Tackling Malnutrition:

Oral nutritional supplements as an integrated part of patient and disease management in hospital and in the community

A summary of the evidence base

Prepared on behalf of

Medical Nutrition International Industry

July 2010

This report synthesises relevant information on the rationale for and value of oral nutritional supplements (ONS) to provide stakeholders with an up-to-date and practical summary of the evidence base. The report draws on the key elements of a comprehensive systematic review of the evidence base for the management of disease-related malnutrition. This has been supplemented with more recent published data on the prevalence, causes and consequences of malnutrition as well as the nutritional, functional, clinical and economic benefits of ONS. Relevant publications were reviewed, selected and collated by a Registered Dietitian who is not affiliated with any Medical Nutrition company. All material cited is in the public domain.

In addition to clinical data, relevant guidelines relating to ONS, as well as examples of implementation of guidelines and good practice have been summarised. We recognize that there are gaps - either real gaps or due to limited access to documentation. We hope this will be the starting point to encourage further documentation and sharing of information.

The first issue of this report was prepared in 2009 and this has been updated for 2010. This report contains an objective view of the state of the art today, but must also be regarded as work in progress. Unpublished data are not included, trials are ongoing and further guidelines and good practice are undoubtedly in development.

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Contents

Definition of terms

Adherence

A term used to describe how well a patient or client is following the advice of their healthcare professional or treatment plan. Also known as compliance.

Care settings

These terms are not used consistently across Europe. For the purposes of this document:

- Hospital

The term 'hospital' refers to care in a hospital

- Outpatient

A patient who attends a hospital or clinic for diagnosis or treatment but does not occupy a bed

- Community

The term 'community' refers to care outside the hospital setting and can include people in institutions, in their own homes or in sheltered housing

- Institution

The term 'institution' refers to care which does not take place in hospital or at home, i.e. it includes care in nursing homes, residential homes, long-term care institutions and mental health units (all of these are sometimes referred to informally as 'care homes')*

  - Nursing home - residents usually require nursing care and are more dependent than residents in residential care
  - Residential home - residents may need assistance with meals or personal care. Qualified nurses are not required to be present
  - Sheltered accommodation - groups of housing units provided for older or disabled people who require occasional assistance from a resident warden but who do not need full residential care

*Where details of the care setting have been provided in original reports this information has been included to help establish the exact setting where studies, care or interventions have taken place. However, in some cases the detail is incomplete as this information was not available.

Care system

A healthcare system is the sum total of all the organizations, institutions and resources whose primary purpose is to improve health[7]. In the UK, for example, healthcare includes hospitals, maternity units and services provided by district nurses.

Social care includes nursing homes, residential homes, care at home and adult placement schemes.

Dietary advice/ counselling

The provision of information with the aim of increasing the frequency of consumption of food and fluids and to increase the energy and nutrient content of the foods and fluids consumed. It may also include food fortification which aims to increase the energy and nutrient density of foods and fluids without significantly increasing their volume.

Enteral nutrition

The term enteral nutrition comprises all forms of nutritional support that imply the use of 'dietary foods for special medical purposes' as defined by the European Commission Directive 1999/21/EC independent of the route of application. It includes oral nutritional supplements as well as tube feeding via nasogastric, nasoenteral or percutaneous tubes[2].

Malnutrition

There is no universally accepted definition of malnutrition. The following definition is now widely acknowledged by many, including ESPEN[2]:

'A state of nutrition in which a deficiency, excess (or imbalance) of energy, protein, and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function, and clinical outcome[3].'

Malnutrition thus includes both over-nutrition (overweight and obesity) and under-nutrition (underweight). For the purposes of this report the term malnutrition will be used to mean under-nutrition (also known as disease-related malnutrition).

Furthermore, the term "malnutrition" is used in this report to encompass the additional concept of nutritional risk (see definition below), reflecting common practice whereby these terms are often used interchangeably. Where possible in relation to studies and trials, attempts have been made in this report to describe in detail the definitions and methods used for detecting malnutrition/nutritional risk where feasible.

Medical nutrition

A term used to describe commercially available products for nutritional support, including oral nutritional supplements, enteral tube feeds and parenteral nutrition.

Nutritional assessment

A detailed, more specific and in-depth evaluation of a patient's nutritional state, typically by an individual with nutritional expertise (e.g. a dietitian, clinician with an interest in nutrition, or a nutrition nurse specialist) or by a nutritional support team. This will usually be conducted in the case of nutritional problems identified by the screening process or when there is uncertainty about the appropriate course of action. The assessment process allows more specific nutritional care plans to be developed for the individual patient[4].

Nutritional care programme

A range of activities including nutritional screening, care planning, nutritional interventions (food, oral nutritional supplements, tube and/or parenteral feeding) and follow-up designed to ensure that patients' nutritional needs are evaluated, met and regularly reviewed.

Nutritional risk

Severe malnutrition (under-nutrition) is clinically obvious. However there is uncertainty about recognising lesser degrees of malnutrition. In the absence of universally accepted criteria for identifying malnutrition with high sensitivity and specificity, the concept of risk is invoked. Risk is a measure of likelihood that malnutrition is present or likely to develop[4]. It also reflects the risk of poor outcome as a result of impaired nutritional status[5].

Nutritional screening

A rapid, simple and general procedure used by nursing, medical or other staff, often at first contact with the patient, to detect those at risk of or with nutritional problems, so that action can be taken, e.g. simple dietary measures or referral for expert help. The screening process should be repeated at intervals[4].

Nutritional support

Nutritional support includes food, oral nutritional supplements, tube feeding and parenteral nutrition[2].

Nutritionally complete

A product may be called 'nutritionally complete' if it contains all essential macronutrients and micronutrients in a quantity that allows the product to be used as a sole source of nutrition for the person for whom it is intended. These products may consequently have a standard nutrient formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition.

Oral nutritional supplements (ONS)

Multi-nutrient liquid, semi-solid or powder products that provide macronutrients and micronutrients with the aim of increasing oral nutritional intake. In many cases ONS are nutritionally complete and could also be used as a sole source of nutrition.

Oral nutritional supplements are distinct from dietary supplements which provide vitamins, minerals and or/trace elements in a pill format (also known as food supplements).

Public health

Public health is concerned with improving the health of the population rather than treating the diseases of individual patients[6].

Abbreviations

ADL	Activities of Daily Living
AIDS	Acquired Immune Deficiency Syndrome
BAPEN	British Association for Parenteral and Enteral Nutrition
BMI	Body Mass Index
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
ENHA	European Nutrition for Health Alliance
ESPEN	European Society for Clinical Nutrition and Metabolism (formerly European Society of Parenteral and Enteral Nutrition)
EU	European Union
FFM	Fat Free Mass
GI	Gastrointestinal
GP	General Practitioner
HIV	Human Immunodeficiency Virus
LOS	Length of Stay
MUAC	Mid upper arm circumference
MNA	Mini Nutritional Assessment
MNA-SF	Mini Nutritional Assessment - Short Form
'MUST'	'Malnutrition Universal Screening Tool'
MNI	Medical Nutrition International Industry
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
N/R	Not Reported
NRI	Nutrition Risk Index
NRS 2002	Nutrition Risk Score 2002
ONS	Oral nutritional supplements
OR	Odds Ratio
QOL	Quality of Life
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
RNI	Recommended Nutrient Intake
RR	Relative Risk
SGA	Subject Global Assessment
TSF	Triceps Skinfold

Executive summary

1 The problem

Malnutrition (encompassing both frank under-nutrition and nutritional risk) is widespread in hospitals and in the community and has detrimental effects on individuals and society

- There is consistent and overwhelming evidence that malnutrition is a universal problem in European countries. An estimated 33 million people are at risk of malnutrition in Europe resulting in an estimated cost of €170 billion.
- Malnutrition affects all age groups, but older people are particularly at risk: a large-scale survey showed that the risk is 40% greater in people aged over 65 years than in people aged less than 65 years.
- Patients in hospital and in institutions are particularly at risk. Large-scale studies show that one in four patients admitted to hospital are at risk of malnutrition or are already malnourished, and up to 90% of residents in long-term care in the community are at risk. Malnutrition is also common across a variety of patient groups and is particularly prevalent in people with cancer.
- Malnutrition is caused primarily by poor food and nutrient intake; the effects of disease and treatment also contribute to the development of malnutrition. Patients in hospital and in the community often fail to meet their daily need for energy, protein and micronutrients.
- Malnutrition increases complication rates, morbidity, mortality, hospital readmissions and length of hospital stay. These consequences result in increased use of healthcare resources. For example, public expenditure on disease-related malnutrition in the UK in 2007 has been estimated at in excess of €15 billion* (£13 billion) per annum, corresponding to 10% of the total expenditure on health and social care. In comparison, the economic costs of obesity plus overweight contribute only about half the cost of disease-related malnutrition.
- Nevertheless, the problem of malnutrition is often overlooked, undetected and untreated.

Key messages

- Malnutrition is a universal and costly public health problem in Europe, but is still largely unrecognised by individuals, by health and social care systems and by governments.
- Malnutrition affects many people across all healthcare settings, from older people living in the community to patients in hospital with specific conditions.
- Malnutrition causes death, disability and discomfort; its far reaching consequences increase the burden and cost of care to individuals and society.
- The problem of malnutrition needs to be tackled at every level; by governments, by health and social care providers, by professionals and by individuals themselves.

* Calculated based on an exchange rate of £ to € of 1.1564 (17/07/2009)

2 The solution

Nutritional support, including ONS, should be an integrated part of the solution to tackle the problem of malnutrition.

- Good nutrition is a vital part of care. Good nutritional care encompasses nutritional screening to identify patients at nutritional risk, and care planning to ensure that patients receive the right nutrition, at the right time. Nutritional intervention takes many forms from providing appetising, nutritious food, to helping people eat and drink to providing individually tailored artificial nutrition support.
- There is consistent evidence that ONS are an effective strategy for the management of malnutrition in hospital and community patients, older people and people who are undernourished.
- ONS have been shown to improve nutritional intake, increase or attenuate weight loss and improve function e.g. walking distances or activities of daily living.
- ONS have been shown to reduce complications, readmissions to hospital and mortality.
- ONS are a cost-effective method of nutrition support.

Key Messages

- There is a wide body of evidence that demonstrates that ONS can be used to help tackle the problem of malnutrition.
- Data on the benefits of dietary counselling and food fortification in the management of malnutrition are lacking; ONS have been shown to be more effective.
- Appropriate use of ONS can achieve cost savings across healthcare systems, especially when used as part of a nutritional screening programme.
- ONS should be used as part of nutritional care in people identified at risk of malnutrition or in people who are malnourished, across all settings, and in the context of nutritional care plans.

3 Implementation

Greater effort is needed to develop evidence-based practical guidelines for nutritional care, to overcome the barriers to implement guidelines and to share good practice.

- Numerous national and professional guidelines already exist that recognise the need to systematically identify patients at risk of malnutrition and to provide appropriate nutritional care. Many of these guidelines recommend the use of ONS as an integral part of patient and disease management. Some guidelines may need to be updated to reflect new evidence.
- Guidelines are not always sufficiently recognised and endorsed at a higher level within healthcare systems (senior management) resulting in a lack of resources and sustained effort to embed these guidelines into every day patient care.

- Good practice in nutritional care does exist in the health and social care system but it is not always easy to identify examples. It is not clear if this is due to a gap between guidelines that are in place but that have not been fully implemented or due to failure to document and share existing good practices.

- Implementation of guidelines for good nutritional care have been shown to have positive outcomes in terms of a reduction in the prevalence of malnutrition, reduced hospital length of stay and costs.

Key messages

- Continued effort is needed to ensure guidelines are updated to reflect the evidence base; to integrate good nutritional care into guidelines for specific diseases (e.g. nutritional support as part of cancer care guidelines); and to ensure that these guidelines are recognised and established as a credible and essential basis for good patient care.

- Translation of "academic guidelines" into practical advice for healthcare professionals is needed to achieve both improved patient outcomes and to ensure appropriate use of resources.

- Sustained effort is needed to implement guidelines in practice; the link between guidelines, practical advice and individual care plans is critical and should be regularly audited and evaluated to identify challenges and successes which should be acted upon and shared.

- Healthcare professionals need the resources, skills and opportunity to share good practice.

Background and context

The problem

Malnutrition can be defined as 'a state of nutrition in which a deficiency, excess (or imbalance) of energy, protein and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function, and clinical outcome'[3]. This definition encompasses overweight and obesity as well as under-nutrition. In recent years, by far the most attention in affluent countries has been paid to the problem of overweight and obesity - both of which are very visible in our communities. What may surprise many to know is that the issue at the other end of the spectrum, under-nutrition, also constitutes a major problem - which is at least as big as that of obesity - particularly in hospitals, care homes and communities where diseases and disabilities are common. Reflecting common practice in this report the term "malnutrition" is used synonymously with under-nutrition and nutritional risk.

Due to lack of adequate nutrition, acute or chronic disease and/or treatment, an individual may move from a good nutritional status to frank malnutrition in a matter of weeks, months or years. Elia suggests that severe malnutrition/emaciation may be clinically obvious but that as uncertainty exists in detecting lesser degrees of malnutrition (due to the lack of universally agreed criteria) the concept of 'risk' is useful[4]. Risk is defined as 'a measure of the likelihood that malnutrition is present or likely to develop'[4], thereby aiming to identify those individuals who are at risk of adverse outcome and who might benefit clinically from nutritional support[5]. The act of regular nutritional screening applies a test to a whole population (e.g. admissions to hospital or nursing home) to identify individuals who are 'at-risk' of malnutrition to ensure that timely and appropriate nutritional care is provided. Figure i illustrates that nutritional screening is intended to identify individuals who are 'at risk' of malnutrition across the spectrum of nutritional status. An 'at risk' status may result from the effects of disease or treatment, or may arise in a well-nourished individual due to an acute event such as sustaining an injury and undergoing emergency surgery that will result in no nutritional intake for a period of time. Individuals identified as high risk are likely to be but are not necessarily frankly malnourished, although a more detailed nutritional assessment should be undertaken for 'at-risk' individuals to establish the degree of malnutrition present, its causes and best course of action.

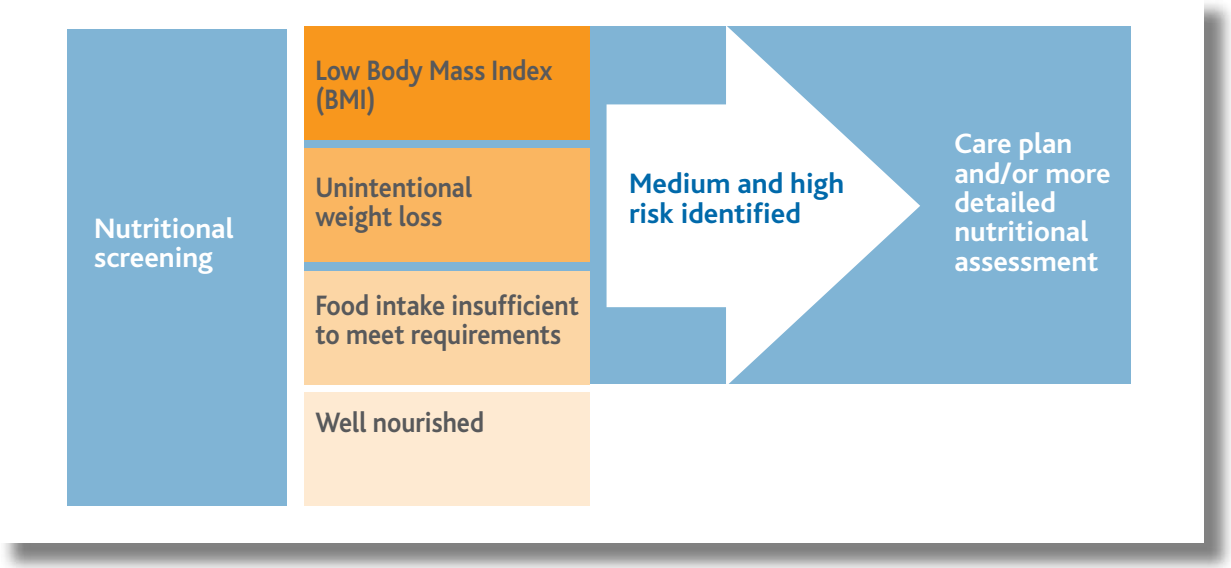


Figure i: Individuals identified as 'at-risk' of malnutrition through nutritional screening may have different degrees of malnutrition

Different screening tests or tools use different criteria and/or cut off points and/or weightings to detect nutritional risk. Furthermore, some tools have been developed for specific settings or for use by specific healthcare workers[4]. This means that not all individuals identified as 'at-risk' are at the same point on the malnutrition spectrum (this is true even if a single tool is used). Stratton et al recommend that wherever the terms 'malnutrition' or 'at-risk' of malnutrition are used they should be defined or explained[1]. In practice, these terms and nutritional risk are often used interchangeably. Where available this report includes information on the type of screening test used, the criteria used to define nutritional risk/malnutrition, the patient groups and the clinical setting as reported in original texts to help avoid confusion. In many cases this information is included in the detailed tables in the Appendices.

Nutritional risk is of relevance because:

- It is widespread, particularly in patients admitted to hospital, residents in care homes, and people receiving community care
- It has severe clinical consequences: weight loss, functional impairments, impaired quality of life, increased complications, and higher mortality
- It results in economic consequences from increased consumption of healthcare resources due to management of complications, prolonged length of stay in hospital, increased admission to hospital, need for community care and thereby increased costs
- It is frequently under-recognised and therefore under-treated
- It is particularly common in the older person. Given that the population is aging (the number of older people in Europe aged 65-79 will increase by +37.4% by 2030[8]) and that the problem is often unrecognised, this means that the costs to healthcare systems are likely to escalate at an unprecedented rate due to adverse clinical consequences

Maintaining function in older people is considered a high priority by the World Health Organisation to help prevent decline and institutionalization (Figure ii).

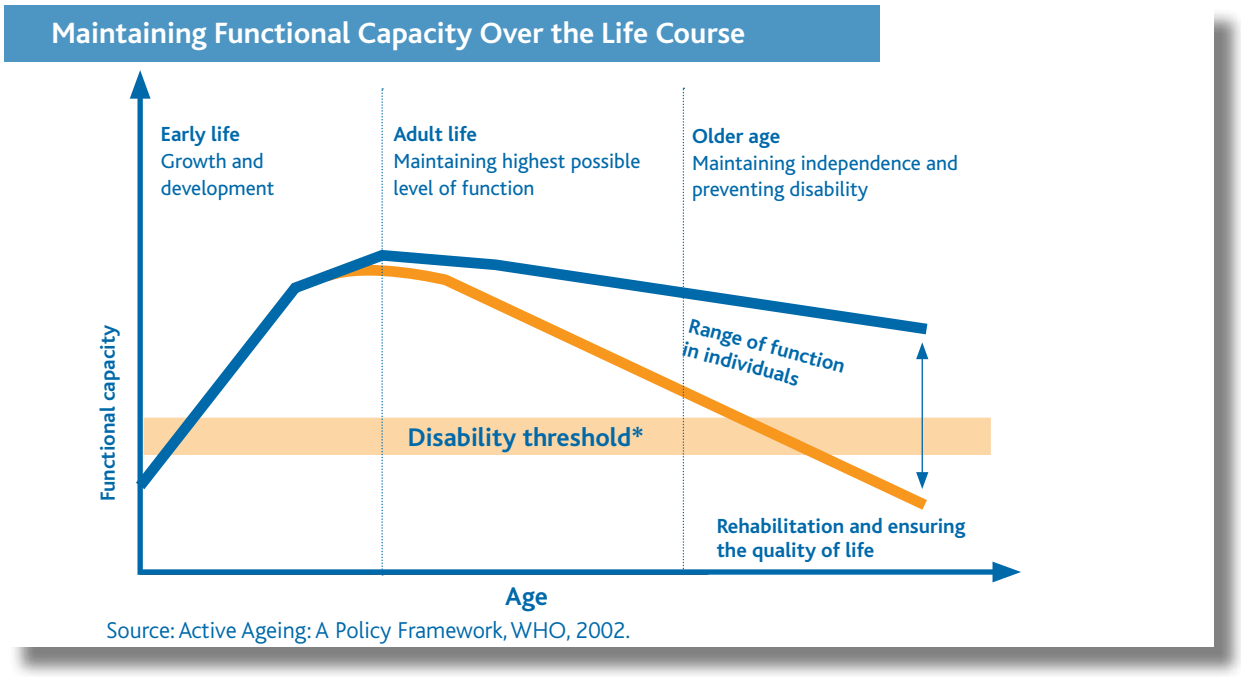


Figure ii: Maintaining functionality and independence.

In recent years, the issue of malnutrition has begun to be recognised at European level. In 2003 the Council of Europe Committee of Ministers adopted a resolution on food and nutritional care in hospitals[9]. In 2008, malnutrition was incorporated into two White Papers where traditionally attention on nutrition was restricted to the problem of obesity. This means that there is growing awareness that malnutrition is a problem that needs to be tackled. In June 2009, representatives of health ministries from the EU Member States and several other stakeholder groups issued a declaration and a set of action points under the banner "Stop disease-related malnutrition and diseases due to malnutrition!" (www.european-nutrition.org). Later in 2009 the Council of Europe Belgian delegation of the Committee of Experts on Nutrition, Food and Consumer Health published 'Nutrition in care homes and home care. Report and recommendations: from recommendations to action'[10].

The solution

The central factor in the development of malnutrition is nutritional intake that is insufficient to meet requirements. This can arise due to a number of different reasons related to disease and disability impacting on food intake, losses of nutrients and/or increased requirements. Although in some cases improvement of the quality or quantity of food supplied can ameliorate the problem, in many cases the person concerned is simply unable or unwilling to consume sufficient normal food to meet their requirements and maintain a healthy nutritional status. In this case, it is vital to consider other options to improve nutritional intake (see Figure iii). Dietary counselling, conventional food and ONS are all considered as oral strategies for improving nutritional intake. When patients are unable to consume sufficient via the oral route, then tube feeding may be required. In cases of severe gut dysfunction, nutrition given orally or via tube feeding is not an option and intravenous (parenteral) nutrition will be needed.

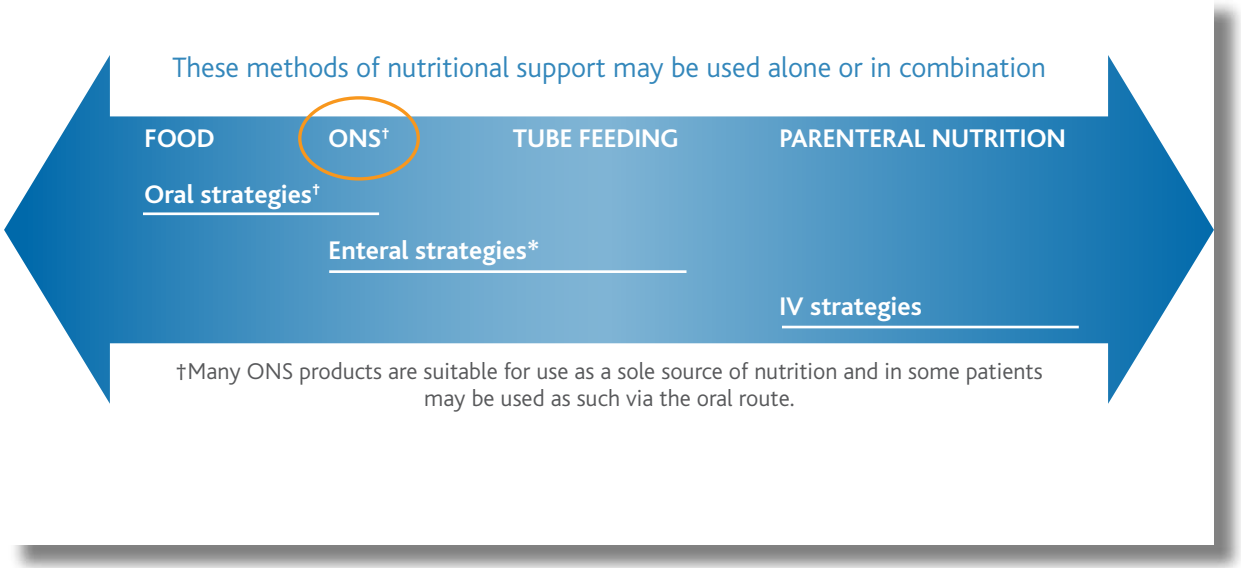


Figure iii: The spectrum of nutritional support (*ESPEN definition of Enteral Nutrition includes ONS)

The challenge

There is a growing body of evidence demonstrating the benefits of nutritional intervention on improving nutritional status, reducing adverse health outcomes and reducing the economic burden of malnutrition on society. Evidence-based national, international and professional guidelines for nutritional intervention strategies in general and specific patient populations are also widely available. However, implementation of good nutritional practices remains patchy, and poor awareness of the value of nutritional care, and especially ONS, is prevalent. This in combination with pressure on finite healthcare budgets which places nutritional care funding under threat will lead to poorer health outcomes and higher healthcare costs in the longer term.

