (12 – 30)						
Protein intake	g/day	n=31	n=28	0.627					
median (IQR)		6.9 (4.7 – 12.6)	6.6 (2.9 – 11.7)						
	g/kg/day	n=29	n=27	0.812					
		0.1 (0.1 – 0.2)	0.1 (0.0 – 0.2)						

Daily intake data analysed using independent samples T-test

Mid meal intake data analysed using Mann Whitney U test

^aOral nutritional supplements include commercial products - Resource 2.0, Sustagen, Fortijuce,

Arginaid, sustagen pudding and Forticreme

Energy and protein intake adjusted using weight (kg) at day 14 (or admission) of inpatient stay

Participant satisfaction with the foodservice for participants with a length of stay in subacute care of less than 14 days

Domain (score)	Control	Intervention	p value
median (IQR)	n=12	n=9	
Food quality	1.2 (1.0-1.8)	2.1 (1.8-3.0)	0.011
Meal service quality	1.8 (1.1-2.5)	2.0 (1.5-2.8)	0.427
Staffing and service	1.0 (1.0-1.5)	1.0 (1.0-1.5)	0.962
Physical environment	1.0 (1.0-1.3)	1.3 (1.0-1.8)	0.310

Time point	2	14	28	41	55	67
(days since admission)	(1 – 3)	(13 – 14)	(27 – 18)	(41 – 42)	(55 – 56)	(63 – 71)
median (IQR)						
n	120	75	35	12	4	4
Energy intake (kJ/day)	6790	7435	6757	8133	7802	6510
mean (SD)	(2619)	(1995)	(2542)	(2254)	(1753)	(2976)
Protein intake (g/day)	67.4	77.2	69.1	78.8	85.9	68.0
mean (SD)	(28.9)	(25.0)	(33.1)	(31.4)	(26.4)	(40.3)

Daily energy and protein intake data obtained at each data collection point for all participants