To further strengthen the position of nutritional care, awareness of the added value of evidence based, practical nutritional care (economic benefits as well as clinical) must be explicit and decision makers must be convinced. The increasing recognition of malnutrition as a public health issue on the political agenda means that the time is right for action by governments, health and social care organizations and healthcare professionals.

This document

Care providers and payers need access to information that helps them to make informed, evidence-based decisions about the types of care that they provide. This report aims to synthesise all relevant information on the rationale for and value of ONS as a key strategy in the management of malnutrition. It is intended to provide all stakeholders with an up-to-date and practical summary of the evidence base.

Version 1 of this document prepared in 2009 contains the first attempt to gather relevant guidelines relating to ONS, as well as examples of implementation of guidelines and good practice. This updated version for 2010 includes further examples, however we recognize that there are gaps - either real gaps or due to difficult accessibility of documentation. We hope this will be the starting point to encourage further documentation and sharing of information.

A pragmatic approach was used to identify relevant publications for inclusion. This document draws on the key elements of a comprehensive systematic review of the scientific evidence base for the management of disease-related malnutrition[1]. It builds on it by adding recent data on the prevalence, causes and consequences of malnutrition as well as the nutritional, functional, clinical and economic benefits of ONS. Interpretation of key recent publications has been included such as the 2009 Cochrane review on protein and energy supplementation in older people 'at-risk' from malnutrition[11].

SECTION 1

Prevalence, causes, consequences and costs of malnutrition

Summary

Malnutrition is not a new problem and with an ageing population it continues to be a major public health concern. It is not confined to developing countries, but is highly prevalent in the European healthcare system.

- Based on work done in the UK (showing > 3 million people are at risk of malnutrition[12]) and extrapolated to the rest of Europe, an estimated 33 million people are at risk of malnutrition in Europe[13] (20 million in the European Union (EU)[14]).

- Malnutrition is prevalent across all healthcare settings particularly in patients in hospital and in institutions. Large-scale studies show that about one in four patients in **hospital** are at risk of malnutrition or are already malnourished, and up to 90% of residents in **long-term care** in the community are at risk. People living at home are also at risk (13-30%). In the UK 93% of the estimated three million people malnourished or at risk of malnutrition live in the community[12].

- Malnutrition is prevalent across all ages but is particularly a problem in older people. In the UK Nutrition Screening Week Survey in 2008 the risk was 40% greater in patients aged 65 years and over than those aged less than 65 years[15].

- Malnutrition is common across a variety of patient groups e.g. in patients with gastrointestinal, respiratory and neurological disease. It is particularly prevalent in people with cancer, where rates of malnutrition have been found to be twice as high when compared with patients without cancer.

Poor food and nutrient intake due to disability and disease are at the heart of the cause of malnutrition, for example patients with cancer may have altered taste, nausea and anorexia due to treatment; patients with stroke or other neurological conditions may have swallowing difficulties or problems with self-feeding.

Malnutrition leads to physical and psycho-social effects that in turn contribute to increased morbidity and mortality. Significantly higher mortality and complication rates have been found in 'at-risk' patients compared with 'not-at-risk' patients (12% vs 1%, 30.6% vs 11.3% respectively)[16]. Average length of hospital stay may be increased by 30% in malnourished patients[17].

It is thus unsurprising that malnutrition is costly to the individual, to society and to the economy. The estimated cost of disease-related malnutrition in Europe is €170 billion[13] or €120 billion in the EU[14]. This estimate is based on economic evidence from the UK showing costs for managing patients at risk of malnutrition exceed €15 billion[18].

A variety of methods or tools exist to detect malnutrition risk in practice. Generally these follow the basic principles of measuring weight/height and/or Body Mass Index (BMI), weight loss over a prior period of time and recent appetite/food intake. They provide reliable ways for healthcare professionals to identify patients who are malnourished or at risk of malnutrition. However, malnutrition still often goes undetected and untreated in hospitals, care homes and in people living in their own homes all across Europe.

Key Messages

- Malnutrition is a universal and costly public health problem in Europe, but is still largely unrecognised by individuals, by health and social care systems and by governments.
- Malnutrition affects many people across all healthcare settings, from older people living in the community to patients in hospital with specific conditions.
- Malnutrition causes death, disability and discomfort; its far reaching consequences increase the burden and cost of care to individuals and society.
- The problem of malnutrition needs to be tackled at every level; by governments, by health and social care providers, by professionals and by individuals themselves.

1.1 Prevalence of malnutrition

Malnutrition is not a new problem

- A systematic analysis of a large number of studies reporting on malnutrition according to healthcare setting, clinical condition and diagnostic criteria from as early as 1977 revealed a prevalence of up to 60% in hospitals and nursing homes[1].

One in four hospital patients are malnourished or at-risk of malnutrition

- Despite differences in the age of subjects there is consistent and overwhelming evidence that malnutrition is a widespread problem in hospitals across Europe (Tables A1.1 and A1.2 in the appendix pages 110 and 115) (Figure 1.1). Variation in prevalence figures may in part reflect the different methods that exist to detect malnutrition risk.

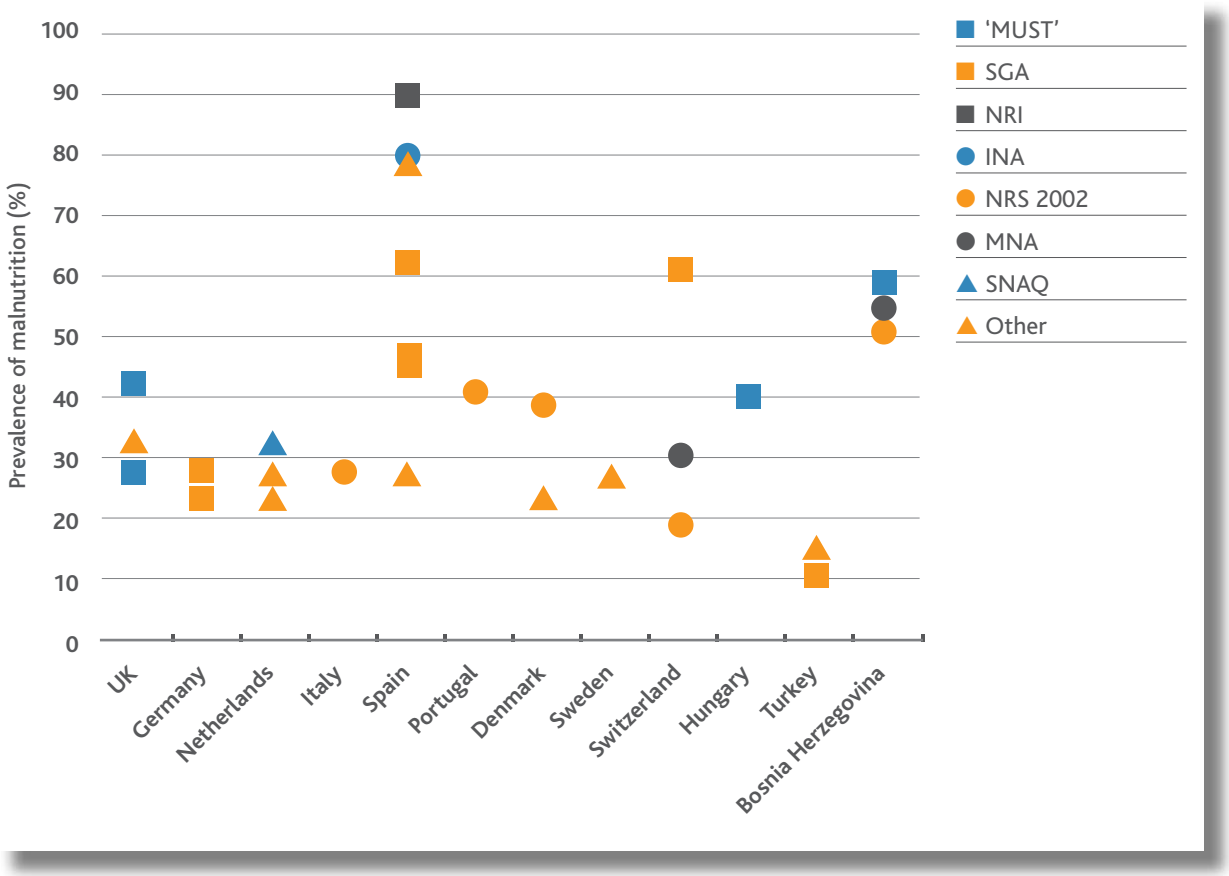


Figure 1.1 Prevalence of malnutrition in hospitals in European countries using different screening methods (see Table A1.1 for full details page 110)

- Large-scale multi-centre surveys (n >5000 in each study) show that about one in four (18 - 28%) hospital patients are malnourished or at risk of malnutrition[15;19-21].

- In smaller studies, rates of malnutrition and risk of malnutrition of up to 90% have been reported in hospital patients (Table A1.1 and A1.2 pages 110 and 115)[22;23].

- Malnutrition is common across a variety of hospital **ward types**, with a particularly high prevalence in care of the elderly, oncology, medical and gastroenterology wards (Figure 1.2)[15;20;24].

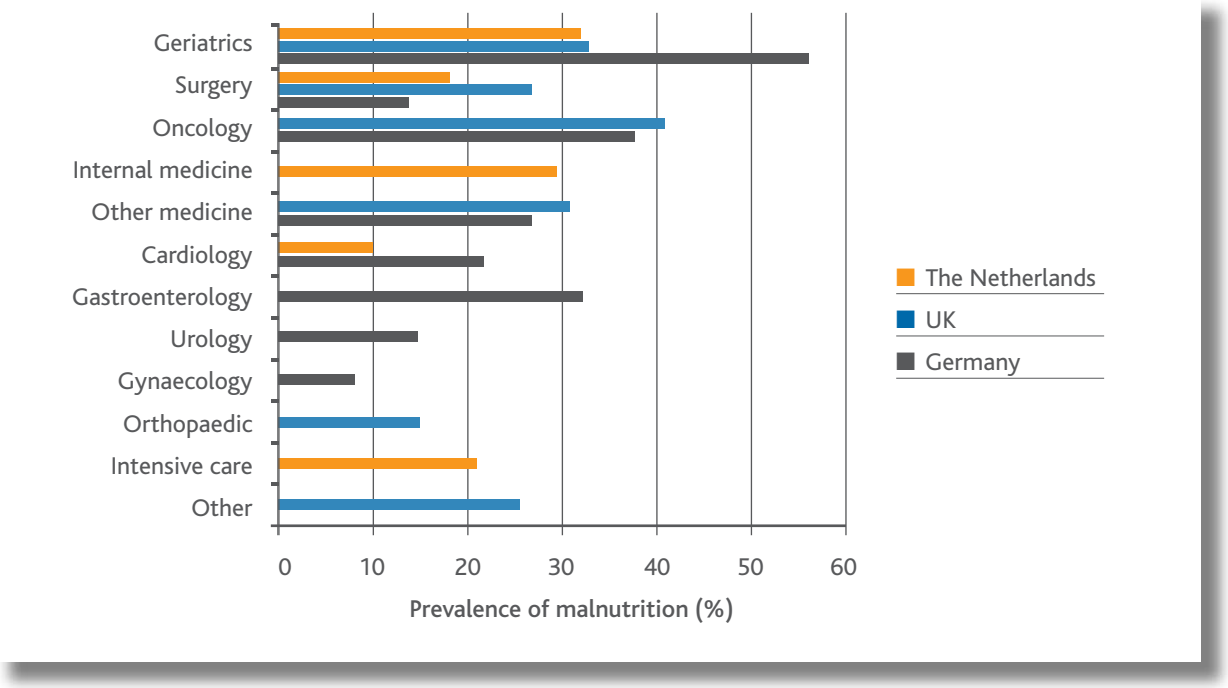


Figure 1.2 Prevalence of malnutrition according to hospital ward/primary admitting speciality
(The Netherlands n = 8028 (defined by BMI, undesired weight loss, nutritional intake*), UK n = 5089 ('MUST' medium + high risk), Germany n = 1886 (SGA B+C))[20;21;24] (*see details in Table A1.1 - page 110)

Malnutrition is common in outpatients

- Between 7-16% of patients across hospital outpatient departments have been found to be malnourished or at risk of malnutrition (Table A1.3 page 116)[25;26].

- The prevalence varies considerably depending on the department:

  - A large multicentre study in The Netherlands (n = 2288, 9 hospitals) found the highest prevalence of malnutrition in oral maxillofacial surgery outpatients (17%) although this could be an underestimate as no patients with head and neck cancer were present on the day of the survey (Figure 1.3)[25].
  - In a study of 1,000 outpatients with cancer in Italy, 39.7% were found to have experienced significant weight loss (10%) and 33.8% were found to be at nutritional risk[27]. A small study (n = 207) in medical oncology outpatients in a UK hospital found that the prevalence of risk of malnutrition ranged from 45 - 83% depending on the tumour site[28] (see Table A1.3 for details page 116).
  - Depending on the severity of disease as many as 1 in 4 patients with Chronic Obstructive Pulmonary Disease (COPD) outpatients are malnourished or at risk of malnutrition[29;30].
  - About 1 in 3 adult gastroenterology outpatients have been identified as at risk of malnutrition[31].

- Routine screening for nutritional risk in hospital outpatient departments offers the opportunity to identify many more at risk patients, and potentially at an earlier point in their disease, due to the large number of patients attending outpatients compared to hospital admissions.

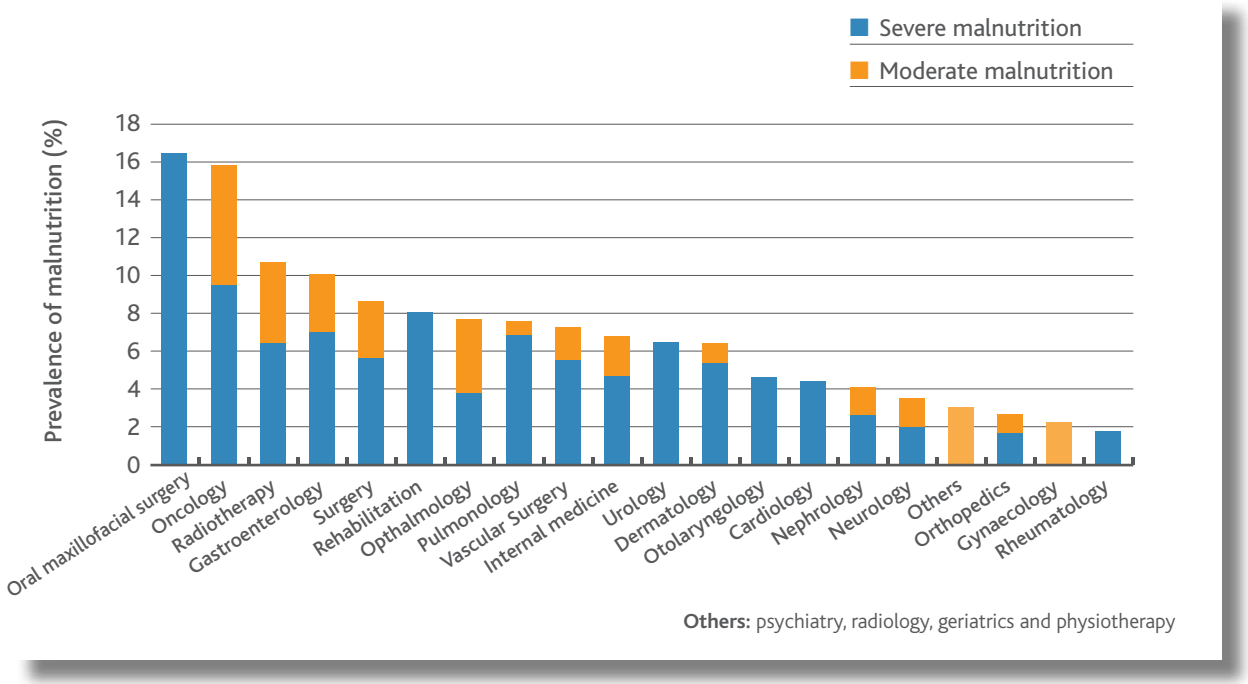


Figure 1.3 **Prevalence of malnutrition in outpatient departments in The Netherlands (n = 2288)**[25].
(see Table A1.3 for details page 116)

In the community the risk of malnutrition can be over 90% depending on the care setting

- The high prevalence of malnutrition risk on admission to hospital emphasises the lack of adequate nutritional care in the community, where the majority of undernourished individuals live. In the UK, for example, 93% of the estimated three million people malnourished or at risk of malnutrition live in the community[12].

- Older people in care homes appear to be at highest risk of malnutrition. Estimates, using a variety of methods, suggest that between 17 - 97% of residents in long-term care facilities are at risk or already malnourished (Figure 1.4) (Table A1.4 page 117).

- Studies in the UK using 'MUST' show that the risk appears to increase with increasing dependency (35-46% in nursing homes vs 22-36% in residential homes) (Table A1.4 page 117). In a study of the prevalence of risk of malnutrition in a Primary Care Trust in England (n = 703) a significantly higher prevalence was found in nursing care compared with residential care (38% vs 25%, p = 0.001)[32].

- Malnutrition risk is also common in free-living older people (13-30%) (Table A1.6 page 122).

- A prevalence of risk of malnutrition of 12-14% (using 'MUST') has been found in residents of sheltered accommodation in the UK (Table A1.5 page 121) and 31-37% in recipients of meals on wheels in the UK and Ireland (using 'MUST' and MNA) (Table A1.6 page 122)[33;34] .

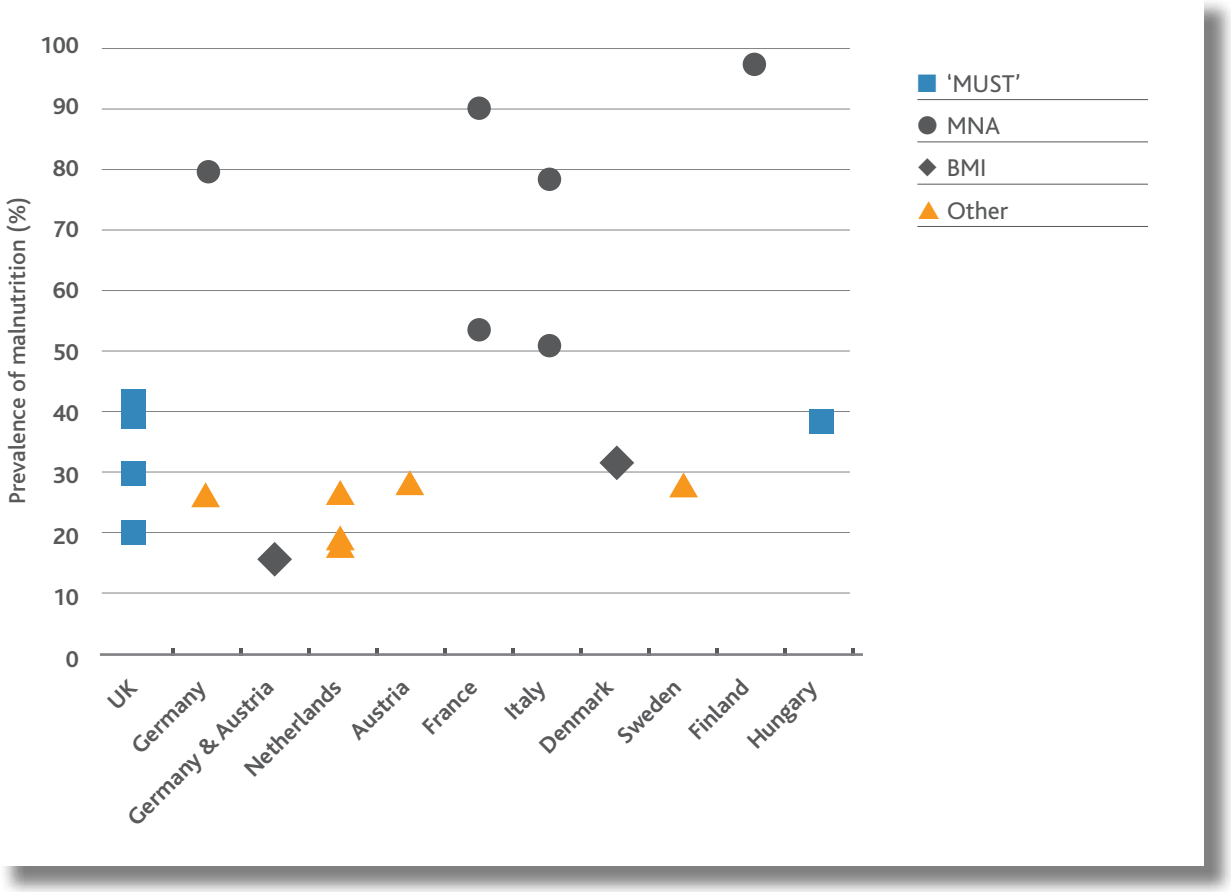


Figure 1.4 **Prevalence of malnutrition in care homes in European countries using different screening methods** (see Table A1.4 for full details page 114)

Malnutrition is prevalent in a wide variety of diseases

- Recent large-scale multi-centre surveys consistently show that malnutrition risk is common across many **diagnostic groups** in hospitals, with a particularly high prevalence in patients with cancer, gastrointestinal, haematological, neurological and respiratory disease (Figure 1.5)[20;21].

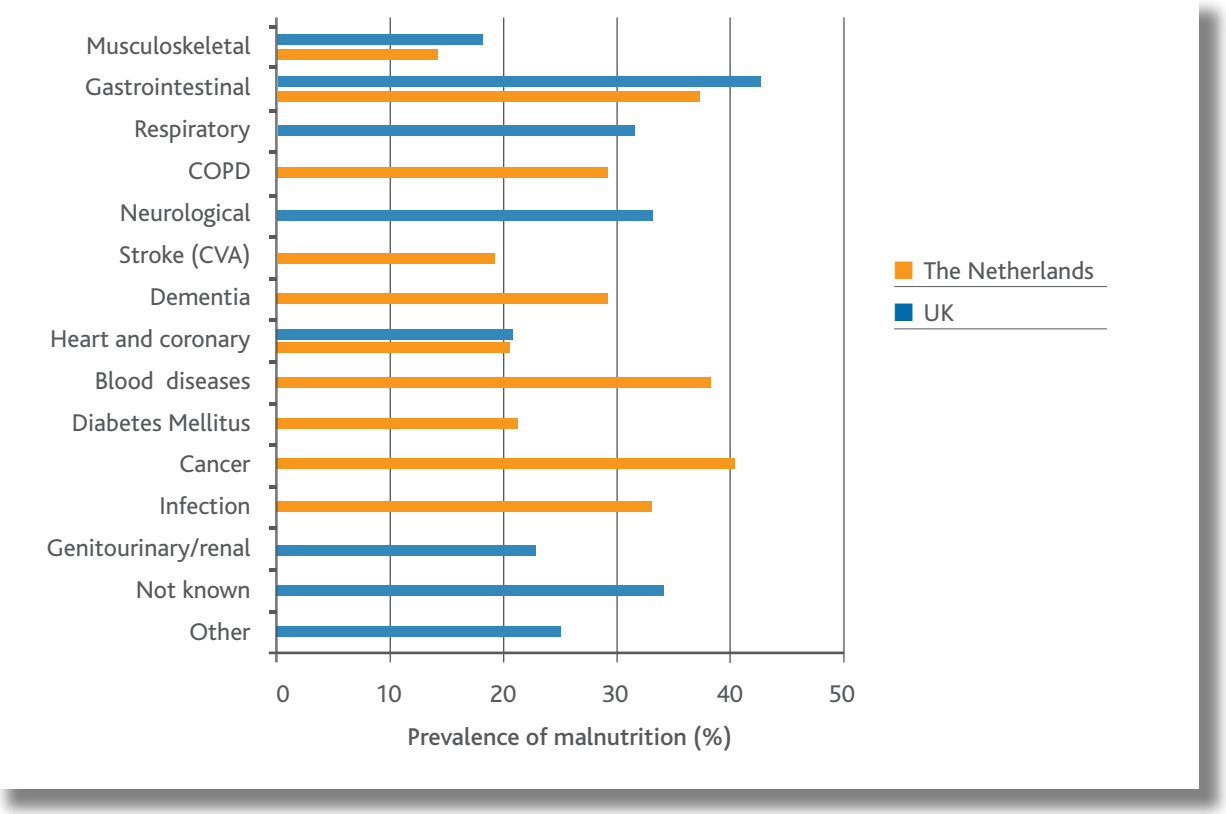


Figure 1.5 Prevalence of malnutrition in hospital by diagnosis (UK n = 9290 ('MUST' medium + high risk), The Netherlands n = 8028 (defined by BMI, undesired weight loss, nutritional intake*))[20;21] (*See details in Table A1.1 page 110)

Cancer

- Not unexpectedly, the rate of malnutrition is more than twice as high in patients with malignant disease (n = 54) than in patients with non-malignant disease (n = 448) (50.9% vs 21.0%, p < 0.0001, assessed using Subjective Global Assessment (SGA))[35]. Similarly in the 2008 UK Nutrition Screening Week risk of malnutrition was significantly higher in patients with cancer than those without cancer (40% vs 26%, p < 0.001)[15].

- Reports of the prevalence of malnutrition in patients with cancer vary according to cancer site, stage or treatment[36]. In a prospective, observational multicentre study conducted in French cancer centres (n = 1545 inpatients and patients admitted for 1 day (outpatients), median age 59.3 ±13.8 years, 23.4% aged 70 years) the overall prevalence of malnutrition was reported to be 30.9% (with 18.6% cases classed as moderate malnutrition and 12.2% as severe)[36]. Table 1.1 shows the prevalence of malnutrition according to tumour type.

- In a study of patients with locally advanced or metastatic cancer in Spain (n = 781, median age 62 years (range 19-92)) using a Patient-Generated Subjective Global Assessment (PG-SGA) more than 50% of patients with cancer were found to have moderate or severe malnutrition[37].

- Sixty eight percent of patients receiving palliative home care services in the Stockholm region were found to be at risk of malnutrition (based on modified NRS-2002) with prevalence ranging from 52 - 76% depending on the tumour site[38].

Table 1.1 Prevalence of malnutrition in expert cancer centres in France by tumour type (adapted from Pressoir 2010[36])

Tumour type	Overall prevalence of malnutrition %	Prevalence of moderate and severe malnutrition %
Breast	18.3	11.2 + 7.1
Head and neck	45.6	22.5 + 23.1
Colorectal	31.2	22 + 9.2
Haematological	34.2	26.3 + 7.9
Upper digestive	49.5	26.3 +23.2
Gynaecological	32	16.4 +15.6
Lung	40.2	21.9 + 18.3
Other*	27	18 + 9

*Prostate, urinary, brain, thyroid, testicular and kidney cancers; trunk and limb sarcomas; melanoma; other thoracic or abdominal cancers; unclassified tumour.

	Age ≤70 years of age	Age >70 years of age
Moderate malnutrition	Weight loss over last 6 months ≥10% or BMI <18.5 kg/m²	Weight loss over last 6 months ≥10% or BMI <21 kg/m²
Severe malnutrition	Weight loss over last 6 months ≥15% or BMI <16 kg/m²	Weight loss over last 6 months ≥15% or BMI <18 kg/m²

Definitions of malnutrition used

Malnutrition is found in almost one in five people with intellectual disability and mental health problems

- In UK adults aged 20 years and over with intellectual disability the prevalence of 'underweight' (BMI ≤ 20 kg/m²) is 18.6%[39].
- In the UK (data largely reflects England, n = 320) the prevalence of malnutrition risk in mental health units is 19% (acute 31%, long stay/rehabilitation 21% and mixed acute and long stay/rehabilitation 17%) (Table A1.7 page 123)[21].

Older people are at significantly higher risk of malnutrition

- Malnutrition affects all age groups but increasing age is associated with an increased risk of malnutrition[21;24;40-45]. Older people are vulnerable to malnutrition as they often have several co-morbidities that are often chronic and progressive[12]. In the UK Nutrition Screening Week Survey in 2008 the risk was 40% greater in patients aged 65 years and over than in those aged less than 65 years (32% vs 23%, p = 0.001)[15].

- The prevalence is high in older people in hospital (Table A1.2 page 115) but malnutrition is also of concern in older people in the community (Tables A1.4-A.1.6 pages 117, 121 and 122). In the UK the Nutrition Screening Week survey found that one in three people admitted to care homes are malnourished or at risk of malnutrition[21].

- Results from a world-wide international pooled database on malnutrition in older people according to the MNA (n = 6257, 27 datasets, mean age 82.3 years) found that about two thirds of older people are either at risk or already malnourished (overall 22.8% malnourished and 46.2% at risk). The prevalence in community-dwelling older people was 5.8% and 50.5% in patients in recuperative care[46].

- In Italy older patients with mild cognitive impairment (MCI) (n = 65) and dementia (n = 84) are more likely to be malnourished than those with no cognitive impairment (NoCI) (n = 439) (dementia 59.5% vs NoCI 15%, p < 0.001 and MCI 44% vs NoCI 15%, p < 0.001)[47].

- The ageing population is a concern (the number of older people in Europe aged 65-79 will increase significantly after 2010 and until around 2030 (+ 37.4%)[8]) as failure to address the issue of malnutrition now will only allow the situation to get worse as this high risk population increases.

Malnutrition still goes undetected and untreated in hospital inpatients

- As many as 40% of patients found to be at risk of malnutrition had not been screened for nutritional problems in a Danish hospital[48].

- Rasmussen (2004) found that nearly 40% of patients in internal medicine, gastrointestinal and orthopaedic surgery departments were at nutritional risk and two thirds did not have a nutrition care plan or monitoring of dietary intake[49].

- A prospective study of 395 newly admitted patients to general medical wards in a Dutch hospital revealed that nutritional assessment and intervention were not sufficiently applied by any professional (medical doctor, medical student, nurse) at any stage of the pre-, actual and post- hospitalisation period[50].

- In one UK hospital only 69% of patients were screened for malnutrition on admission with only 45.2% of high risk patients appropriately referred to dietetic services. In almost 40% of high risk cases no action was taken[51].

- In the 2007 UK Nutrition Screening Week Survey most hospitals reported that in spite of a screening policy being in place (89%), weighing (assessment of body weight on admission) on all wards was carried out in less than half of the hospitals surveyed (Figure 1.6)[21].

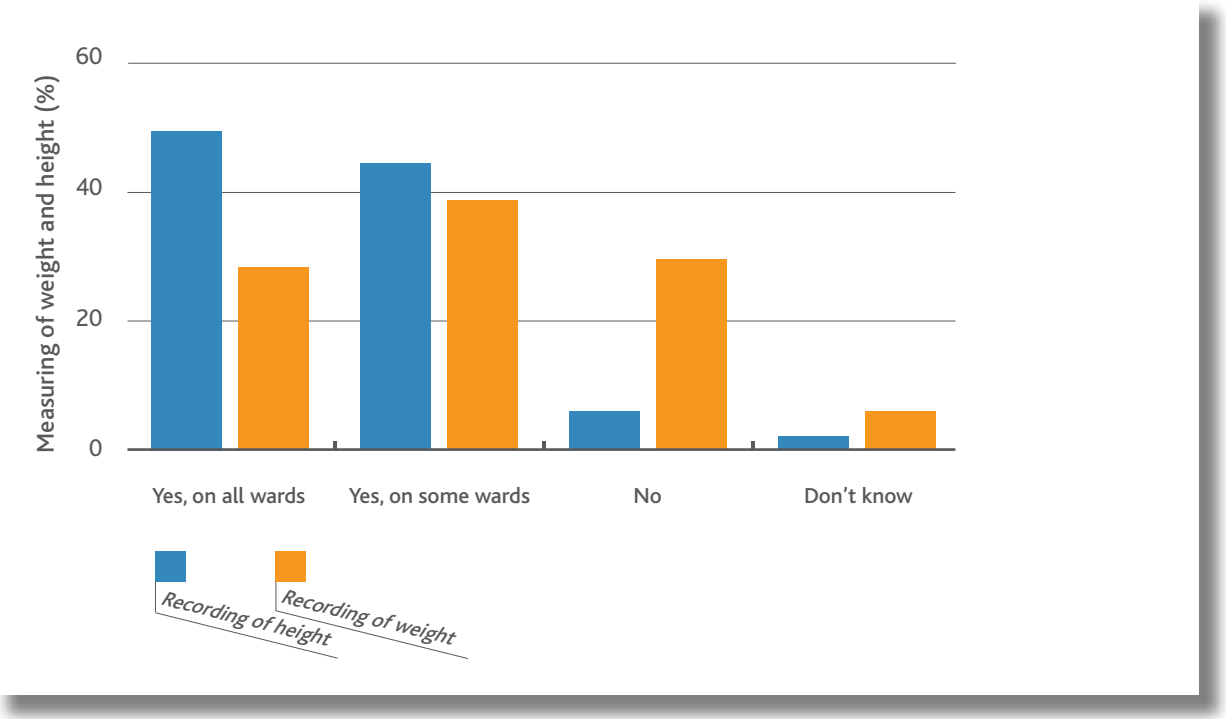


Figure 1.6 Measurement of height and weight in UK hospitals participating in the National Nutrition Screening Week Survey in 2007 (adapted from Russell 2008)[21].

Malnutrition still goes undetected and untreated in the community

- In a multi-centre survey of hospital outpatients in The Netherlands (n = 2288, 9 hospitals) only 17% of severely malnourished and 4% of moderately malnourished patients reported receiving dietetic treatment.
- In a Dutch study nutritional treatment interventions were applied in fewer than half of all the malnourished patients identified across hospitals, nursing homes and patients receiving care in their own home. In fact, only 20% of patients in their own home received appropriate treatment[52].
- In a large international multi-centre study (n = 3248, 49 care homes) despite screening on admission (undertaken more frequently in German (94%) than Dutch (88%) and Austrian care homes (86%)) less than 50% of all residents identified as malnourished received nutritional interventions (Germany 46%; Austria 40% and The Netherlands 46%)[53].
- An audit of the use of ONS in care homes in the South of England (n = 1176, 43 care homes) found that most residents identified as at risk of malnutrition did not receive ONS in the four weeks prior to the audit and none were under the care of a dietitian (39% of residents malnourished (medium and high risk); 8.2% of all residents received ONS). Further work is needed to establish if other forms of nutrition support are used[54].

Malnutrition is more than just weight loss

- Deficiencies of specific micronutrients (vitamins and minerals) are common and should be considered part of malnutrition[55].

- Vitamin D deficiency is one of the most common nutrient deficiencies among older people[56;57]. Low vitamin D levels (< 20 ng/ml) have been found in nearly 50% of independent community-dwelling older men and women[58].

- Research findings in targeted population groups indicate that vitamin D deficiency is prevalent in 57% of medical inpatients, in 49% of patients admitted to sub-acute rehabilitation facilities and in 23% (12% deficient, 11% severely deficient) of patients with gastrointestinal disease[59-61].

- Poor status of a range of micronutrients has been reported in the UK National Diet and Nutrition Survey (people aged 65 years and over), for example[62]:

    - 40% of older people (both free-living and institutionalised) had low biochemical status of riboflavin
    - 40% of older people living in institutions and 15% of free-living older people had low status of vitamin C and folate
    - 52% of older men and 39% of older women living in institutions had haemoglobin levels below the World Health Organisation (WHO) cut-off for anaemia (13.0g/dl for men and 12.0g/dl for women)
    - 15% of older men and 7% of older women living in institutions had plasma zinc concentrations below 10µmol/l indicating zinc deficiency

- Plasma zinc and selenium levels below reference levels have been observed in hospitalised older patients with hip fracture and older people attending day care centres in the UK[63].

1.2 Causes of malnutrition

The main causes of malnutrition are related to lower food intake and thus lower intake of macronutrients e.g. energy and protein, and micronutrients e.g. vitamins, minerals and trace elements, and a higher need for some nutrients due to malabsorption, altered metabolism, or excess losses as a result of acute or chronic disease. Treatment of the underlying condition is essential. In addition, an appreciation of the extent of the problem of poor food and nutrient intake and its causes is necessary to understand how the problem may be overcome.

Inadequate food intake is common in patients in hospitals and care homes

- Inadequate food intake is common in hospitals despite adequate food provision[64-66].
- The NutritionDay survey conducted in European hospitals (748 units in 25 countries, total n = 16455) showed that more than 50% of patients did not eat their full meal provided by the hospital[67].
- In a longitudinal observational study of 100 older (mean age 81.7 years (SD 7.2)) inpatients in an inner city hospital elderly care unit in the UK, patients were judged to be eating inadequately at 67% of assessments (285 out of 425) carried out during the study period of four weeks[68].
- A cross-sectional observational study in Sweden found eating difficulties to be common in hospital patients (49%) and special accommodation residents i.e. nursing home-type care (56%). Patients with a low BMI had significantly more eating difficulties than patients with normal or high BMI[69].
- Serious eating problems exist in 68% of patients with cancer, with lower than usual food intake reported by 48% of patients[37].
- Poor food and nutrient intake may be due to disability and disease, for example patients with cancer may have altered taste, nausea and anorexia due to treatment, patients with stroke or other neurological conditions may have swallowing difficulties or problems with self-feeding.
- In a recent large survey (NutritionDay) in Austrian and German nursing home residents (n = 1922) one in three residents ate ≤ 50% of their lunch on the day of the assessment[70].

Energy intake is compromised and fails to meet recommended intake levels

- Stratton et al (2003) collated studies that measured food intake in a variety of patient groups, both in hospital and the community and demonstrated that in hospital patients energy in takes fell consistently short of requirements across a spectrum of diseases. In community patients intake was better but still of concern in a number of patient groups[1].
- In community-based older people with medium and high risk of malnutrition (identified using 'MUST') total daily energy intake was found to be significantly lower than the national average for older people (1368 (SD 513) kcal vs 1628 (SD 464) kcal, z score $p < 0.004$)[71].

Protein intake is compromised, particularly in older people

- Older people and people with compromised health have difficulty meeting recommended intakes for protein, particularly hospitalised older people and orthopaedic patients[1;63;64;72;73]. When compared with typical daily intakes in the healthy population it is clear that protein intake in a variety of patient groups is severely compromised[1].

- Older people and people with a variety of diseases also have a special need for protein, with requirements above those needed by younger healthy individuals[74-76], thus the protein intake of many patients may fall considerably short of their needs.

- In a study of nutritional status of older people in low-level care facilities in Australia (semi-independent ambulatory residents; similar to residential care homes in the UK) (n = 95, mean age 85.8 ± 6.6 years) 3-day weighed food intake showed that 30% of residents consumed less than the estimated average requirement (EAR) for protein (i.e. 46g/day). However, when intake was compared with a requirement of 1g/kg/day of protein, 77% of residents were found to have an inadequate intake[77].

Micronutrient intake is compromised in patients in the community and in hospital

- Low intakes (below reference values) of some but not all micronutrients are evident in a substantial proportion of free-living and institutionalised older adults and in those at risk of malnutrition[55;78]. Over 80% of older adults have intakes below the reference nutrient intake (RNI) for potassium, magnesium, copper and vitamin D (see Figures 1.7 and 1.8).

- Assessment of energy and nutrient intakes in 52 Swedish nursing home residents showed that of 16 micronutrients considered, males had a mean intake below the Swedish Nutrition Recommendations (SNR) for nine nutrients and females for eight nutrients. Intake of vitamin D, vitamin E, folic acid and selenium were very low, reaching only 40-60% of the SNR[79].

- Hospital patients, particularly older hospital patients have lower than recommended intakes of a range of vitamins and minerals. In female orthopaedic inpatients median intakes of vitamin D, magnesium, potassium and selenium were found to be even below the lower reference nutrient intake[i,73]. Compared with day centre visitors, hospitalised hip fracture patients had significantly lower micronutrient intakes e.g. 29% lower vitamin B_6, 23% lower selenium, 21% lower iron, 20% lower calcium and 20% lower magnesium[63].

- In community-based older people with medium and high risk of malnutrition (identified using 'MUST') mean total daily intake for micronutrients such as magnesium, iron, zinc, selenium, iodine, vitamin A and folate was found to be below the reference nutrient intake and the national average daily intake in older people identified as at risk of malnutrition[71].

[i]Lower reference nutrient intake (LRNI) an amount of a nutrient sufficient for only the few people in a group who have low needs

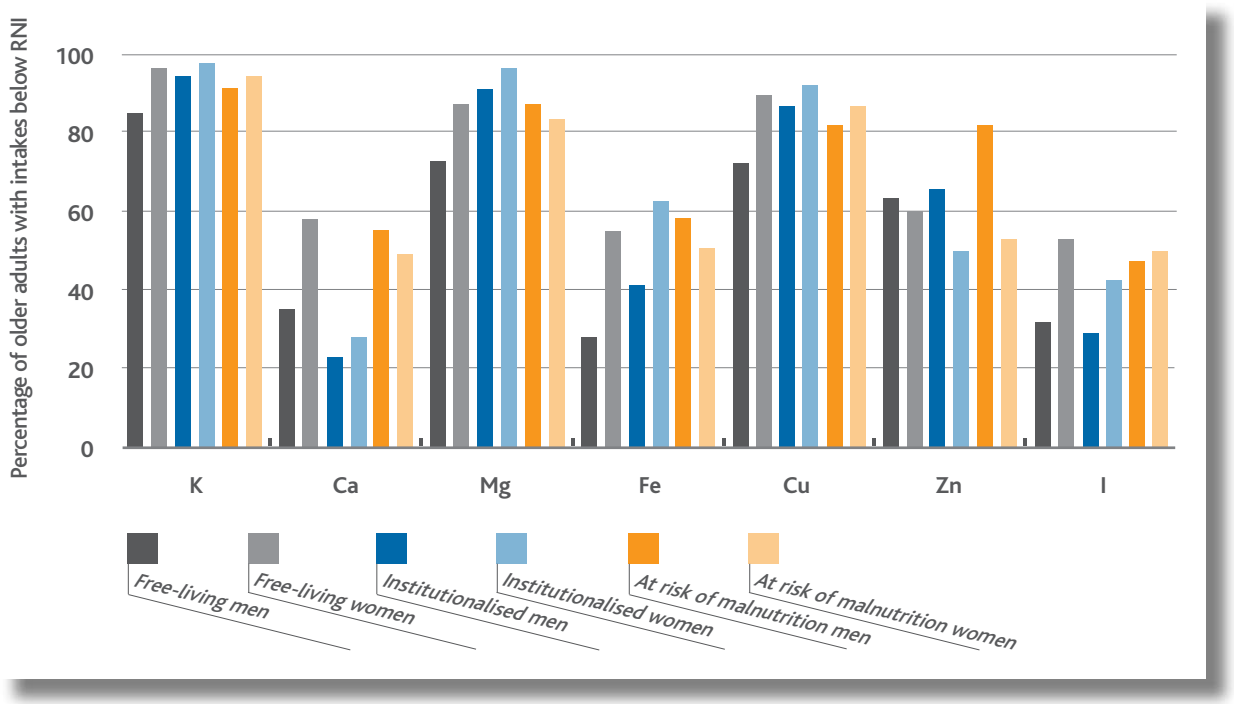


Figure 1.7 Percentage of older adults in the UK with vitamin intakes below the reference nutrient intake (RNI). RNI for men and women aged ≥50 years. Number of patients varies according to micronutrient and group (male and female): Free-living (n = 540-735), Institutions (n = 93-319), at risk of malnutrition (all settings n = 55-80) (adapted from Stratton 2007)[55].

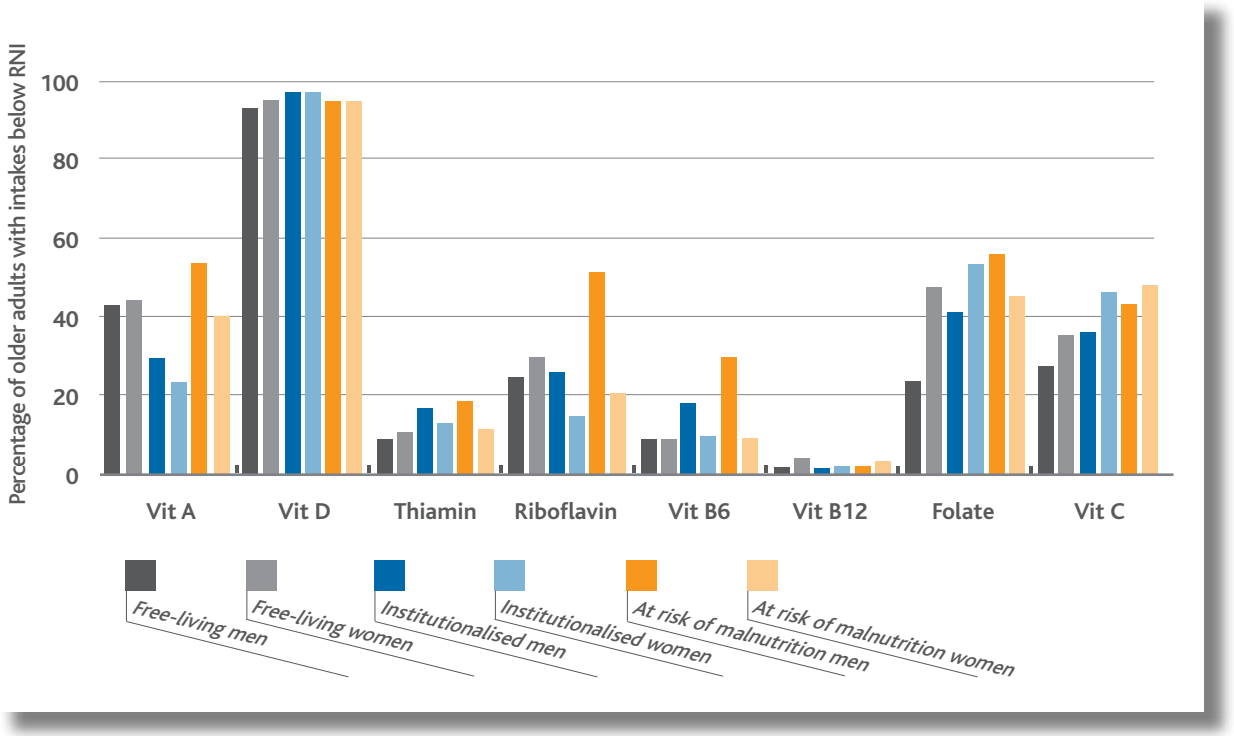


Figure 1.8 Percentage of older adults in the UK with vitamin intakes below the reference nutrient intake (RNI). RNI for men and women aged ≥50 years. Number of patients varies according to micronutrient and group (male and female): Free-living (n = 540-735), Institutions (n = 93-319), at risk of malnutrition (all settings n = 55-80) (adapted from Stratton 2007)[55].

There are numerous reasons why food intake is poor

- Food intake is affected by factors arising from the patient's condition and situation, healthcare worker's knowledge and action, and institutional organisation[37;48;49;68;69;80;81]. Examples include eating difficulties, inadequate provision of energy and nutrients, lack of guidance for staff, poor knowledge of nutrition and failure to follow nutritional policies (Figure 1.9).

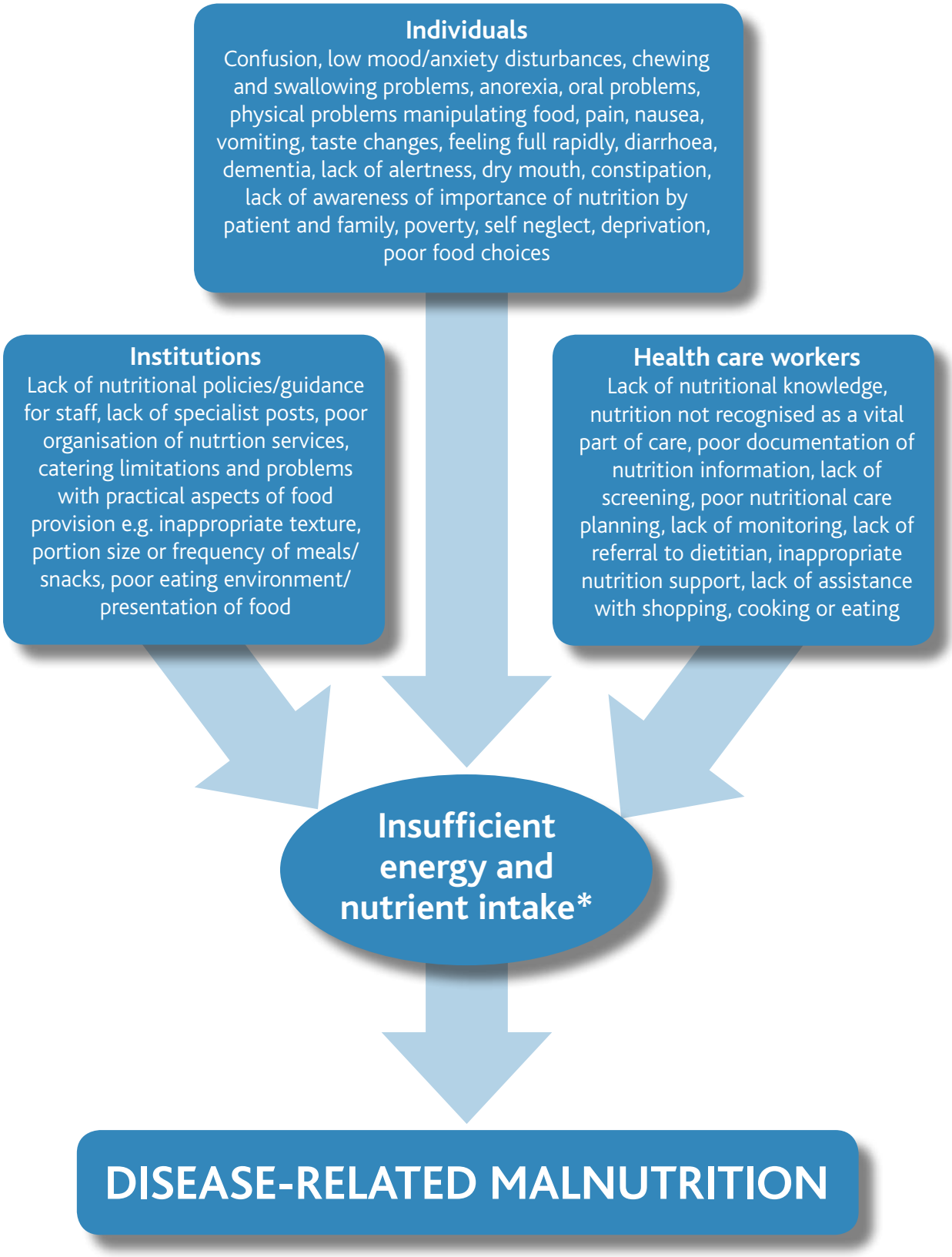


Figure 1.9 Factors leading to insufficient energy and nutrient intake as a cause of disease-related malnutrition (adapted from Stratton 2003)[1]

*Requirements for some nutrients may be increased due to malabsorption, altered metabolism and excess losses.

1.3 Consequences of malnutrition

- Malnutrition adversely impacts on every organ system in the body with potentially serious consequences (Table 1.3)[12].

- Restricted recent dietary intake has been shown to affect metabolic, psychological and physical function in the presence and absence of disease, and in surgical patients to reduce collagen deposition, with implications for effective wound healing[1].

Table 1.2 Key physical and psycho-social effects of malnutrition (adapted from Elia 2009)[12]

Effect	Consequences
Impaired immune response	Impaired ability to fight infection
Reduced muscle strength and fatigue	Inactivity, and reduced ability to work, shop, cook and self-care. Poor muscle function may result in falls, and in the case of poor respiratory muscle function result in poor cough pressure - delaying expectoration and recovery from chest infection
Inactivity	In bed-bound patients, this may result in pressure ulcers and venous blood clots, which can break loose and embolise
Impaired temperature regulation	Hypothermia
Impaired wound healing	Increased wound-related complications, such as infections and un-united fractures
Impaired ability to regulate salt and fluid	Predisposes to over-hydration, or dehydration
Impaired psycho-social function	Apathy, depression, introversion, self-neglect, hypochondriasis, loss of libido and deterioration in social interactions

Malnutrition has functional consequences

- Malnutrition is associated with decreased muscle function and impaired functional status. In adult hospital patients decreased handgrip strength is a predictor of loss of functional status[82]. Reduced muscle strength and fatigue can lead to falls, reduced ability to self-care and poor recovery from chest infection[12].

- Low vitamin D levels (< 20 ng/ml) have been associated with poorer physical performance and a greater decline in physical performance than subjects with vitamin D levels of at least 30 ng/ml[58]. In addition, low vitamin D concentrations have been associated with a greater risk of future nursing home admission and are independently associated with an increased risk of falling in older people, particularly in those aged 65-75 years[83;84].

Malnutrition is associated with impaired quality of life

- Malnutrition has been shown to impair quality of life in free-living older people and in patients with cancer, hip fracture and COPD. Poor quality of life is also reported in malnourished surgical patients, patients with end-stage renal disease undergoing haemodialysis and in general admissions to the acute hospital setting[1].

Malnutrition increases morbidity

- Malnutrition is associated with markedly increased morbidity in both acute and chronic disease e.g. development of pressure ulcers, poor wound healing and post operative complications such as acute renal failure, pneumonia and respiratory failure. Malnutrition affects morbidity by impairing wound healing and immune function with increased rate of infectious and non-infectious complications and a general impairment of convalescence. The increased morbidity results in increased mortality, duration and intensity of treatment, and length of hospital stay. It is obvious that these consequences of malnutrition result in increased treatment costs (Figure 1.10)[85].

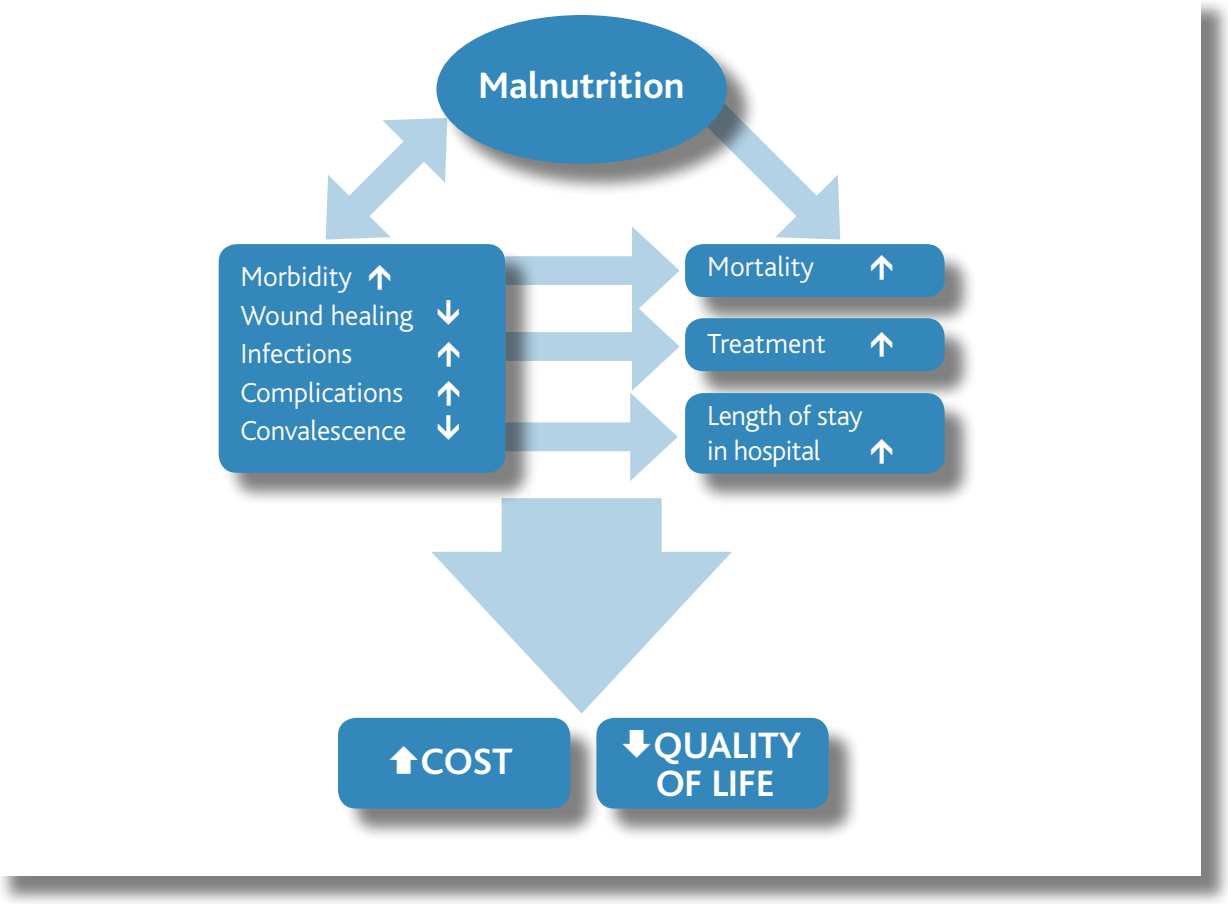


Figure 1.10 Prognostic impact of malnutrition (adapted from Norman 2008)[85].

- The risk of infection is more than three times greater among hospitalised malnourished patients than well nourished patients[56].

- In a large (n = 5051, mean age 59.8 years (± 0.3 SEM)) multi-region (12 countries; Western Europe = 4, Eastern Europe = 5 and Middle East = 3), multi-centre (26 hospital departments; surgery, internal medicine, oncology, intensive care, gastroenterology and geriatrics) study the rate of complications was more frequent in 'at-risk' patients than 'not-at-risk' patients (30.6% vs 11.3%, $p < 0.001$) (Figure 1.11)[16].

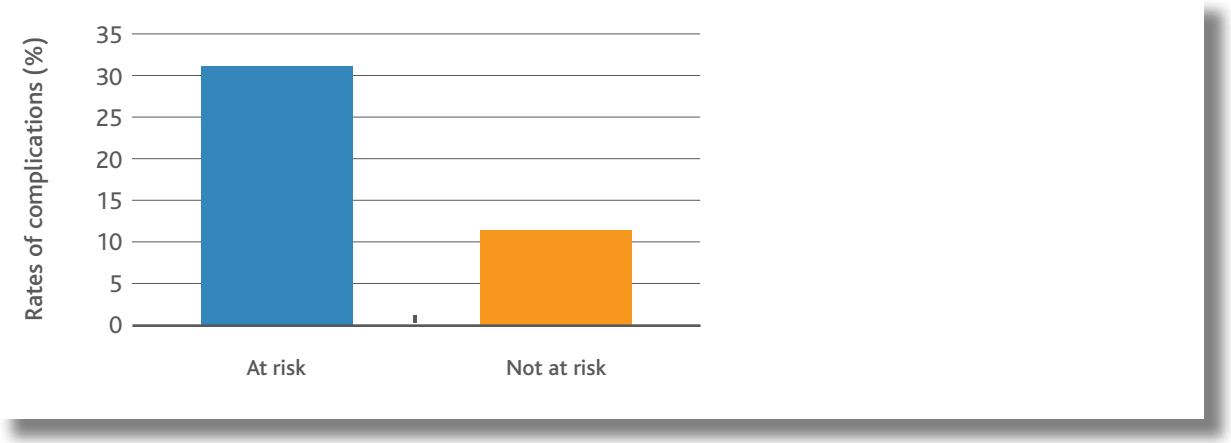


Figure 1.11 **Increased rate of complications in at-risk patients vs not-at-risk patients (p<0.001)**
(adapted from Sorensen 2008)[16]

Malnutrition is associated with increased mortality

- A comprehensive review of studies addressing the associations between malnutrition and mortality showed that malnourished patients a have higher mortality rate than well nourished patients. This effect was seen in a wide variety of patient groups and in younger patients[1]:
  - general hospital admissions, medical and surgical patients (particularly abdominal, orthopaediac or cardiac surgery and patients undergoing liver or lung transplant)
  - older people in a variety of care settings e.g. hospital, intensive care, medical units, rehabilitation and long-term care
  - patients with stable COPD or acute exacerbations
  - patients with HIV infection and AIDS
  - patients with cancer
  - patients with renal failure prior to dialysis or with end-stage renal failure receiving dialysis
  - patients following stroke
  - patients in the community with chronic respiratory, gastrointestinal, neurological or cardiovascular disease, or cancer

- In a large (n = 5051, mean age 59.8 years (± 0.3 SEM)) multi-region (12 countries; Western Europe = 4, Eastern Europe = 5 and Middle East = 3), multi-centre (26 hospital departments; surgery, internal medicine, oncology, intensive care, gastroenterology and geriatrics) study death was more frequent in 'at-risk' patients than 'not-at-risk' patients (12% vs 1%, $p < 0.001$) i.e. mortality was 12 fold higher in 'at risk' patients (Figure 1.12)[16].

Figure 1.12 **Increased frequency of death in at at-risk patients vs not-at-risk patients (p<0.001)**
(adapted from Sorensen 2008)[16]

- A survey of outpatients with COPD found that those at risk of malnutrition (medium and high risk using 'MUST') were more likely to die within six months than patients not at risk (6 month mortality rate 16.3% vs 5.8%, p = 0.023)[87].

Malnutrition has a particularly high adverse impact in the older person

- The clinical criteria for frailty ('shrinking' (i.e. unintentional weight loss/sarcopenia), weakness, poor endurance and low activity) are associated with chronic under-nutrition resulting in loss of weight and muscle mass, and poor muscle function[88]. Without appropriate intervention, frail older people are likely to experience functional limitations and disability, increased morbidity and use of healthcare resources, and mortality[35].

- A recent review of the links between nutrition and frailty suggested that loss of appetite, weight loss, sarcopenia, low energy and protein intake, low intake and blood levels of vitamins (B,C,D,E, folate), antioxidants (carotenoids) and trace elements (selenium and zinc) influence the development or aggravation of frailty[89].

- Older women with weight loss have increased rates of hip-bone loss and two-fold greater risk of subsequent hip fracture[90].

- Two-year mortality in nursing home residents in Sweden was found to be 52%. Male gender and low body-weight were associated with increased risk of mortality[79].

- Disease-related malnutrition has been found to double the risk of mortality in hospital patients and triples mortality in elderly malnourished patients in hospital and after discharge (Figure 1.13)[91;92].

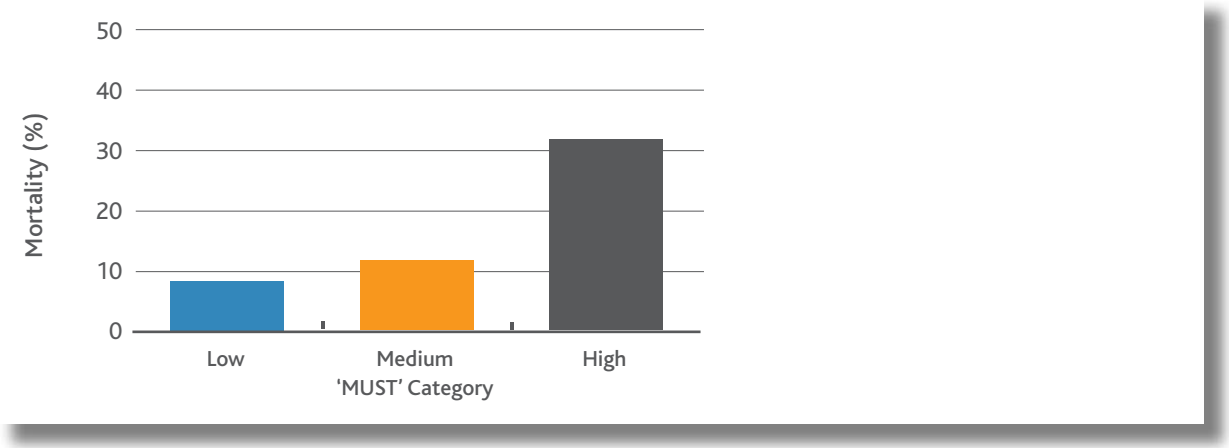


Figure 1.13 Significant increase in in-hospital mortality with increasing malnutrition risk category (p=0.01) (adapted from Stratton 2006)[91].

Malnutrition increases use of healthcare resources

Due to the increased morbidity, malnourished patients or patients identified as at risk of malnutrition experience significantly longer hospital stay, increased readmissions rates and more GP visits than well-nourished patients (Table 1.4).

Table 1.3 Examples of significantly increased use of healthcare resources by patients identified as malnourished or at risk of malnutrition compared with non-malnourished patients

Study	Population (n)	Method	Outcome
Pirlich (2006)[24]	Adult, hospital (1886)	SGA	• ↑**LOS** (average difference 4.6 days or 42%, p < 0.001)
Planas (2004)[93]	Adult, hospital (400)	SGA	• ↑**LOS** (overall population 7.5±5.4 days vs 5.0±5.1 days; scheduled admitted 7.1±6.2 days vs 4.8±4.4days, both p < 0.05) • ↑**readmission rate** (total - overall 30.1% vs 15.1%, scheduled 32.8% vs 15.9%, cancer 39.7% vs 21.4%, all p < 0.05; non-elective - overall 20.7% vs 13.2%, scheduled 21.4% vs 12.8%, cancer 29.3% vs 17.2%, all p < 0.05)
de Luis (2006)[94]	Adult, hospital internal medicine (213)	MNA	• ↑**LOS** (increase of 2.6 days for each decrease of 1 kg of body weight, decrease of 3.2 days for each 1 point increase in MNA score)
Pressoir (2010)[36]	Adult, cancer Hospital (879)	See details*	• ↑**LOS** (median 19.3±19.4 days vs 13.3±19.4 days, p < 0.0001)
Feldblum (2009)[95]	Older people, community (204)	MNA	Healthcare use before index hospital admission: • ↑**no. diagnosed diseases** (mean 7.4±0.21 vs 5.9±0.16, p = 0.001) • ↑**no. family physician visits** (mean 7.7±0.95 vs 3.7±0.75, p = 0.001) • ↑**no. hospital admissions before current admission** (mean 1.7±0.19 vs 1.1±0.15, p = 0.02) Healthcare use after index hospital admission: • ↑**LOS** (current event) (mean 7.14±0.8 days vs 5.0±0.4 days, p = 0.01) • ↑**LOS** (in following 3 months) (mean 2.8±0.54 days vs 1.4±0.29 days, p = 0.03)
Cawood (2010)[96]	Adults, outpatients (194)	'MUST'	• ↑**LOS** (All hospital admissions: low risk 0.90±3.9 days vs medium risk 2.04±4.9 days vs high risk 4.92±8.1 days, p = 0.007) • ↑**hospital admissions in 6 months** (12.6% vs 26.1% vs 66.7%, p = 0.000) • ↑**emergency admissions in 6 months** (5.0% vs 8.7% vs 41.7%, p = 0.000) • ↑**planned admissions in 6 months** (7.5% vs 21.7% vs 25.0%, p = 0.025)
Collins (2010)[87]	Adult COPD, outpatients (205)	'MUST'	• ↑**no. emergency & elective admissions per patient in 6 months** (low risk 0.65±1.1 vs medium & high risk 1.10±2.0, p = 0.043) • ↑**no. emergency admissions per patient in 6 months** (low risk 0.48±0.9 vs medium & high risk 0.92±1.8, p = 0.023)

LOS, length of stay.*See Table 1.1 for definitions of malnutrition used by Pressoir 2010.

1.4 Costs of malnutrition

Malnutrition increases healthcare costs

- Increasing efforts are being made to establish the cost of malnutrition in Europe and in different countries including the UK, Germany, Belgium, The Netherlands, the Republic of Ireland and Australia.

United Kingdom

- Malnourished patients have more GP visits, more hospital admissions (e.g. 56% and 82% more, respectively, for those ≥ 65 years of age), > 30% longer hospital stays, and greater likelihood of admission to care homes than well nourished individuals[17]. These factors were used to help calculate the overall cost of malnutrition in the UK.

- The annual healthcare cost of malnutrition and any associated disease in the UK in 2003 was estimated to be in excess of €8.4 billion* (£7.3 billion) per year (Figure 1.14, Actual costs)[17]. The costs were split approximately as:

  - €4.4 billion* (£3.8 billion) due to the treatment of malnourished patients in hospital
  - €3.0 billion* (£2.6 billion) due to the treatment of malnourished patients in long-term care facilities
  - €0.57 billion* (£0.49 billion) from GP visits
  - €0.21 billion* (£0.18 billion) from hospital outpatient visits and
  - €0.06 billion* (£0.05 billion) from artificial nutrition support in hospital
  - €0.17 billion* (£0.15 billion) from artificial nutrition support in the community (artificial nutrition support includes parenteral nutrition, enteral tube feeding and ONS)

- Figure 1.14 also shows the **extra** cost of treating all patients in the general population with medium and high risk of malnutrition and associated disease, compared with treating the same number of patients with low risk of malnutrition and associated disease. This is referred to as the annual additional healthcare cost (or incremental cost) and is estimated to be over €6.1 billion* (£5.3 billion). Most of this cost was due to more frequent and more expensive hospital inpatient spells, and greater need for long-term care in those with medium and high risk of malnutrition than low risk of malnutrition[17].

- It was estimated that more than half of the expenditure on disease-related malnutrition goes to people aged ≥ 65 years of age, who account for only about 15% of the population[17].

*Calculated based on an exchange rate of £ to € of 1.1564 (17/07/2009)

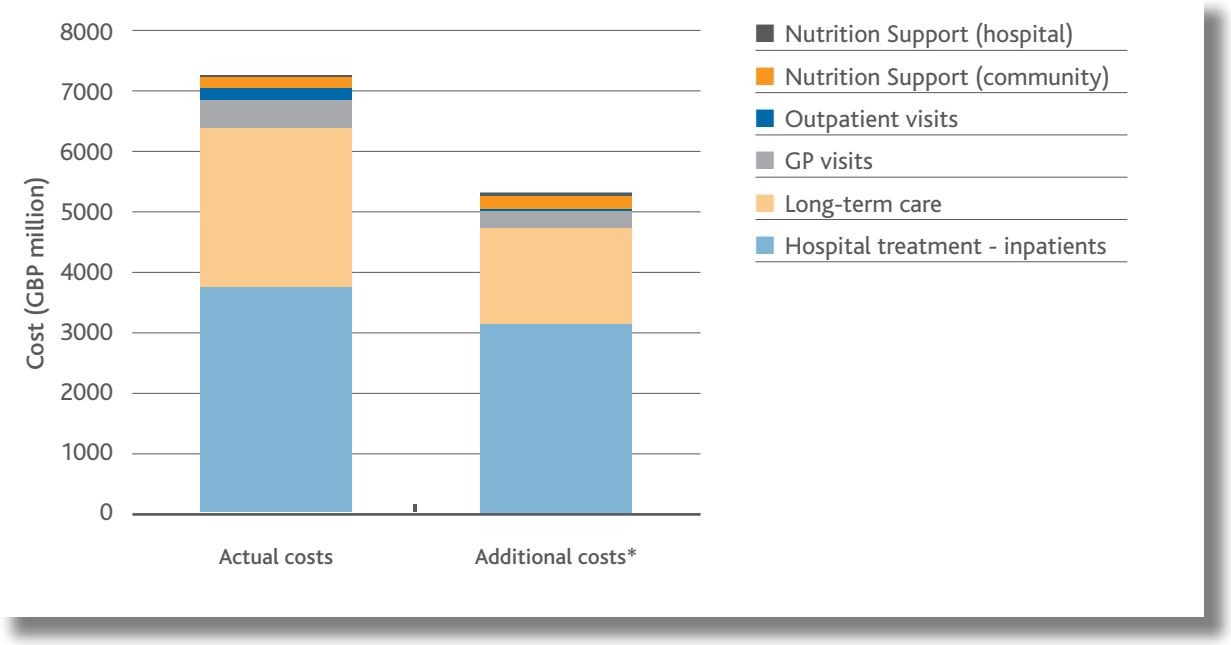


Figure 1.14 Estimated annual public health expenditure in medium and high risk of malnutrition (adapted from Elia 2005)[17] *Additional annual cost for treating community patients with medium and high risk of malnutrition compared with the same number with low risk of malnutrition.

- In 2007 an update of this calculation was performed to account for the rising public expenditure on health and to include the cost of services providing support to malnourished patients such as care at home and GP visits to people aged 65 years and over that were not included in the 2003 estimate. Public expenditure on disease-related malnutrition in the UK in 2007 was estimated to be in excess of €15 billion* (£13 billion) per annum, corresponding to ≥ 10% of the total expenditure on health and social care[18]. Healthcare costs (UK) include cost of hospital inpatients, hospital outpatients and primary care (prescriptions and General Medical Services). Social care costs include costs of adult nursing, residential, home care, assessment and management and other, and children and family services. Estimates are based on mean proportion of malnourished patients (Figure 1.15).

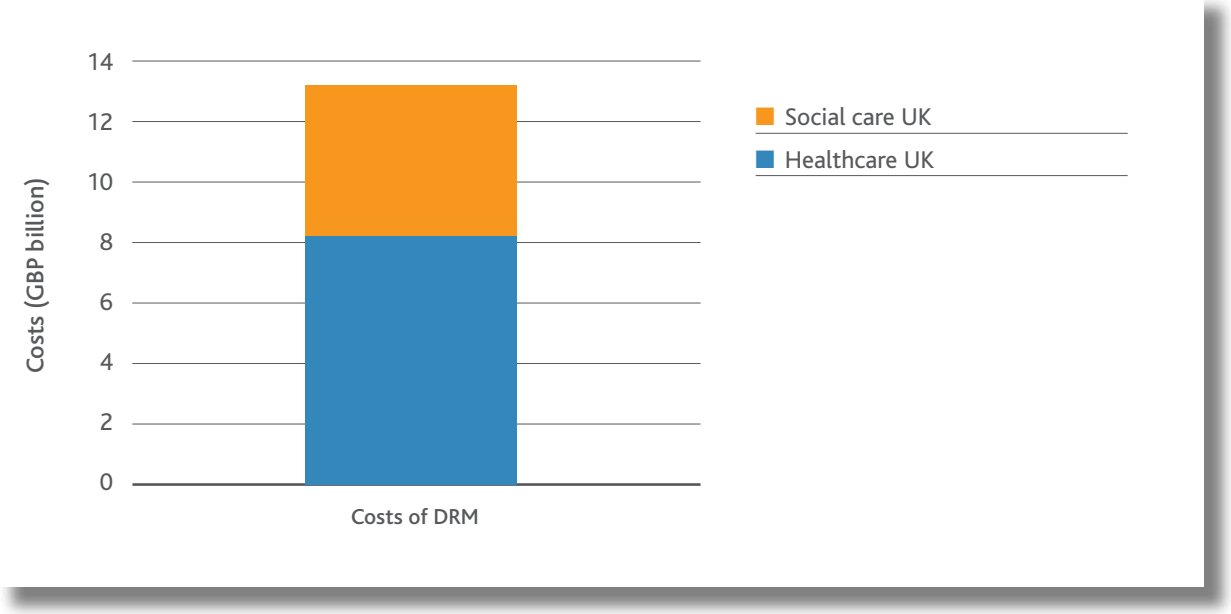


Figure 1.15 The cost of disease-related malnutrition in the UK in 2007 (adapted from Elia 2009)[18].

- In comparison, the economic costs of obesity are estimated at €3.8-4.3 billion* (£3.3-3.7 billion) per year and even if the estimate includes obesity plus overweight (€7.6-8.6 billion* (£6.6-7.4 billion))[97] the figure is still approximately half the cost of disease-related malnutrition.

Germany

- In Germany, the total additional costs of malnutrition were calculated by considering the additional costs that arise due to malnutrition from patients in hospital (e.g. longer hospital stay, higher hospitalisations, higher rates of complications), in home care (higher complexity and decreased mobility) and in ambulant physician care (increased visits, cost of clinical nutrition). Figure 1.16 shows the costs of malnutrition in hospital and the additional costs caused by extended length of stay in malnourished patients[98].

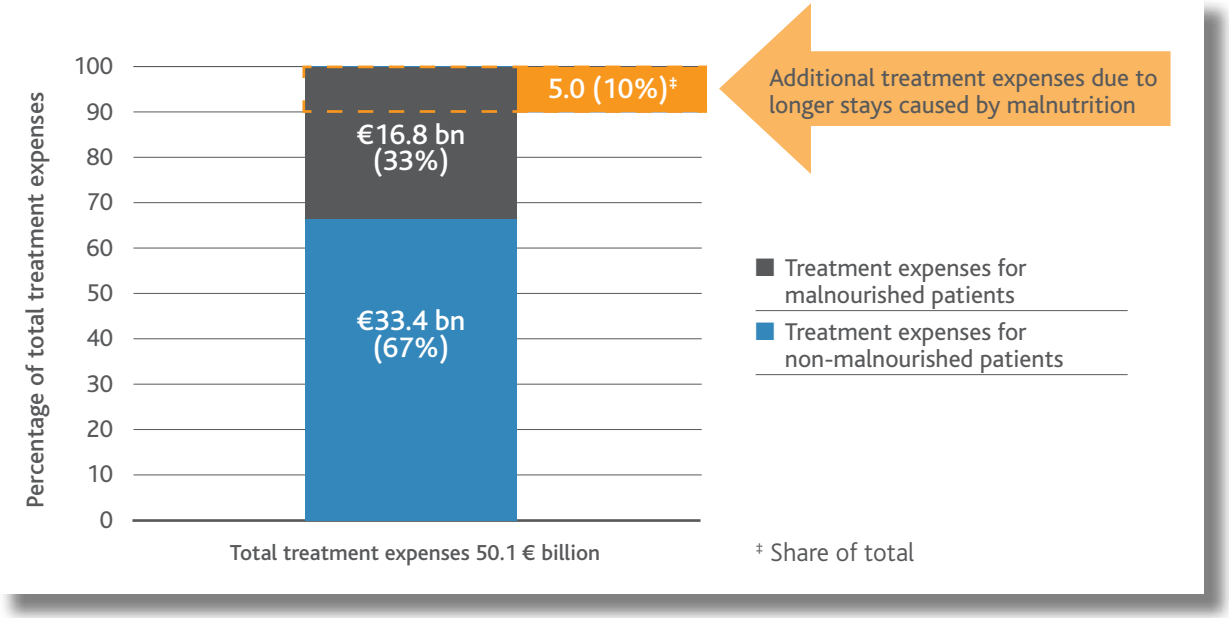


Figure 1.16 Costs of malnutrition in hospitals in Germany (adapted from Cepton 2007)[98]

- In total, across all care settings, the additional costs of malnutrition in Germany accumulate to €9 billion and are expected to rise to €11 billion by the year 2020, with the highest increase expected in the home care sector (Figure 1.17)[98].

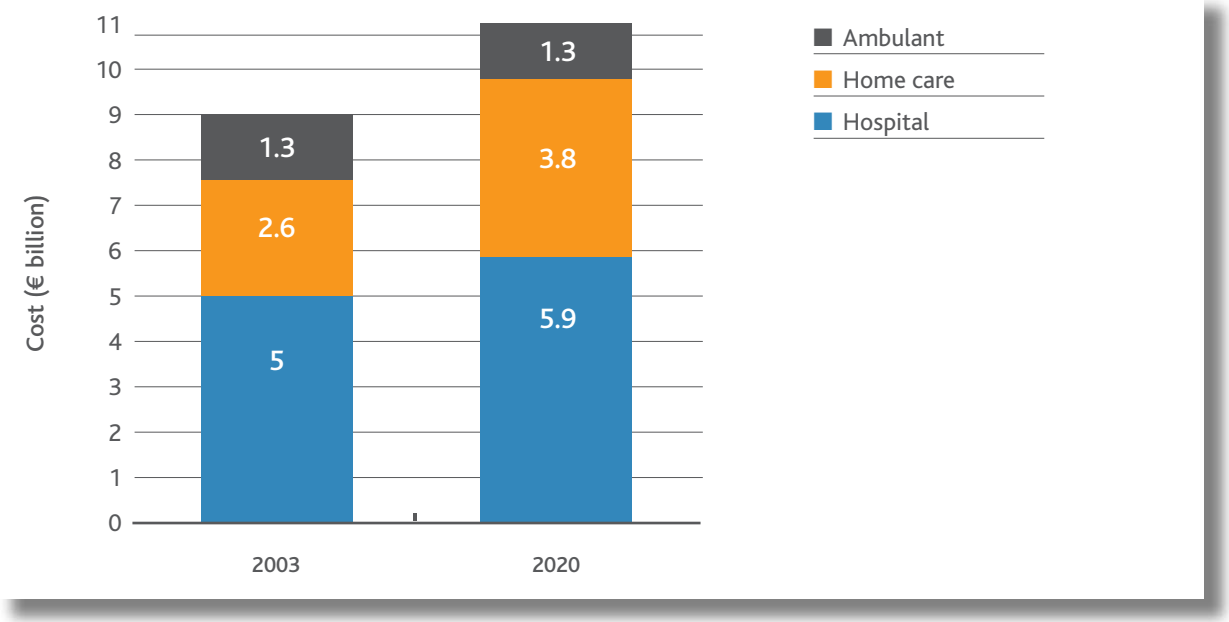


Figure 1.17 Additional costs due to malnutrition in Germany calculated for 2020
(all care sectors, 2003 vs 2020; adapted from Cepton 2007)[98]

Belgium

- Using information from a large observational database from 26 hospitals in Belgium an analysis was conducted to compare inpatient pharmaceutical costs, procedure costs, hotel costs and overall costs between malnourished patients (coded within the database as having a secondary diagnosis of 'underweight' and 'severe weight loss', n = 927) and normally nourished patients (matched controls, n =26,067)[99]. The analysis showed that:
  - The overall mean cost difference per stay between malnourished and normally nourished patients averaged €1152 (95% CI: €870; €1433)
  - The average differences for specific costs were:
    - Pharmaceuticals €264 (€192; €336)
    - Procedures €137 (€113; €161)
    - Hotel costs €754 (€508; €1000)

The Netherlands

- An economic evaluation of the cost of disease-related malnutrition in The Netherlands showed that the total additional costs in 2006 were €1.7 billion representing 2.8% of the total healthcare costs and 5.8% of costs in hospitals, nursing and care homes and homecare. Half of the total costs were accounted for in the hospital sector. Total costs were the highest for patients over 60 years of age. (van der Heijden E et al 2009. Behandeling van ondervoeding noodzakelijk en (kosten)effectief onderdeel van het medisch handelen. tsg jaargang 87 (8 forum): 341-345; www.tsg.bsl.nl)

Republic of Ireland

- An economic evaluation of the cost of malnutrition in the Republic of Ireland using methodology adapted from Elia and Stratton 2009[18] found that malnutrition is estimated to have cost over €1.5 billion in 2007, representing over 10% of the public expenditure on health and social care (Nutrition and Health in an Ageing population: University College Dublin Institute of Food and Health, Policy Seminar Series No.1, 2010). http://www.ucd.ie/foodandhealth/seminarseries/

Europe and the European Union

- The estimated cost of disease-related malnutrition in Europe is €170 billion[13] or €120 billion in the EU[14]. This estimate is based on health economic evidence from the UK showing costs for managing patients at risk of malnutrition exceed €15 billion[18].

Australia

- The costs arising from pressure ulcers attributable to malnutrition have been estimated to be €7 million for 2002/2003 in public hospitals in Queensland, Australia. The estimate is based on approximately one third of pressure ulcers being attributable to malnutrition and only includes the costs of increased length of stay associated with pressure ulcers. Nevertheless a cost of €7 million is considered as substantial[100].

SECTION 2

Benefits of ONS to both patients and healthcare systems

Summary

Good nutritional care is a vital part of care and includes nutritional screening, provision of appetising and nutritious food and nutritional support. ONS are one of a spectrum of nutritional support strategies that can be used to tackle malnutrition (e.g. food, dietary counselling, ONS, tube feeding and parenteral nutrition).

ONS are an effective and non-invasive solution to malnutrition. ONS have been demonstrated to be more effective than dietary advice and snacks; greater intakes of energy, protein and micronutrients and significantly fewer complications have been shown in patients with fractured neck of femur when compared with snacks (with equal energy content)[101-103].

ONS have proven nutritional, functional, clinical and economic benefits in both the hospital and community setting in a wide variety of patient groups. Studies show that ONS increase energy and protein intakes in both hospital and community patients without reducing spontaneous intake from food; indeed ONS may actually help to stimulate appetite e.g. in post-surgical patients and in older people.

Meta-analyses show that ONS lead to weight gain in patients in hospital and in those transferred to the community including older people e.g. average weight change between supplemented and control group +3%[1]. Improvement in activities of daily living, muscle strength, respiratory muscle function and sleep scores have been demonstrated in patients receiving ONS[81].

Meta-analyses consistently show a reduction in mortality in patients given ONS compared with standard care (e.g. 24% reduction[1]), particularly in undernourished older people[11;104;105]. Reductions in complication rates of between 25% and over 50% are seen in meta-analyses of ONS compared with routine care[1;75]. Significantly lower readmission rates have been reported in older people supplemented with protein-rich ONS compared with placebo and in patients with gastrointestinal disease who received protein-rich ONS compared with dietary advice, as well as reductions in length of hospital stay[1;106-108].

Potential cost savings as a result of reduced healthcare use having been demonstrated in patients supplemented with ONS and can be realised in both the hospital and the community setting. Economic modelling undertaken by NICE (2006) showed ONS to be cost-effective as part of a screening programme[75].

Research recommendations often call for better quality studies in the field of nutrition support. Milne (2009) reported that quality was poorest with regard to actions taken to blind assessors of outcome[11]. Efforts should be made to address this. Equally it should be recognised that studies are often difficult to perform in the field of medical nutrition; suitable comparators are not always available, it may be difficult to blind patients and care givers to the intervention and it may be difficult to recruit subjects.

Although more research in specific subgroups is welcome to further enhance the evidence base, robust and consistent evidence exists to demonstrate the clinical and cost benefits of ONS.

A holistic approach must be taken when considering the investment needed to manage malnutrition; the cost may be incurred in one setting whilst the benefit appears to occur in another. However, taken as a whole, effective prevention and management of malnutrition will realise cost savings across the social and healthcare system.

Key Messages

- There is a wide body of evidence that demonstrates that ONS can be used to help tackle the problem of malnutrition.
- Data on the benefits of dietary counselling and food fortification in the management of malnutrition are lacking; ONS have been shown to be more effective.
- Appropriate use of ONS can achieve cost savings across healthcare systems, especially when used as part of a nutritional screening programme.
- ONS should be used as part of nutritional care in people identified at risk of malnutrition or in people who are malnourished, across all settings, and in the context of nutritional care plans.

2.1 Good nutritional care

Good nutrition is an essential part of care, and encompasses ensuring that the right people receive the right nutritional support at the right time during their care regardless whether that care is delivered in hospital, in an institution or in the person's own home. Good nutritional care starts with ensuring that people have access to appetising and nutritious food that meets their preferences, nutritional, cultural and religious needs and that they are supported to either provide this for themselves or to be able to avail of it when provided by others e.g. through assistance with shopping or cooking, lunch clubs, meals on wheels or assistance with eating and drinking.

Good nutritional care also includes ensuring that people who are malnourished or at risk of malnutrition are identified through screening programmes and that action is taken to ensure that they receive appropriate and timely nutrition support. Nutrition support may take many forms e.g. dietary counselling, food fortification, ONS, tube feeding and parenteral nutrition. Healthcare professionals should look to evidence based guidelines to assist them in selecting the most appropriate method of nutritional support for their patient taking account of the patient's nutritional needs, ability to eat, diagnosis and prognosis and ability to adhere to the intervention. It is essential that healthcare professionals combine their clinical experience with a sound knowledge of the evidence base and practical common sense in the provision of nutrition support e.g. a patient with a poor appetite may not be able or willing to consume extra food or may lack the energy or ability to prepare it.

Efforts are being made to bring agencies together to raise awareness of the issue of malnutrition and to provide a co-ordinated approach to tackling the problem of malnutrition across healthcare settings. The 2009 'Prague Declaration' is an example of such an initiative at European level. Issued at a key meeting on 11-12th June 2009 hosted by the Czech Presidency of the EU, this joint declaration (from EU health ministries, ESPEN, healthcare officials and professionals, health insurance groups and the European Nutrition for Health Alliance (ENHA)) called for the following actions to end malnutrition:

- Public awareness and education
- Guideline development and implementation
- Mandatory screening
- Research on malnutrition
- Training in nutritional care for health and social care professionals
- National nutritional care plans endorsed, and their implementation and funding across all care settings secured
- Consideration of malnutrition as a key topic for forthcoming EU Presidencies

ONS can be used as part of the spectrum of nutritional support strategies to tackle malnutrition. This will be the focus in the next chapters.

2.2 Nutritional benefits of ONS

2.2.1 Nutritional intake

ONS increases total energy intake in patients in hospital

- A comprehensive systematic review of trials in the hospital setting (58 trials, 34 RCT, 25 (74% of the total RCTs) assessed intake with ONS) indicated the efficacy of ONS in increasing total energy intake in a variety of patient groups; patients with COPD, older people, post-surgical patients, orthopaedic patients, patients with liver disease, patients with cancer[1].

- The effect was observed regardless of whether the mean BMI of the group was < 20 kg/m^2 or > 20 kg/m^2 [1].

- In hospital patients, ONS have been shown not to substantially reduce food intake. In some patient groups (e.g. post-surgical patients) ONS even appear to stimulate appetite and food intake (Figure 2.1)[109]. During acute illness the effectiveness of ONS at increasing total energy intake may be limited[1].

- In patients with cancer undergoing radiotherapy, meta-analysis (3 RCTs) showed that ONS significantly increased dietary energy intake (381 kcal/day, 95% CI 193 - 569) compared with routine care[110].

- A randomised controlled trial of nutritional support in an acute trauma ward found that patients supported by a dietetic assistant had a mean energy intake of 349 kcal/24 h greater than the 756 kcal/24 h achieved by patients receiving conventional nursing care. Of the additional 349 kcal/24 h, 286 kcal/24 h (82%) came from ONS[111].

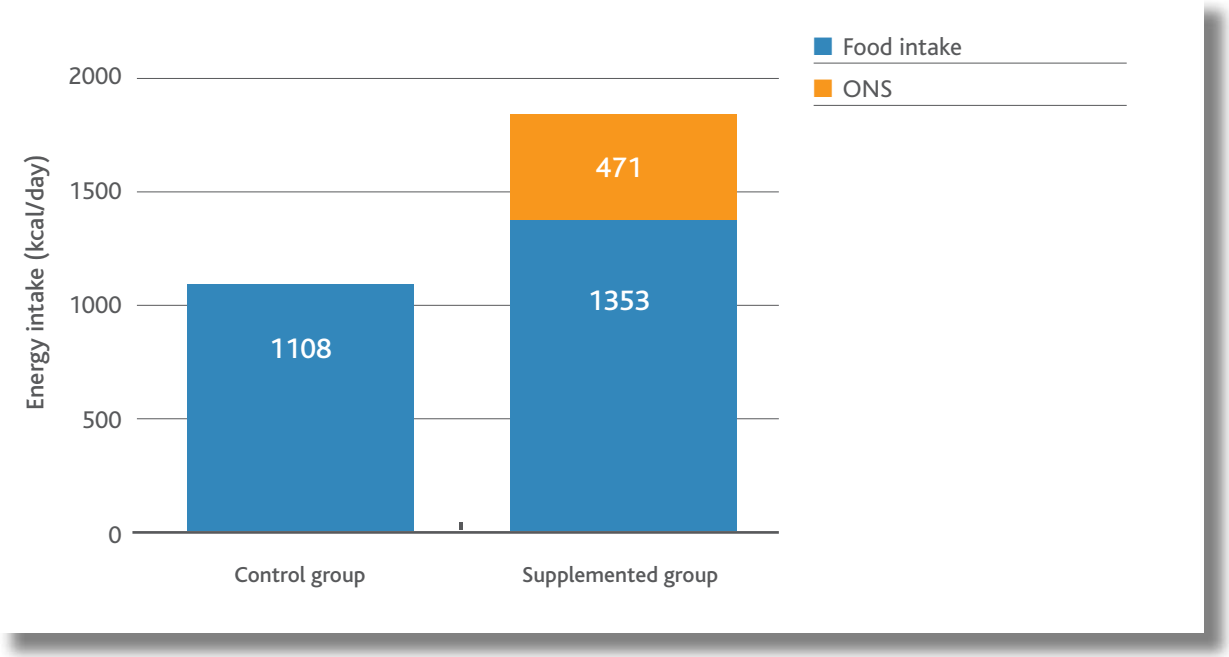


Figure 2.1 Higher total food and energy intake in hospitalised post surgical patients with ONS (significant increase in total energy intake p < 0.0001; significant increase in intake from ward diet, p < 0.02) (adapted from Rana 1992)[109]

ONS increase total energy intake in patients in the community

- In a systematic review in patients in the community setting (108 trials, 44 RCT, n = 3747, the effect of ONS on energy intake was assessed in 32 RCT) ONS increased total energy intake across a variety of patient groups; patients with COPD, older people, patients with cystic fibrosis, patients with Crohn's disease, patients with HIV, surgical patients and patients with liver disease[1]. 91% of the RCTs assessing energy intake (n = 29) showed improvements of which > 70% were significant. The mean increase in total energy intake was equivalent to 69% of the ONS energy, although there was wide variation across studies. The increase was greater in studies of patients with a mean BMI of < 20 kg/m^2 than > 20 kg/m^2 [1].

- Significant improvements in energy intake have been observed in adult malnourished patients after three-month post-hospital nutritional intervention with high protein ONS (in addition to dietary counselling) compared with dietary counselling alone (2568.7 ± 585.5 kcal vs 1706.8 ± 688.5 kcal (p < 0.0001). Supplementation did not result in reduced intake of normal food (Figure 2.2)[107].

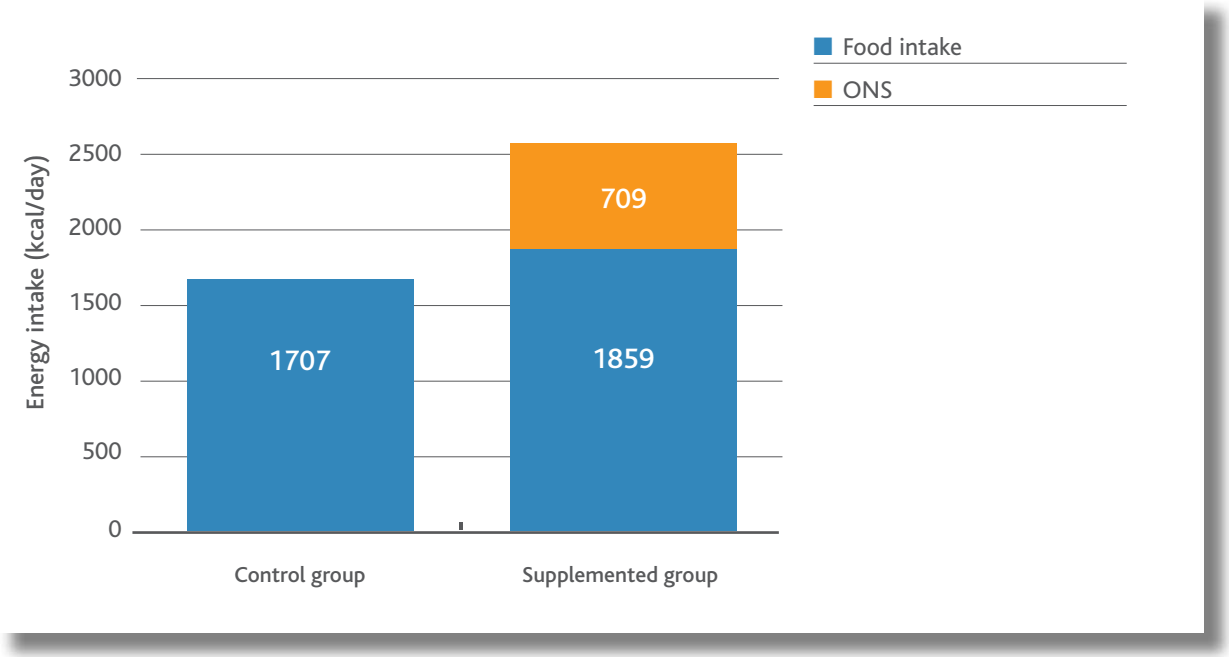


Figure 2.2 Higher energy intake in ONS group vs control group in the community (p<0.0001). Based on completed food intake questionnaires from three consecutive days per month (n = 50) (adapted from Norman 2008)[107]

ONS are effective at increasing energy intake in older people in a variety of hospital and community settings

- In a large systematic review of protein and energy supplementation (ONS) specifically in older people (62 trials, n = 10,187 randomised participants) a significant increase in total daily energy intake was reported in the majority of studies (variety of **in-patient and community settings**)[11].

- In a prospective randomised controlled trial in older patients (> 75 years of age, at risk of malnutrition) investigating the effect of ONS (n = 35) vs no ONS (n = 35) throughout **hospitalisation and convalescence**, spontaneous intake was maintained despite supplementation i.e. ONS may have stimulated appetite. The spontaneous energy intake (excluding ONS) was calculated for 10 control and 16 supplemented patients and was found to be significantly higher in the supplemented group ($p < 0.01$) (Figure 2.3)[112].

- Significant improvements in energy intake with ONS vs usual care have been observed in older patients with Alzheimer's disease at risk of malnutrition in **hospital and day care centres** (total energy intake at three months was 291 kcal/d greater than at baseline) and in older malnourished patients (≥75 years of age) **discharged from hospital to the community** (significant greater energy intake in ONS group vs control group $p = 0.022$)[113;114].

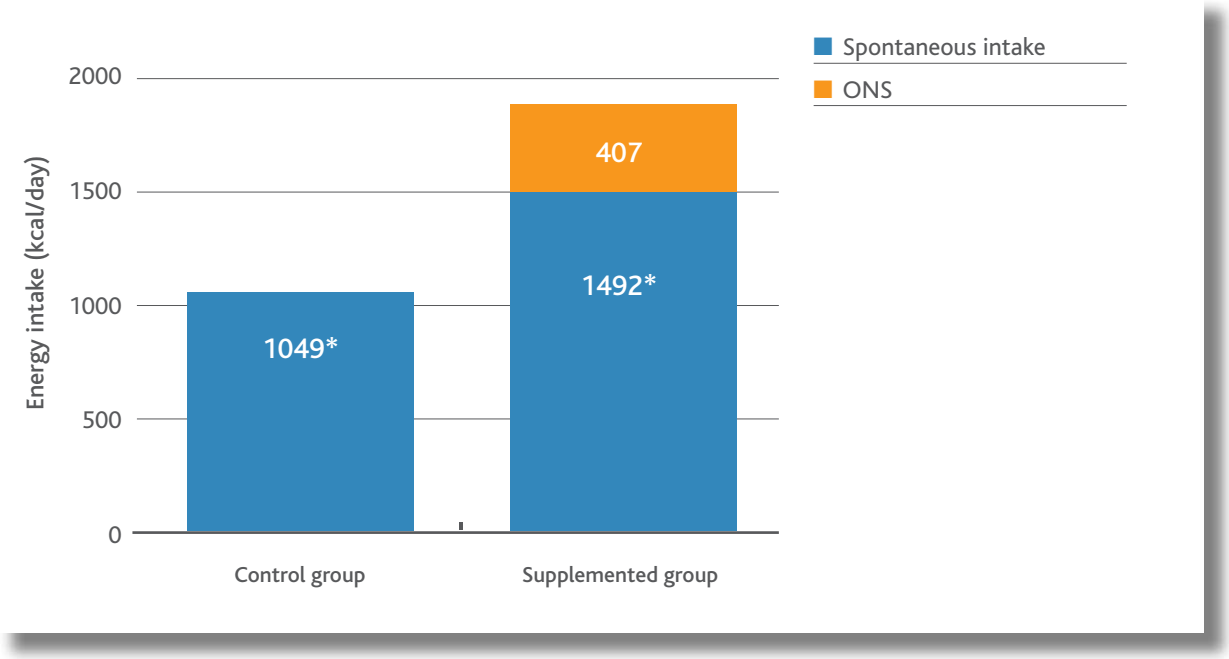


Figure 2.3 Greater total energy intake with ONS in supplemented group vs control group (ONS started in hospital and continued in the community); spontaneous intake maintained despite supplementation with ONS (60 days after inclusion in the study; *$p < 0.01$) (adapted from Gazzotti 2003)[112]

ONS are effective at increasing protein intake in older people in a variety of hospital and community settings

- In a large systematic review of protein and energy supplementation specifically in older people (62 trials, n = 10,187 randomised participants) a significant increase in total daily protein intake was reported in the majority of studies (variety of **inpatient and community settings**)[11].

- Use of ONS has been demonstrated in clinical trials to increase protein intake in:
  - patients recently **discharged home** (Figure 2.4)[112]
  - malnourished older patients in **hospital** (n = 17) compared with controls (n = 6) who received no ONS but careful attention from nursing staff to finish meals (+ 65% protein intake vs + 32%, p < 0.0001)[115]
  - older patients recovering from hip fracture in a **rehabilitation hospital** given high protein supplements (vs standard supplements (63 g vs 50 g protein/day p < 0.048))[116]
  - older patients with Alzheimer's disease at risk of malnutrition, in **hospital and day care centres** (total protein intake at three months was 16 g/d greater than at baseline p < 0.001)[113]

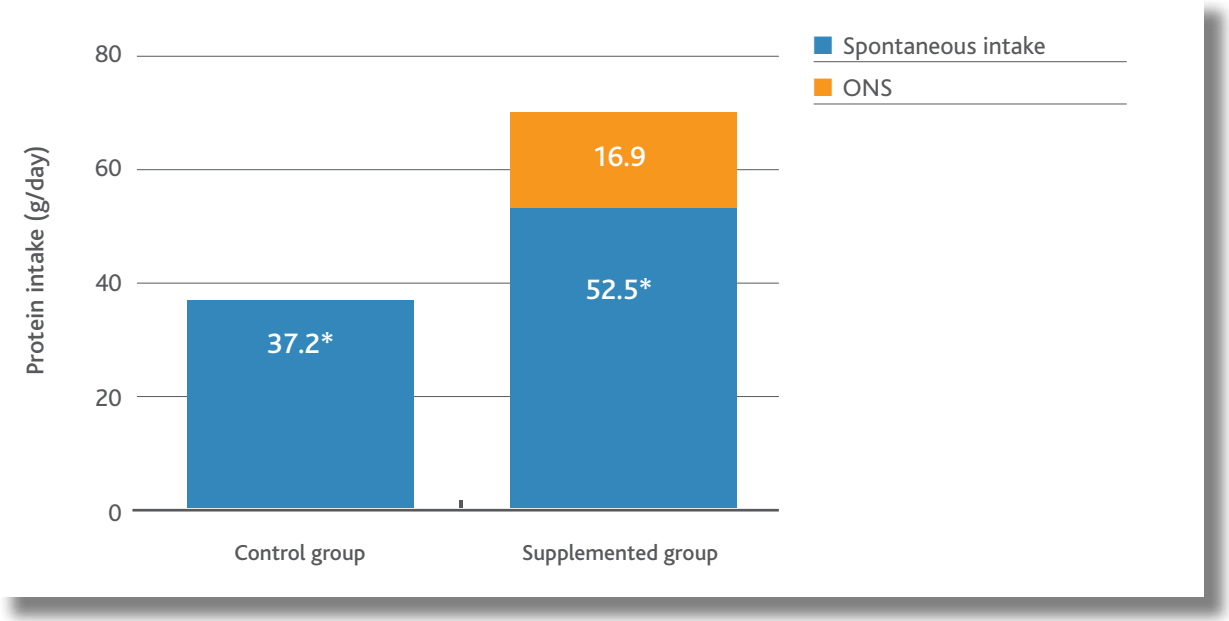


Figure 2.4 Greater total protein intake with ONS in the supplemented group vs control group
(ONS started in hospital and continued in the community) (60 days after inclusion in the study; *p < 0.01) (adapted from Gazzotti 2003)[112]

ONS increase micronutrient intakes as well as energy and protein, and can be more effective than food snacks

- In a review of trials of ONS versus standard care (**hospital and community**, malnourished or at risk of malnutrition) < NICE (2006) reported higher protein intakes in the supplemented groups, and that ONS may be more effective in increasing intake than dietary advice[75]. Stratton et al (2003) also reported significant increases in protein intake in patients receiving ONS[1].

- Malnourished **community** adult patients with benign gastrointestinal disease randomised to receive a high protein ONS plus dietary counselling for three months achieved a significantly higher total protein intake than patients randomised to receive dietary counselling alone (117.1 ± 34.7 g protein/day vs 74.6 ± 44.6 g/day, p < 0.0001)[107].

- In a study of older people resident in **nursing homes** a non-randomised sub-group analysis (n = 66) showed an increased intake of a wide range of vitamins and minerals in patients who received a nutrient enriched ONS compared with placebo ($p < 0.001$)[117].

- Food snacks are often used with the aim of increasing nutrient intake. However, in a trial of **hospital** patients with fractured neck of femur at risk of malnutrition (screened using 'MUST') (n = 50, median age 82 (range 46-97), median BMI 19 (range 12.5-26 kg/m^2)) randomised to receive either ONS (300 kcal per carton) or isoenergetic readily available snacks ad libitum post-operatively, the ONS group had significantly greater intakes of protein, energy and water soluble vitamins than the snack group (Figure 2.5, Table 2.1)[101;102]. Although intakes of some vitamins were above the RNI they fell within safe intakes. Furthermore, significantly fewer patients in the ONS group had complications than in the snack group (27% vs 58%, p = 0.04) and although not significant, a reduction in the incidence of specific complications was observed i.e. infections 17% vs 33% and wound-related complications (poor wound healing, pressure ulcers) 17% vs 38%[103]. See Table A4.1 page 138 for a comparison of average nutrient content of ONS with typical food snacks.

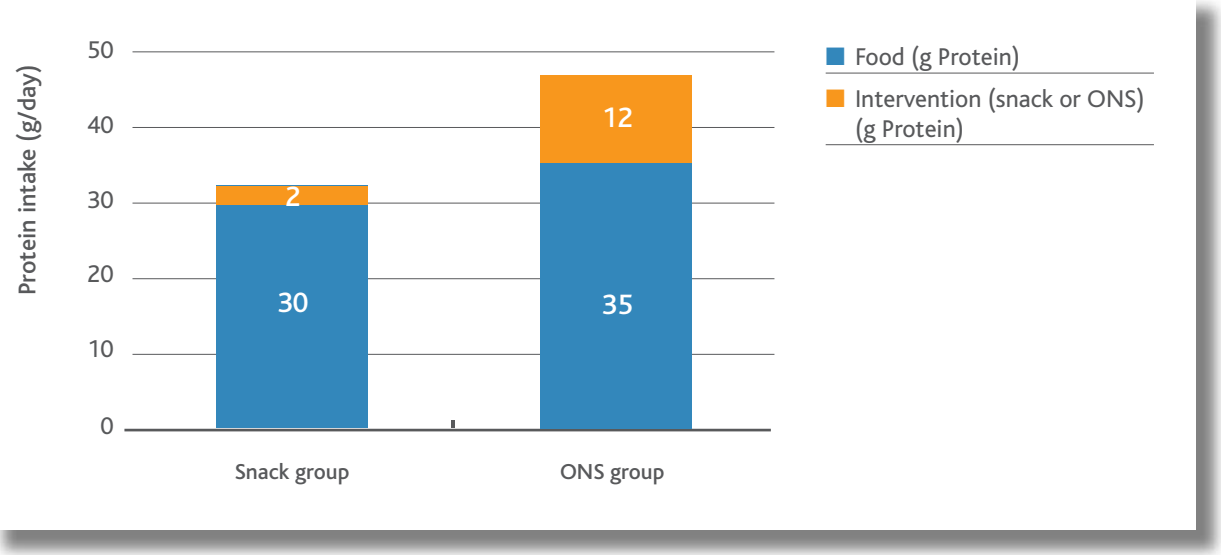


Figure 2.5 Greater total protein intakes with ONS vs isoenergetic food snacks (p<0.03) (adapted from Stratton 2006 [101])

Table 2.1 Greater total mean intakes of water-soluble vitamins with ONS vs isoenergetic food snacks (adapted from Stratton 2006[102])

Vitamin	Food snack group (n 24) Mean	SD	ONS group (n 26) Mean	SD
Thiamin (mg/d)	0.73	0.38	1.59*	1.36
Riboflavin (mg/d)	0.98	0.49	1.80*	1.24
Vitamin B_6 (mg/d)	0.84	0.41	1.60**	0.75
Folate (µg/d)	108	49.6	221**	110
Niacin (mg/d)	7.98	4.73	15.8**	7.72
Vitamin C (mg/d)	37.4	20.1	77.0**	41.1

Mean total intakes were significantly greater than those for the food snack group (unpaired t test): *p < 0.004, **P < 0.0005. Intakes of biotin and panthothenate for the ONS group were significantly greater than those for the food snack group (P < 0.0005)

2.2.2 Nutritional status

ONS lead to weight gain and prevention of weight loss in patients in hospital

- In the hospital setting ONS were found to improve body weight in 81% of trials (35 assessed weight) of which 46% were significant. Average weight change between supplemented and control patients was + 3% (17 RCT) across a variety of patient groups; (surgical patients, older people, patients with COPD). A similar effect was seen in trials in which mean BMI was < 20 kg/m^2 or > 20 kg/m^2 [1].

- In a meta-analysis of ONS vs standard care in hospital patients who were malnourished or 'at risk' of malnutrition it was demonstrated that the use of ONS led to statistically significant increases in weight (weighted mean difference 1.13 (95% CI 0.51 - 1.75, p = 0.0003)) (Figure 2.6)[75].

ONS lead to weight gain and prevention of weight loss in patients in community settings

- In community patients improvements in body weight were documented in 90% of RCTs assessing weight, of which 60% were significant increases. There was considerable variety between patient groups and individual trials, however mean weight change in supplemented vs unsupplemented was greater in trials of patients with a mean BMI < 20 kg/m^2 than > 20 kg/m^2 (+ 3.1% and + 1.3%; 24 RCT)[1].

- Meta-analysis of % weight change in 13 RCT (COPD, older people, HIV, liver disease, cancer, post surgical patients) showed a mean significant effect size with ONS of 0.61 (95% CI 0.50-0.71), though with considerable heterogeneity between trials[1].

- In the meta-analysis of ONS vs standard care in patients who were malnourished or 'at risk' of malnutrition conducted by NICE, it was demonstrated that the use of ONS led to increases in weight in patients in the community (weighted mean difference 1.48 (95% CI 0.74 - 2.22, p = 0.0001)) (Figure 2.6)[75].

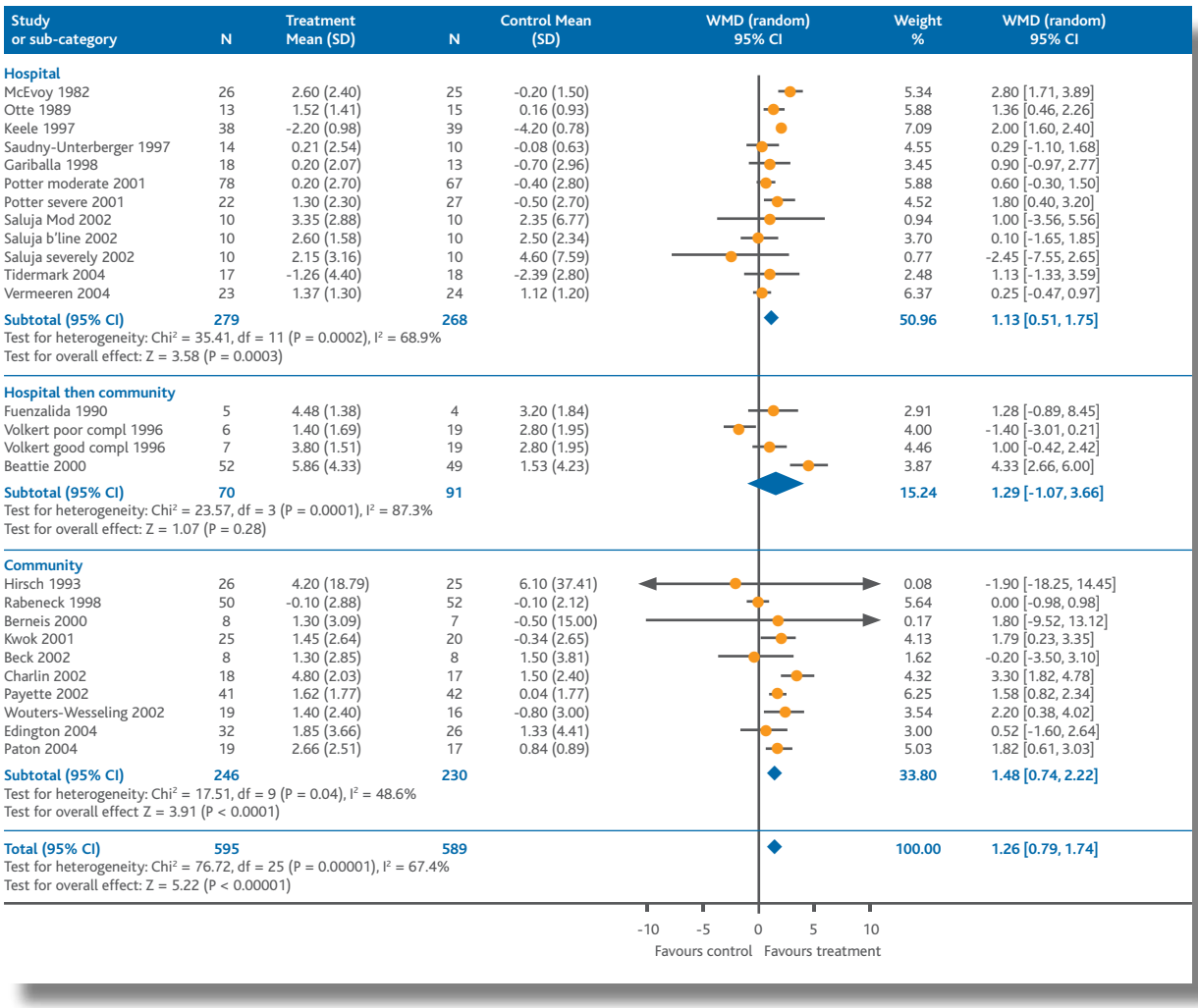


Figure 2.6 ONS vs standard care (all patients): weight change by setting (adapted from NICE 2006)[75]

ONS lead to weight gain in older people in hospital and in the community

- In a large meta-analysis of studies in older people, greater weight gain was seen with ONS compared with routine care (pooled weighted mean difference for percentage weight change was 2.15%; 95% CI 1.8 - 2.49) (variety of **inpatient and community settings**) (Figure 2.7)[11]. Analyses for weight change carried out in sub-groups based on diagnosis showed a significant increase in weight with supplementation for:
  - mixed group of patients with geriatric conditions (weighted mean difference 2.65%; 95% CI 2.19 - 3.10)
  - patients with chest conditions (weighted mean difference 1.58%; 95% CI 0.99 - 2.17)
- Dietary advice and ONS given for four months to older people at risk of malnutrition on **discharge from a geriatric service** resulted in prevention of weight loss whereas controls lost 3.1 kg during the study[118].
- Similar results have been shown (weight gain or weight maintenance) in older people with Alzheimer's disease in **hospital and day care centres**[113†] and older people during and after **hospitalisation**[112†].

†also included in meta-analysis by Milne (2009)

- ONS have been shown to increase body weight in **community** dwelling undernourished older people compared with controls (weight gain mean difference of 1.17 kg (95% CI = 0.07-2.27, p = 0.04) following adjustment for adherence)[119].

- A randomised double-blind placebo controlled trial in older **care home residents** has shown that supplementation with a nutrient enriched ONS leads to weight gain (1.6 kg difference in change p = 0.035)[120].

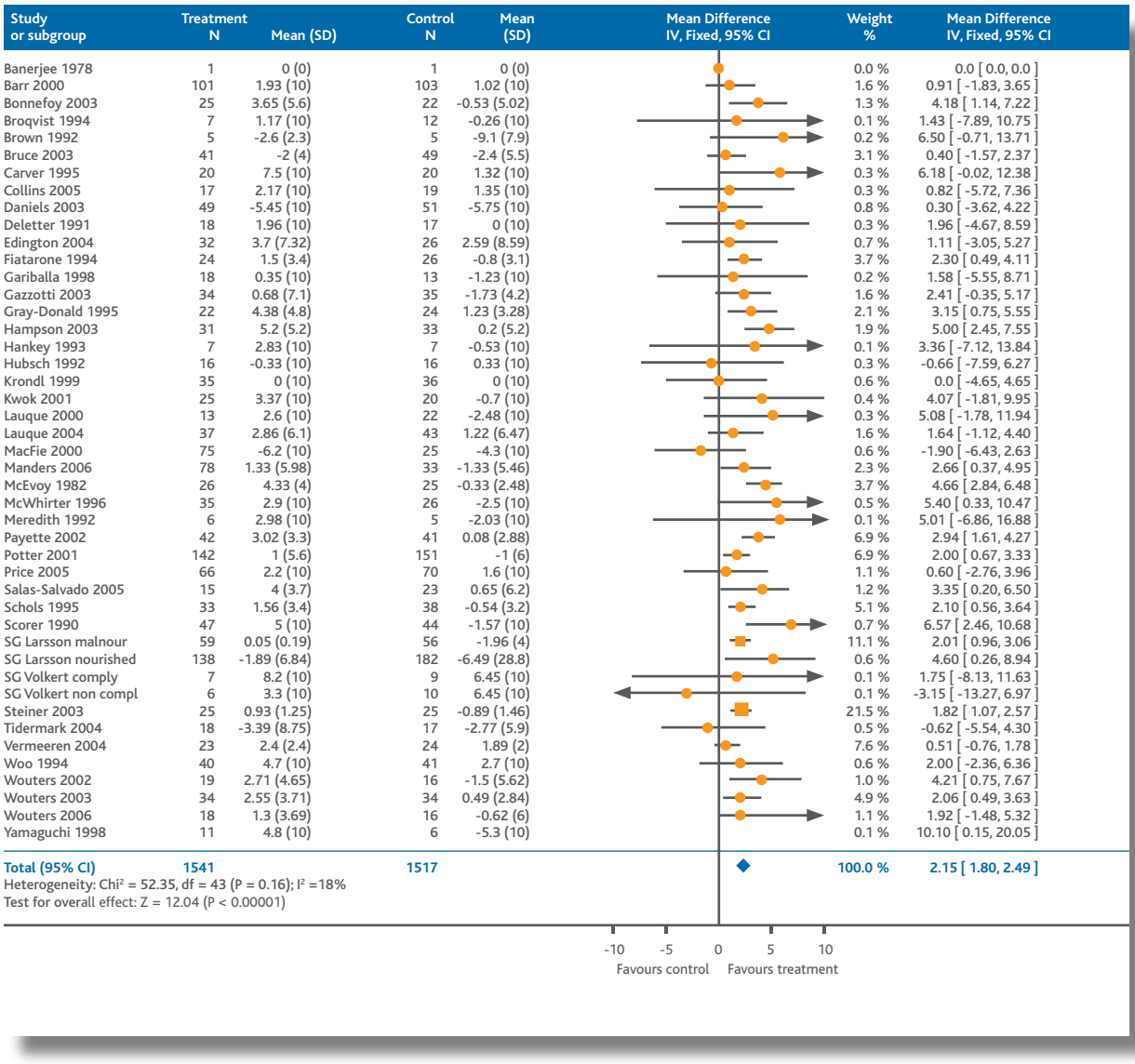


Figure 2.7 Weight change in older people with protein and energy supplementation vs routine care (adapted from Milne 2009)[11]

ONS improve micronutrient status

- NICE (2006) highlight that care should be taken when using food fortification strategies as a means of increasing oral nutrient intake, as food fortification tends to increase energy and/or protein intake without increasing micronutrient intake. Oral nutrition support should contain a balanced mixture of protein, energy, fibre and micronutrients[75].

- In a randomised, double blind, placebo-controlled trial of high protein ONS during **acute illness** in older people **(ONS continued after discharge)** significant improvements were seen in markers of micronutrient status e.g. red-cell folate and plasma vitamin B_{12} levels compared with the decrease seen in the placebo group. This effect was sustained at 6 months (Figure 2.8)[106].

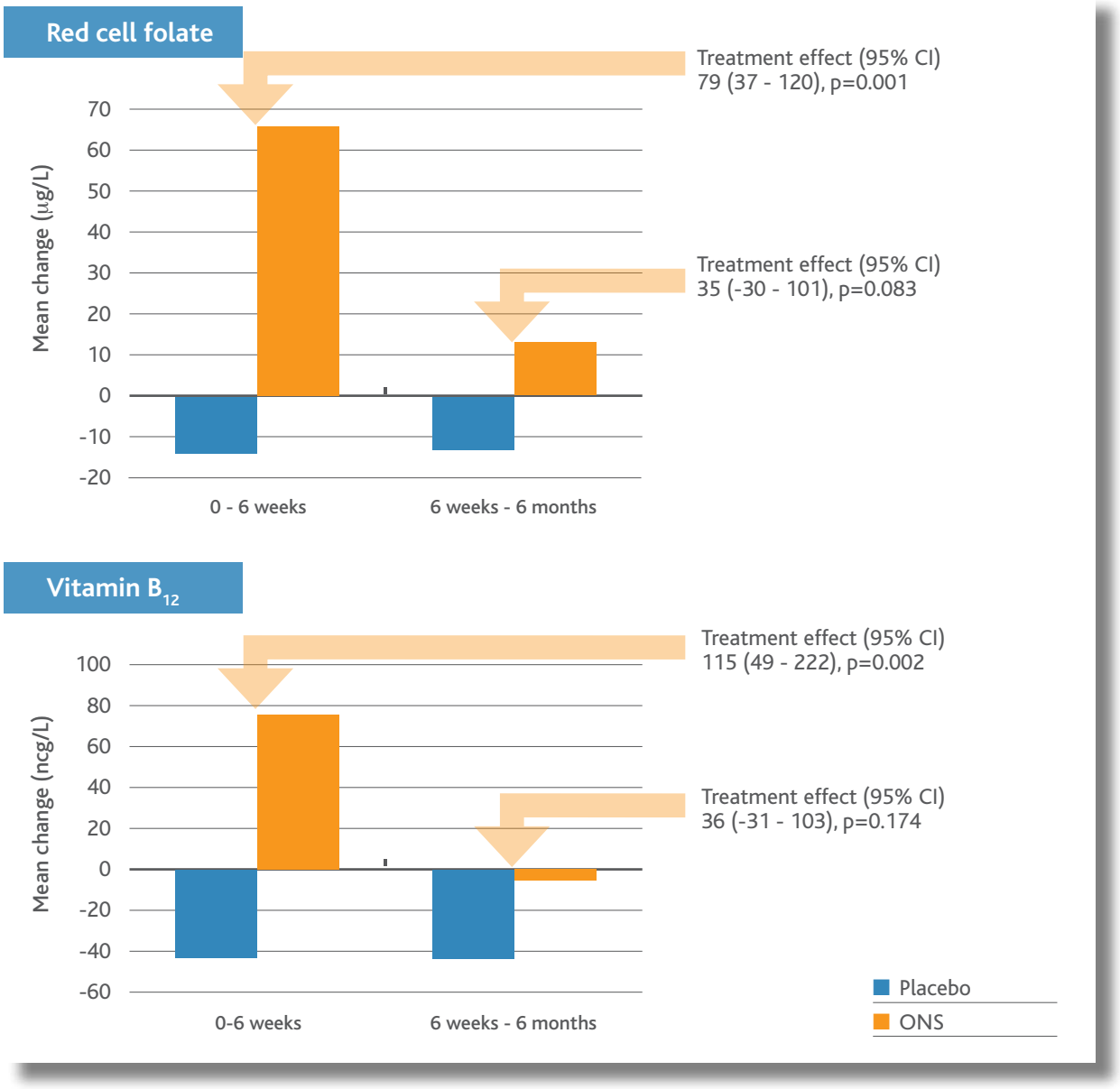


Figure 2.8 Improved red-cell folate and plasma vitamin B_{12} concentrations in patients supplemented with ONS compared with placebo group (adapted from Gariballa 2006)[106]

- An improvement in micronutrient status (vitamin B_1, thiamine diphosphate, vitamin B_6, vitamin B_{12}, folate and vitamin D) has also been observed following supplementation with ONS compared with placebo in a group of psycho-geriatric **nursing home** patients[78].

- Improved plasma vitamin D, vitamin B_{12}, vitamin B_6, homocysteine and folate levels have been observed in older **residents of care homes** given ONS vs placebo[120]. Most vitamin deficiencies normalised, most notably vitamin D (10% vs 75% remained deficient in the ONS vs placebo groups)[117].

ONS can improve lean body mass in older people

Loss of lean body mass (muscle) can lead to reduced muscle function and fatigue, and in turn reduced function e.g. ability to self-care, ability to undertake normal daily activities, risk of falls (see also Section 2.3 Functional Benefits of ONS).

- Use of ONS has been demonstrated in clinical trials to improve lean body mass among:

  - older people with Alzheimer's disease in **hospital** and **day care centres** who are nutritionally at risk (significant increase in fat free mass 0.78 ± 1.4 kg $p < 0.001$)[113]
  - older **hospital** patients who are malnourished (significant increase in fat-free mass + 1.3 kg, $p < 0.001$)[115]
  - older patients in a meta-analysis of 15 trials, n = 1382 (pooled weighted mean difference for % arm muscle circumference change 1.20%; 95% CI 0.45 - 1.96)[11]

Evidence for the use of dietary advice in managing disease-related malnutrition is lacking

- Baldwin (2008) in a review of 36 studies (n = 2714) found a lack of evidence for the provision of dietary advice in managing illness-related malnutrition, and that dietary advice plus ONS are more effective than dietary advice alone or no advice in enhancing short-term weight gain[121].

- NICE (2006) was also unable to demonstrate any evidence of effect of dietary advice; studies were too small and heterogeneous to allow any conclusions to be drawn and many failed to report outcomes of interest[75].

- A review designed to assess the specific impact of the provision of adequate nutritional care (including the routine provision of food and drink) rather than artificial nutritional support (e.g. ONS) concluded that there is a serious lack of evidence to support interventions designed to improve nutritional care meaning that firm conclusions for practice could not be made[122].

2.3 Functional benefits of ONS

ONS lead to functional benefits in hospital patients

- Within the review by Stratton (2003) a number of individual randomised controlled studies in hospital patients showed significant improvements in functional measures with ONS, compared with a control group, such as[1]:
    - improved ventilatory capacity in patients with COPD
    - improved functional benefits including increased activity (assessed using Norton scores) and activities of daily living levels in older people
    - retention of skeletal (hand-grip) muscle strength and improved physical and mental health/quality of life in surgical patients

- In post-stroke patients admitted to a stroke service in a rehabilitation hospital and allocated to receive an 'intensive' ONS (higher energy, protein and vitamin C content) compared with a standard ONS, significant improvement in functional and mobility measures were observed in the intensive ONS group (Functional Independence Measure (FIM) total score (31.49 'intensive' vs 22.94 'standard', $p < 0.001$), FIM motor subscore (24.25 vs 16.71, $p < 0.001$), 2-minute walk (101.60 vs 43.98, $p < 0.001$), and 6-minute walk (299.28 vs 170.59, $p < 0.001$))[123].

ONS lead to functional benefits in patients in the community

- The comprehensive review undertaken by Stratton (2003) showed that in individual randomised controlled studies ONS led to significant improvements in functional parameters, compared with controls, in patients in the community such as[1]:
    - improved respiratory muscle function, hand-grip strength and walking distances in patients with COPD
    - increased activities of daily living and reduced number of falls in older people

- Supplementation with a high-protein ONS (in addition to dietary counselling) in patients with benign gastrointestinal disease in the community improved both hand-grip strength and peak-expiratory flow significantly compared with dietary counselling alone. Reported total protein intake correlated with changes in hand-grip strength ($r = 0.32$, $p = 0.027$) suggesting that the high energy and protein content was most likely responsible for the positive effects on muscle function observed in the ONS group (Table A2.1 in Appendix page 124)[107].

ONS lead to significant functional benefits particularly in older people in the community

- Significant functional improvements have been reported in patients receiving ONS in a number of trials, particularly in older people in the community (Table A2.1 page 124).

- In studies where older patients were given high protein ONS, improvements in hand-grip strength, objective measures of physical activity, peak expiratory flow, depressive symptoms and quality of life, particularly in physical scales, have been reported compared with controls[107;119;124;125].

- Supplementation with ONS for between six and sixteen weeks has shown positive effects on functional outcomes (patients receiving supplements for six weeks commenced ONS in hospital and continued after discharge)[124;125].

- Improvement in Katz activities of daily living (ADL) was observed in older patients at risk of malnutrition randomised to ONS and dietary counselling at discharge from hospital for four months in treated-as-protocol analysis ($p < 0.001$; $p < 0.05$ between groups) (Figure 2.9)[118].

- Milne (2009) reported that meta-analysis of measures of functional status was not possible as the measures reported in trials were often disease specific and too diverse to integrate for analysis[11]. Some studies were not included in this review and appear to have been published after the point at which searches were completed e.g. Norman (2008) and Gariballa (2007)[107;124;125].

- Edington (2004) reported a significant improvement in hand-grip strength during supplementation of older malnourished patients in the community but this was not sustained after supplementation was stopped. Furthermore, positive effects on QOL were not seen, although mobility scores were better in the ONS group than in controls. The authors concluded that in a group of already malnourished subjects, who have many serious underlying disorders, it may be too late to expect to see improvements in functional or quality of life parameters simply by providing a short course (eight weeks) of ONS and that supplementation for a longer period may possibly have a more profound effect[126].

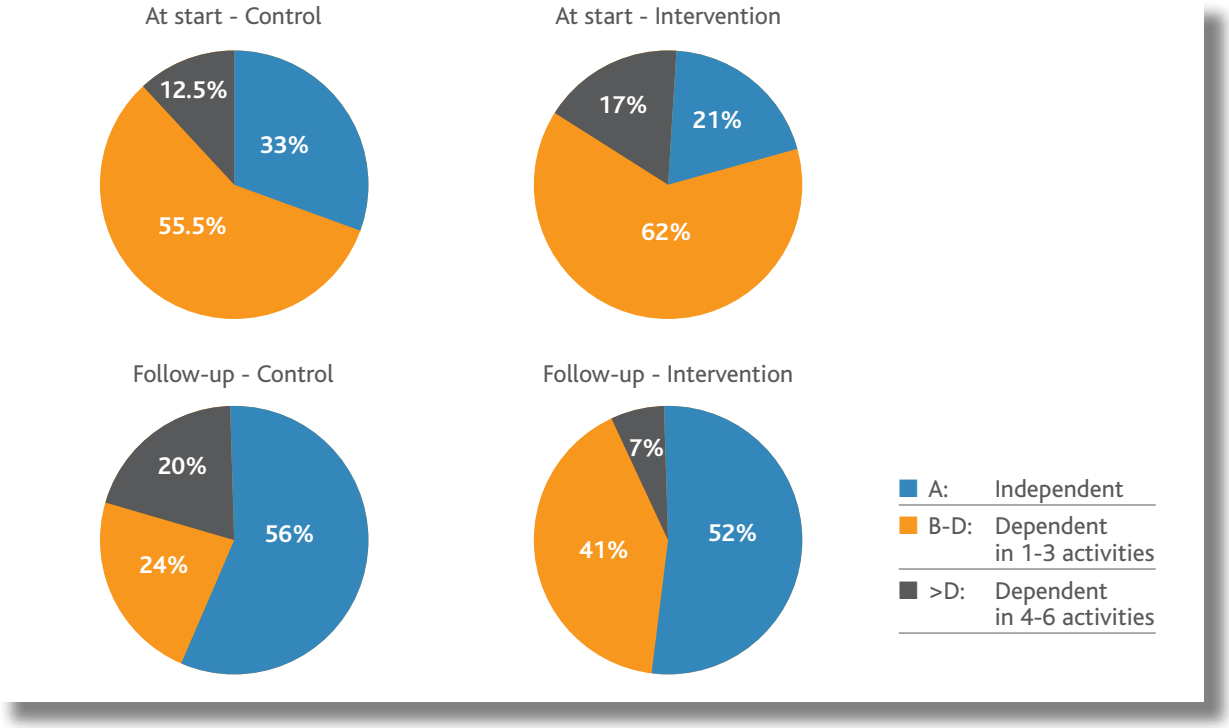


Figure 2.9 Activities of daily life (ADL) registered by the Katz Index at the start and after four months of intervention (activities included: bathing, dressing, toilet, transfer, continence and feeding) (adapted from Persson 2007)[118]

ONS in combination with exercise training can improve muscle strength

- Improvements in muscle strength and muscle power have been observed among frail older people in the community and in long-term care settings who received resistance training/ physical exercise in conjunction with ONS[127;128].

2.4 Clinical benefits of ONS

2.4.1 Mortality

Meta-analyses consistently show a reduction in mortality in patients given ONS versus standard care:

Patients in hospital

- Stratton et al (2003) found that in hospital patients mortality rates were significantly lower in supplemented (19%) than control (25%) patients (Figure 2.10) (older people, liver disease, surgery and orthopaedics, $p < 0.001$; odds ratio 0.61 (95% CI, 0.48 - 0.78), meta-analysis of 11 trials, n = 1965; no significant heterogeneity between individual studies)[1]. This represented a 24% reduction in mortality.

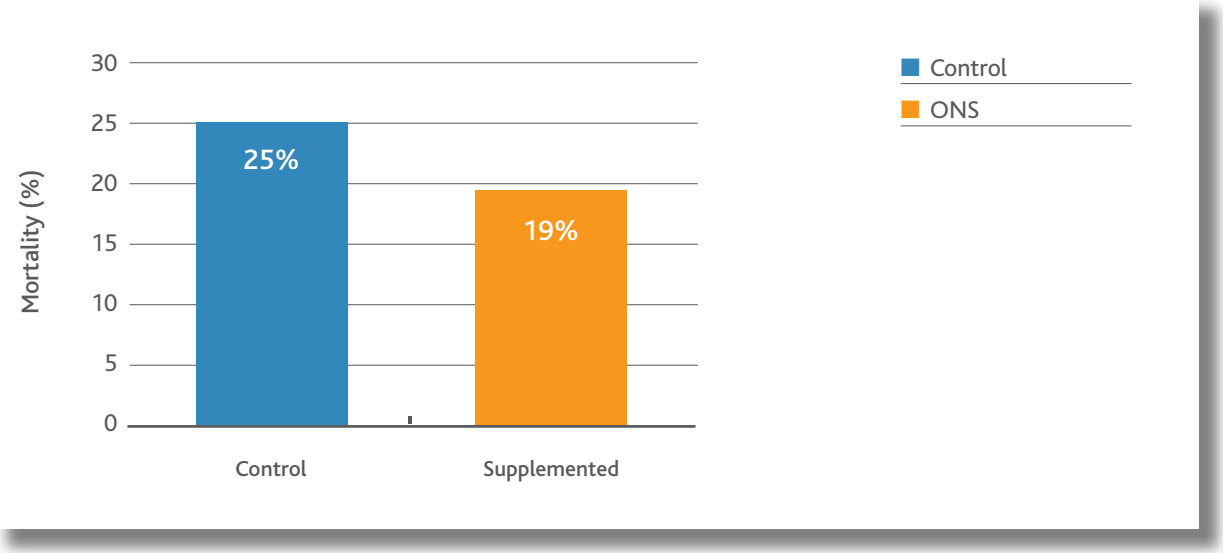


Figure 2.10 Lower mortality in supplemented versus control patients (p<0.001) (adapted from Stratton 2003)[1]

- The reduction in mortality with ONS tended to be greater in patient groups in which the average BMI was < 20 kg/m^2 than in those with a BMI > 20 kg/m^2 [1].

Patients in hospital and the community

- Meta-analysis by NICE (2006) of RCTs of ONS versus standard care in malnourished patients across healthcare settings and diagnoses demonstrated a statistically significant reduction in mortality (25 studies, relative risk 0.82, 95% CI 0.69 - 0.98) (Figure 2.11)[75].

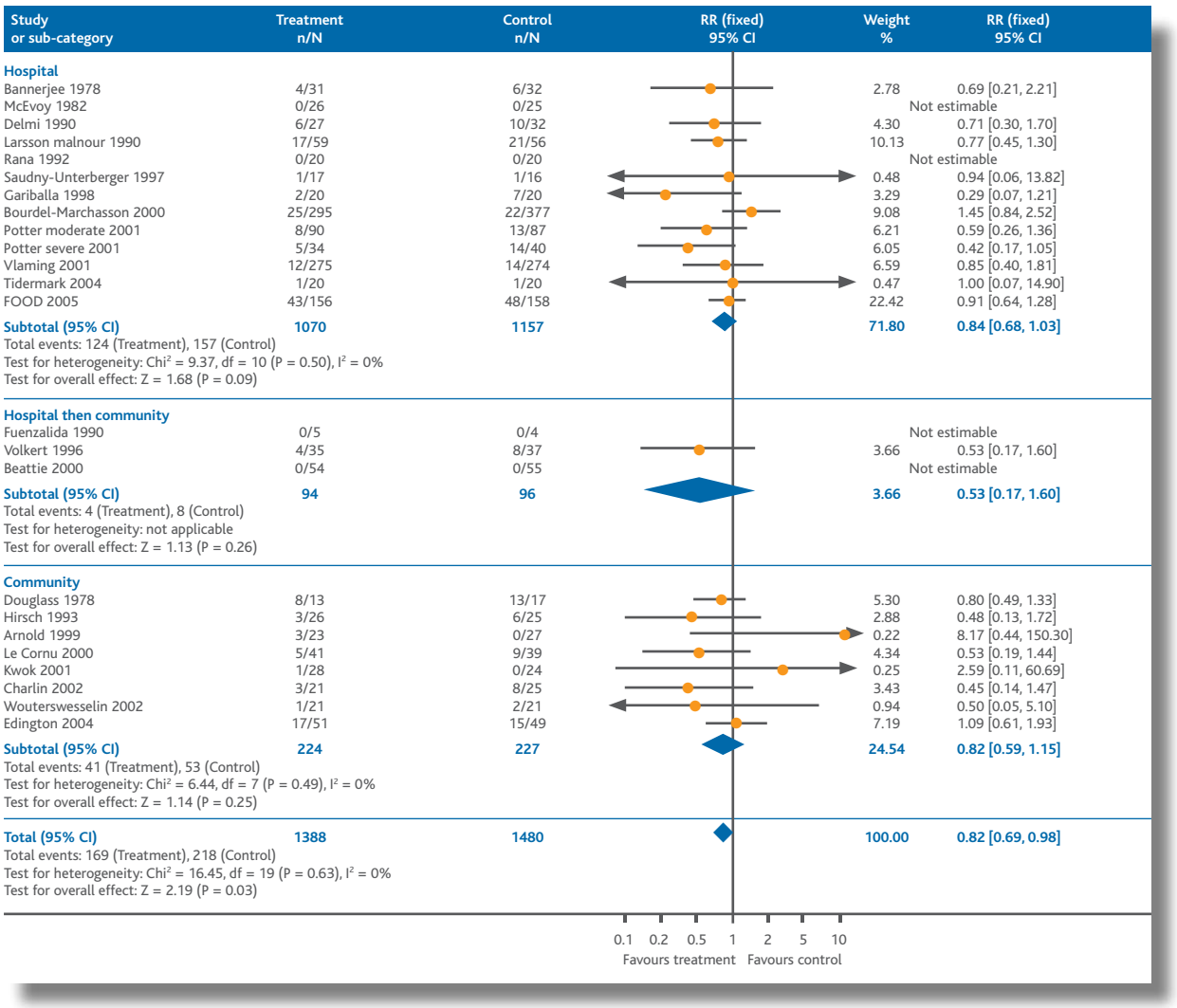


Figure 2.11 ONS vs standard care (all patients): mortality by setting (adapted from NICE 2006)[75]

Undernourished older patients

- A Cochrane systematic review (Avenell 2006) of intervention with ONS among older hip fracture patients suggested that significantly fewer patients had unfavourable outcome (combined outcome of mortality and survivors with medical complications) with ONS vs routine care (RR 0.52, 95% CI 0.32 - 0.84)[129]. A recent update of this review no longer shows a significant effect (original review intervention group n = 66 and control group n =73, updated review intervention group n = 126 and control group n = 103)[130]. The update includes one new study of ONS in normally nourished or mildly malnourished older patients, where malnourished individuals were excluded[131].

- The Cochrane systematic review by Milne on protein and energy supplementation in older people completed in 2005 reported that nutritional supplementation was associated with a statistically significant reduction in mortality (32 trials n = 3021; relative risk 0.74; 95% CI 0.59 - 0.92). In sub-group analyses in this report improved survival with ONS was observed in undernourished patients (21 trials, n = 1825; relative risk 0.72; 95% CI 0.55 - 0.94), when people were aged ≥ 75 years of age (24 trials, n = 2033; relative risk 0.69; 95% CI 0.54 - 0.87), when participants were not well (28 trials, n = 2628; relative risk 0.73; 95% CI 0.59 - 0.92) and when they were offered 400 kcal per day as ONS (19 trials, n = 2177; relative risk 0.71; 95% CI 0.56 - 0.90)[104].

- The reduction in mortality with ONS was borderline statistically significant in an update of this meta-analysis in 2006[105] (25 trials, n = 6852, odds ratio 0.86; CI 0.74 - 1.00), and not significant in a further update in 2009[11] (42 trials, n = 8031, relative risk 0.92; 95% CI 0.81 - 1.04). The updates included the FOOD trial[132] which contributed 4,023 patients of whom only 8% were classified as malnourished at baseline. As most patients were well-nourished, it has been suggested that the wrong patient group was selected for nutrition support[133]. The results of the FOOD trial suggested that routine use of ONS in well-nourished stroke patients is unlikely to be useful; however the potential benefit of ONS in malnourished patients was not investigated in this trial[132]. The patients most likely to benefit from nutrition support, i.e. severely malnourished patients, are often excluded from trials in nutrition support due to ethical reasons[134].

- The 2009 updated Cochrane review by Milne[11] also included Gariballa (2006) where the number of deaths reported at 6 months was higher in the supplemented group (32/223; 14%) compared with the placebo group (19/222; 9%) but this was not significant (p = 0.6). Twelve of the deaths in the supplemented group and seven in the placebo group occurred within the first six weeks of randomisation and fifteen of the patients who died in the supplemented group consumed three or less of the total number of ONS prescribed[106]. This may reflect the nature of study group i.e. acutely unwell older patients.

- However, sub-group analyses in all three meta-analyses by Milne have consistently shown a statistically significant reduction in mortality in undernourished patients receiving ONS compared to routine care (21 trials, n = 1825, relative risk 0.72; 95% CI 0.55 - 0.94[104]; 17 trials, n = 2093, odds ratio 0.73; CI 0.56 - 0.94[105]; 25 trials, n = 2466, relative risk 0.79; 95% CI 0.64 - 0.97[11]). Furthermore, an improvement in survival has also been consistently shown in all three meta-analyses when patients were offered 400 kcal per day as ONS (19 trials, n = 2177, relative risk 0.71; 95% CI 0.56 - 0.90[104]; 15 trials, n = 6157, odds ratio 0.85; CI 0.73 - 0.99[105]; 24 trials, n = 7307, relative risk 0.89; 95% CI 0.78 - 1.00[11]).

2.4.2 **Complications** (including development of pressure ulcers)

Meta-analyses consistently show a reduction in a variety of complications with ONS in:

Hospital patients

- Stratton (2003) showed that complications rates (infective and others such as GI perforation, pressure ulcers, anaemia, cardiac complications) were significantly lower in supplemented (18%) than in unsupplemented (41%) hospital patients (see Figure 2.12 (surgical, orthopaedic, older people, neurology, p < 0.001; odds ratio 0.31 (95% CI 0.17 to 0.56), meta-analysis of 7 trials, n = 384; no significant heterogeneity between studies))[1]. This represented a 56% reduction.

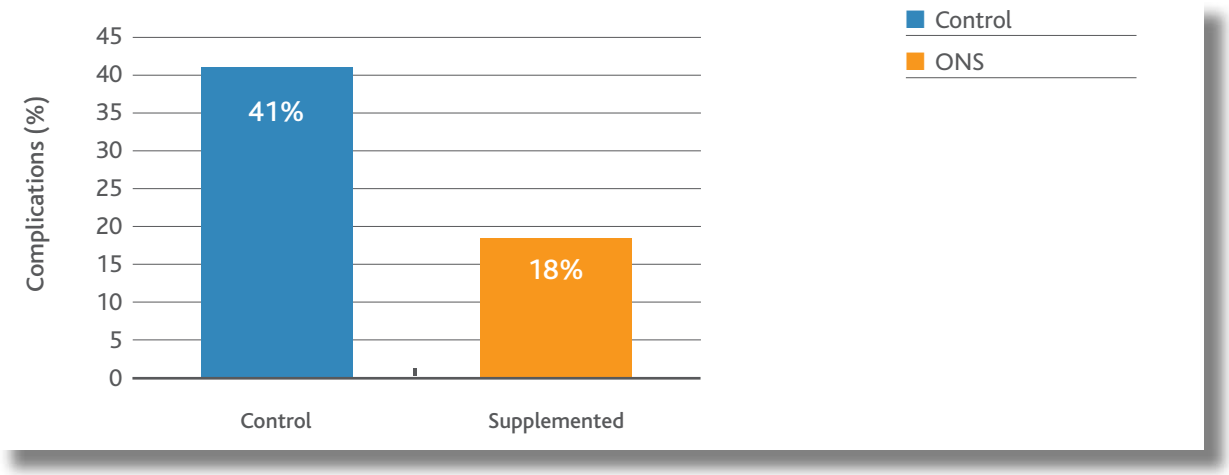


Figure 2.12 Lower complication rates in supplemented versus control patients in hospital (p<0.001) (adapted from Stratton 2003)[1]

- Complications rates were reduced by ONS in patient groups independent of BMI (with a BMI < 20 kg/m^2 (three trials, 12% vs 27%; odds ratio 0.38 (95% CI 0.07 - 1.97)) and > 20 kg/m^2 (one trial, 12% vs 27%)) or when BMI was unknown (three trials, 38% vs 75%, odds ratio 0.21 (95% CI 0.04 - 1.18))[1].

- NICE (2006) similarly found a significant reduction in complications in hospital patients given ONS versus standard care (9 trials, relative risk 0.75 CI 0.64 - 0.88) (Figure 2.13)[75].

- Meta-analysis by Milne (2009) showed a reduction in complications in older people treated with ONS compared to routine care (24 trials, n = 6225, relative risk 0.86; 95% CI 0.75 - 0.99) and in a sub-group analysis of patients with hip fracture (6 trials, n = 298, relative risk 0.60; 95% CI 0.40 - 0.91) but not in other patient sub-groups (variety of hospital and community settings) (Figure 2.14)[11].

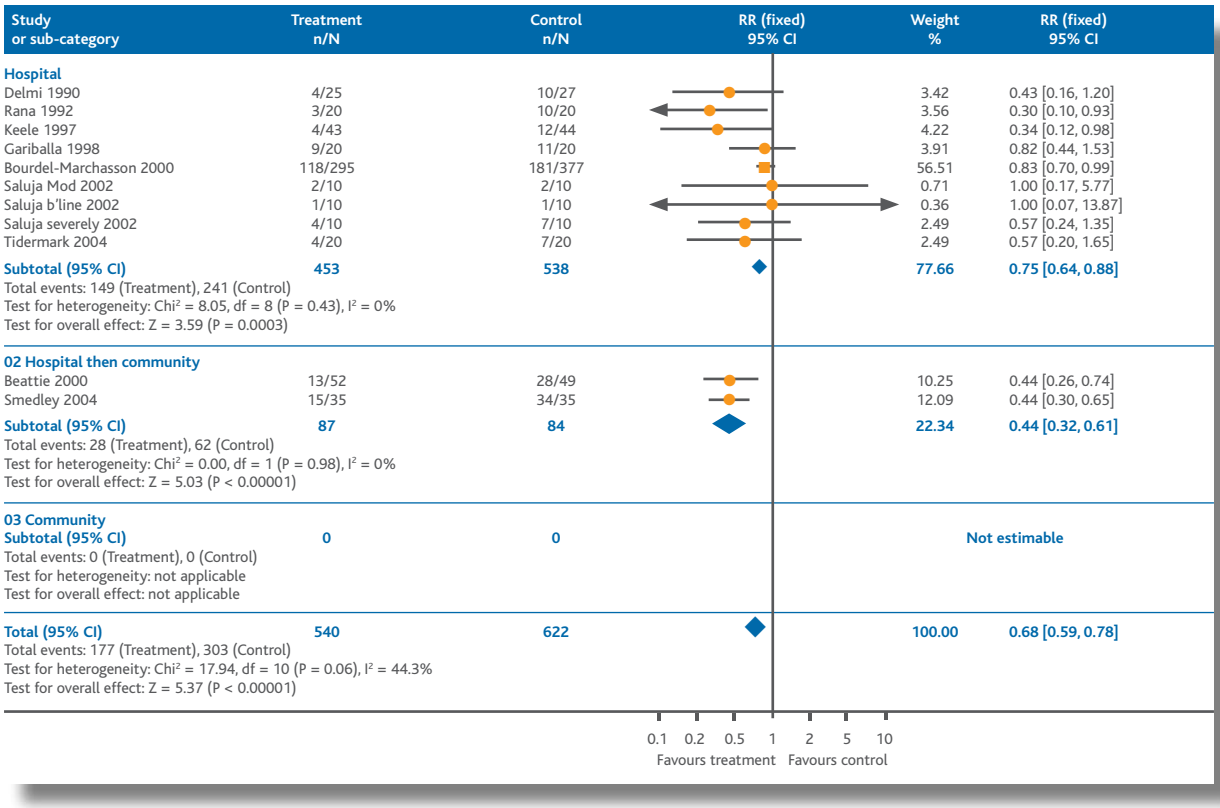


Figure 2.13 ONS vs standard care (all patients): complications by setting (adapted from NICE 2006)[75]

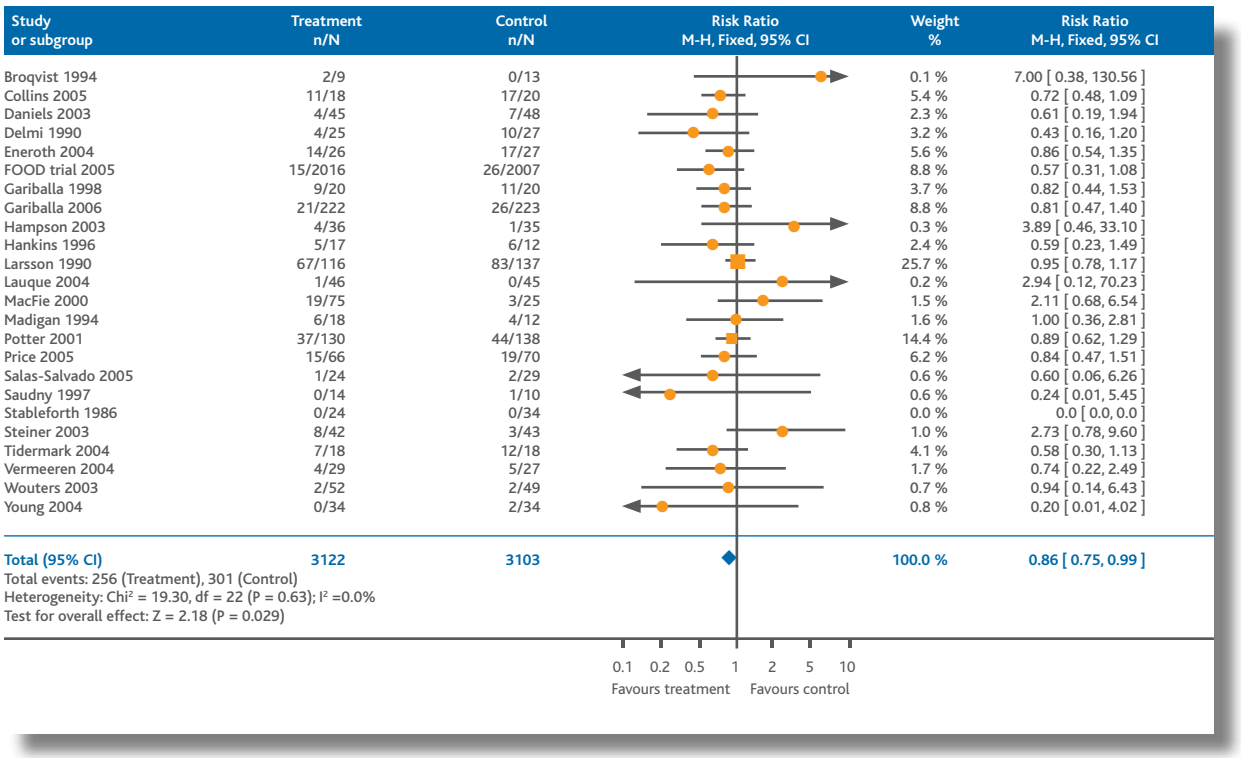


Figure 2.14 ONS vs routine care in older patients (variety of settings): complications (adapted from Milne 2009)[11]

In patients who start ONS in hospital, and continue in the community

- The meta-analysis undertaken by NICE (2006) showed fewer complications in patients who started on ONS in the hospital setting and then continued in the community (2 trials, relative risk 0.44, CI 0.32 - 0.61)[75].

- In gastrointestinal surgical patients undergoing a variety of procedures a significant reduction in complication rates was seen in patients receiving ONS (250 - 600 kcal/d for 7 days to 10 weeks, 6 trials, odds ratio 0.37, CI 0.23 - 0.60)[135].

- A systematic review of post-discharge supplementation with ONS in patients undergoing gastrointestinal surgery highlighted the lack of available data specifically on the post-discharge period but nevertheless concluded that it would be sensible to offer nutrition support to malnourished patients at high risk of poor nutritional intake post-discharge[136].

Protein rich supplements may be of special interest in reducing clinical complications

- A Cochrane systematic review (Avenell and Handoll 2010) of intervention with ONS among older **hip fracture patients** concluded that protein-enriched ONS (> 20% total energy from protein) reduces the number of long-term medical complications (relative risk 0.78, 95% CI 0.65 - 0.95)[130].

- Specifically protein rich ONS have been shown to reduce the incidence of complications in **hospital and community** settings in patients with hip fracture, leg ulcer or acutely ill older people compared with routine care (7 trials, n = 1543; odds ratio 0.68, CI 0.54 - 0.86). Complications included infections, poor wound healing, leg and pressure ulcers. In four out of the five trials conducted in the community, patients started on ONS in hospital (Figure 2.15)[137].

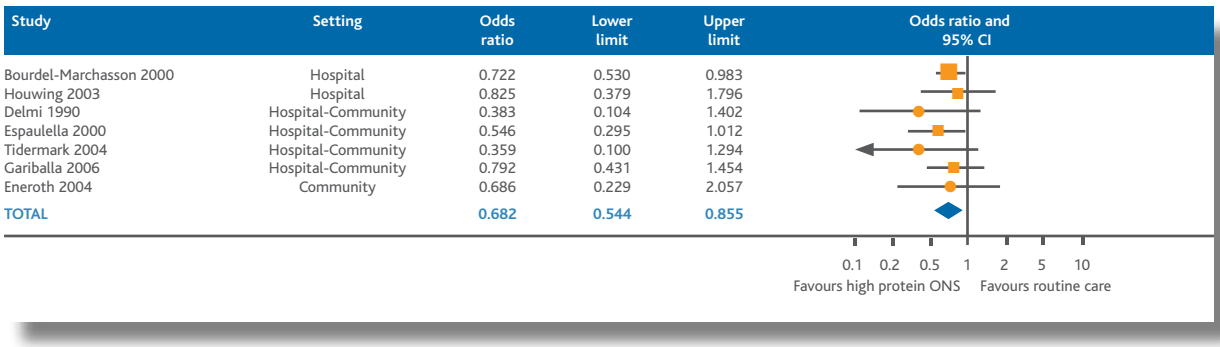


Figure 2.15 Significant reduction in complications with high protein ONS compared with routine care (adapted from Cawood 2007)[137]

Protein rich ONS are of particular interest in the prevention of development of pressure ulcers

- Pressure ulcers affect 10% of people in hospitals and older malnourished people are at highest risk. Older people recovering from illness appear to develop fewer pressure ulcers when given two high protein ONS daily[138].

- Meta-analysis of studies using high protein ONS showed a significant reduction in the risk of developing pressure ulcers in high risk patient groups (by 25%) (4 trials, n = 1224, odds ratio 0.75; 95% CI 0.62 - 0.89) (Figure 2.16)[139].

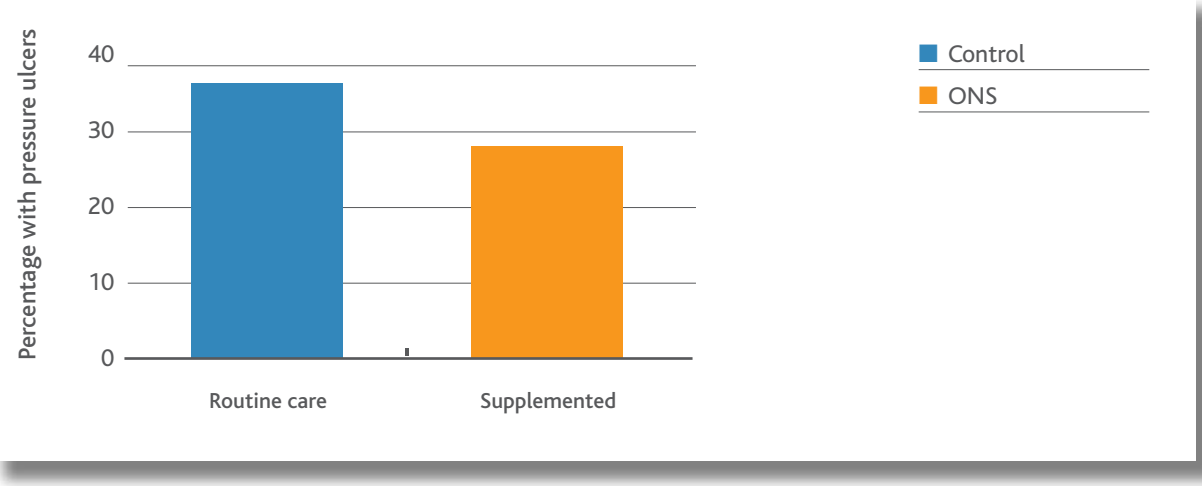


Figure 2.16 Prevention of pressure ulcers in at-risk patients with ONS (hospital and long-term care): summary results from a meta-analysis (odds ratio 0.75; 95% CI 0.62-0.89) (adapted from Stratton 2005)[139].

2.4.3 Length of hospital stay and readmissions

ONS reduce length of hospital stay

- Meta-analysis by Stratton (2003) showed that length of hospital stay in supplemented compared with control patients was reduced significantly in all nine RCTs that presented results, either as means or medians (9/9 trials; two-tailed binomial test, $p < 0.004$). The average reductions ranged from two days (in surgical patients) to 33 days (in orthopaedic patients). Meta-analysis of four trials that recorded mean of LOS in surgical and orthopaedic patients indicated that ONS was associated with a reduced LOS relative to control patients (effect size -0.80 days (95% CI -1.24 - 0.36))[1].

- The reduction in length of stay appeared to be greater in patient groups with a BMI < 20 kg/m^2 than when BMI was > 20 kg/m^2 [1].

- Meta-analysis suggests that high-protein ONS significantly reduce both length of stay and hospital readmissions compared with routine care, with economic implications (Figure 2.17)[108].

Outcome	Statistics	Significance (p)
Length of acute hospital stay (d; three RCT; n 725)	-0.55 (95% CI -1.66, 0.57)*	0.34
Length of acute hospital and community stay (d; two RCT; n 122)	-9.69 (95% CI -12.19, -7.19)*	<0.0005
Readmissions (one RCT; n 445)	OR 0.62 (95% CI 0.42, 0.93)	0.02

*Unstandardised difference in means; d= days

Figure 2.17 Reduced length of stay and hospital readmissions with supplementation with high protein ONS (adapted from Cawood 2008)[108]

ONS reduce non-elective hospital readmissions

- The proportion of acutely ill older people readmitted to hospital at six months was significantly lower in patients randomly assigned to receive high protein ONS (29%) compared with those in the placebo group (40%) ($p < 0.05$) (n = 445, aged between 65 and 92 years) representing a 28% reduction (Figure 2.18). The risk of non-elective readmission in the 6-month follow up period was significantly lower in the supplement group than in the placebo group after adjustment for other clinical risk indicators (hazard ratio 0.68, CI 0.49 - 0.94)[106].

- Three month post-hospital intervention with high protein and energy ONS compared with dietary counselling (DC) showed that in 80 malnourished patients with benign digestive disease, DC patients experienced significantly more readmissions (n = 20) than ONS patients (n = 10) during the study period ($p = 0.041$)[107].

- Chapman (2009) studied the effects of treatment with oral testosterone and ONS administered alone (ONS alone n = 13, testosterone alone n =12) or combined (n = 11) and compared with no treatment (n = 13) in a group of community-dwelling, undernourished older people. They found that the combined treatment group had significantly fewer subjects admitted to hospital compared with the no-treatment group (0 vs 5, $p = 0.03$), had fewer days in hospital (0 vs 74, $p = 0.041$) and had a longer time to admission ($p = 0.017$)[140].

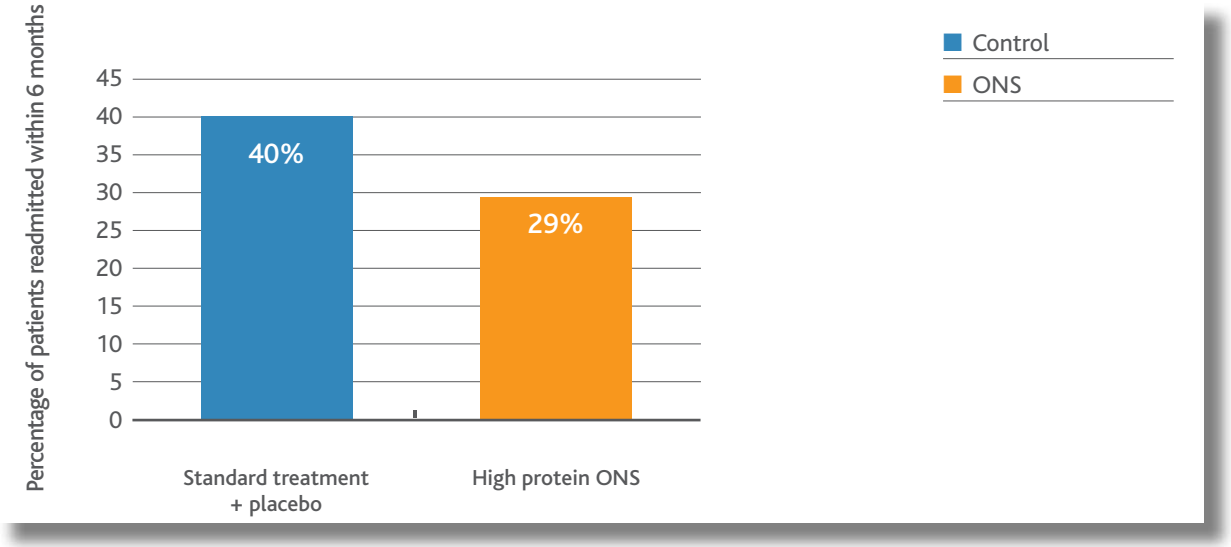


Figure 2.18 Lower readmissions to hospital in patients supplemented with high protein ONS at six months ($p<0.05$) (adapted from Gariballa 2006)[106].

ONS can improve rehabilitation outcome

- In undernourished patients admitted to a stroke service, those randomised to receive an 'intensive' (higher energy, protein and vitamin C content) supplement (n = 51 in both groups) were more likely to be discharged home (63%) compared with those given a standard ONS (43%) ($p < 0.05$) (34% reduction in discharges to institutional settings)[123].

2.5 Economic benefits of ONS

ONS have economic benefits in hospital patients with or at risk of malnutrition

- A retrospective cost analysis was undertaken by Stratton et al (2003) of nine RCT (with and without use of ONS). This simple analysis demonstrated mean cost savings of between €407* (£352) and €9458* (£8179) per patient in surgical, orthopaedic, elderly and cerebrovascular accident patients[1].

- The British Association for Parenteral and Enteral Nutrition (BAPEN) undertook a cost analysis of the use of ONS in hospital. Data was extracted from RCTs of ONS versus standard care. Three key variables were chosen for analysis: the amount of supplement consumed, length of hospital stay and complications. The study suggested that use of ONS in hospital patients results in a cost saving in abdominal surgical patients (Figure 2.19) and in orthopaedic surgical patients, elderly care and stroke patients. The pooled results from the analysis indicated a mean net cost saving from the use of ONS of €982* (£849) per patient based on bed-day costs or €345* (£298) per patient if calculated using complication rates (Table 2.2)[17].

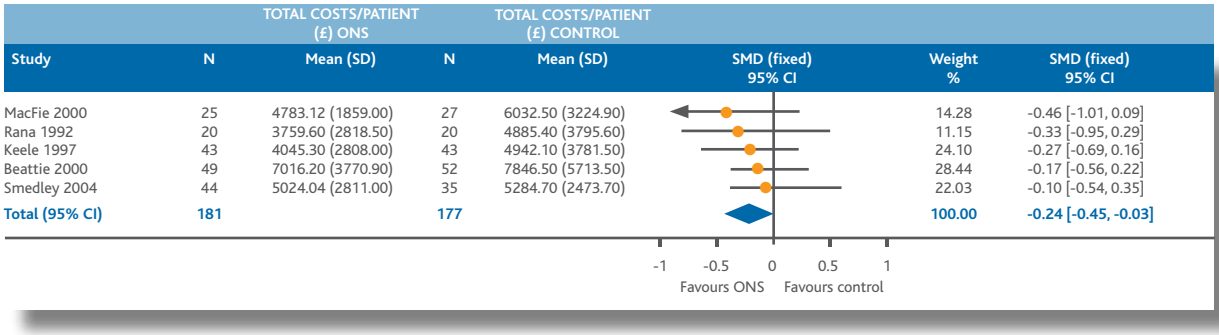


Figure 2.19 Effect of ONS on net cost saving in surgical studies in the UK (based on bed-day costs) (SMD, standardised mean difference) (adapted from Elia 2005)[17]

- A meta-analysis using fixed effects model and standardised costs showed that for all stages of pressure ulcers, high protein ONS result in net cost savings of between €6* (£5) (stage I) and €532* (£460) (stage IV) per patient when given to older patients at risk of developing pressure ulcers (compared with placebo or no ONS). The result was significant for stage III (effect size 0.12 (95% CI 0.00 - 0.11; p = 0.04) and stage IV ulcers (effect size 0.12 (95% CI 0.01 - 0.11 p = 0.04)) (Table 2.2)[141].

Table 2.2 Cost savings per patient with ONS

Patient group	Cost saving per patient
Older patients at risk of developing pressure ulcers (Stage IV) [101]	€532* (£460)
Pooled results from analysis in surgical, elderly and stroke patients[64]	€982* (£849) (bed day costs) €345* (£298) (complication costs)
Abdominal surgery patients[102]	€252* (£218)

ONS have economic benefits in surgical patients

- In The Netherlands the use of ONS reduces costs in treating abdominal surgery patients from €3318 - €3066, which corresponds to a €252 (7.6%) cost saving per patient compared with standard care without ONS. The cost of ONS are more than balanced by a reduction in hospitalisation costs (€3318 - €3044 per patient, 8.3% cost saving corresponding with 0.72 days reduction in length of stay) (Table 2.2). The use of ONS would lead to an annual cost saving of €40.4 million based on the number of abdominal procedures performed (160,283) per year in the Netherlands[142].

ONS as part of intervention to prevent malnutrition can reduce costs

- Early intervention with ONS (as part of a interdisciplinary intervention i.e. screening for malnutrition, dysphagia and dehydration on admission followed by standard high-energy diet, ONS, swallowing therapy and rehydration) in hospital patients helped to reduce the overall cost of care (by an average of €392 per kg weight gained), primarily through reductions in the cost of nursing care[143].

- Lassen (2006) performed a cost analysis that estimated the potential savings achieved by reducing the number of medical inpatient days through the appropriate use of ONS. The analysis considered an average €160** (USD 226) per day (1997 values) cost reduction for each day less spent in hospital. Results of the analysis indicated that with appropriate use of ONS, there is a potential for hospitals in Denmark to realise cost savings of approximately €15.6** (USD 22 million) in the period of a year[144].

ONS have economic benefits in the community

- Data from the community are less amenable to economic evaluation, however, the analyses performed by BAPEN suggest that overall economic benefits can be achieved from use of ONS in the community. If hospital admission is prevented then the cost of prescribing ONS in the community may well be offset[17;145]. Once hospital admission is necessary the costs are likely to accumulate, as patients with or at risk of malnutrition have:

    - higher average cost of care[146]
    - higher rates of complications[147]
    - higher medical costs for medicines, especially antibiotics[148]
    - delayed functional recovery post-discharge[149]
    - greater home healthcare needs[150]
    - higher rates of hospital readmission[93]

- A prospective observational longitudinal cohort study undertaken by Arnaud-Battandier (2004) evaluated the economic impact of using ONS among malnourished older people in the community in France. Intervention with ONS supported clinical and economic advantages including[151]:

    - reduction in healthcare utilisation
    - fewer home nursing visits
    - less GP and physiotherapist visits
    - fewer hospital admissions
    - shorter length of hospital stay with admission

- After considering the investment required for ONS, the average reduction in medical care costs was €195 per patient (Table 2.3)[151].

* Calculated based on an exchange rate of £ to € of 1.1564 (17/07/2009)

** Calculated based on an exchange rate of USD to € of 0.7076 (17/07/2009)

Table 2.3 Adjusted healthcare costs, mean per patient (€) (adapted from Arnaud-Battandier 2004)[151]

	Group 1 (n = 125)	Group 2 (n = 186)	Difference
Oral supplementation [90% CI]	37	565	+ 528 [+478; +578]
Other medical care			
Hospital admissions	2123	1572	- 551
Nurse visits	362	217	- 145
GP visits	42	32	- 10
Physiotherapist visits	39	37	- 2
Specialist visits	2	3	+ 1
Examinations	5	7	+ 2
Other costs	84	66	- 18
Sub-total [90% CI]	2657	1934	- 723 [- 1444; - 43]
Total cost [90% CI]	**2694**	**2499**	**- 195 [- 929; + 478]**

- In The Netherlands, the use of ONS in malnourished patients > 65 years in the community was shown to reduce total healthcare costs from €1353 to €1180, corresponding to a €173 (12.8%) cost saving per patient in 2009[206]. In a budget impact analysis, the additional costs of ONS (€57 million) were more than balanced by a reduction in other healthcare costs (€70.3 million) resulting in overall annual cost savings of €13.3 million (18.9%) when all eligible patients are treated[207].

- In Germany, the cost of ONS in malnourished patients in the community (€534) were more than off-set by a reduction in hospitalisation costs (€768) based on Disease Related Group costs, leading to a total cost saving of €234 per patient. Similar results were obtained when analysis was based on length of stay and per diem costs. The national annual cost savings were calculated to vary between €604 million and €662 million[208].

ONS are cost-effective

- Economic modelling undertaken by NICE (2006) of the use of ONS within the context of a screening programme undertaken in older hospital patients suggests cost-effectiveness in terms of cost per quality adjusted life year (QALY[#]) i.e. €7,864* (£6,800) which is well below the NICE threshold of €23,128-34,692* (£20-30,000)/QALY for treatments deemed to be good value for money[75].

[#]QALY is an index of survival that is adjusted to account for the patient's quality of life. QALYS have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. QALYS are used to measure benefits in cost-utility analysis.

* Calculated based on an exchange rate of £ to € of 1.1564 (17/07/2009)

SECTION 3

ONS as an integrated part of key guidelines

Summary

Good nutritional care includes nutritional screening that leads to the development of an individualised patient nutritional care plan that takes account of evidence based guidelines in the selection of the most appropriate nutritional intervention. This care plan should be clearly documented and communicated and the patient's progress monitored regularly against the goals set out in the care plan. This ensures an evidence-based, joined up approach to nutritional care.

ONS are increasingly recognised as an integral part of the overall patient management strategy for malnutrition, in hospitals and in the community, based on the good quality evidence that ONS lead to improvements in nutritional intake, body composition, clinical, functional and economic outcomes. Evidence-based national and professional guidance have been developed in many countries to ensure that malnutrition is treated e.g. ESPEN Guidelines for nutrition support in a variety of different patient groups, NICE Clinical Guideline Nutrition Support for Adults (2006). Guidelines must be regularly updated to reflect new evidence and efforts need to be made to include nutritional care in treatment guidelines for specific patient groups.

In recent years screening as part of a programme of nutritional care for malnutrition has been introduced as a mandatory requirement in hospitals in Scotland (2003) and in hospital and community care in The Netherlands (2007). From 2011 nutritional screening will be mandatory as part of accreditation in hospitals in Denmark. In The Netherlands participation in audits and improvement programmes linked to mandatory standards has resulted in a lower prevalence of malnutrition[152].

However, in order to be successful, guidelines based on sound evidence must be translated from theory into practice. Nationally or locally developed nutritional care protocols based on the guidelines should be available to healthcare professionals to assist them in providing the right nutrition support to the right patients at the right time, including how to set and review goals of treatment to inform decisions about stopping nutritional support.

Barriers to implementing effective nutritional screening programmes exist with consequences that affect individual patients and their use of healthcare resources. Elia (2003) identified such barriers as[4]:

- diffuseness of responsibility
- inadequate infrastructure
- lack of consistent criteria or weightings to identify malnutrition/risk of malnutrition using screening tests
- lack of education

These barriers lead to under-recognition and under-treatment of nutritional risk, failure to link a screening tool to a care plan and failure to establish continuity of care.

Key messages

- Continued effort is needed to ensure guidelines are updated to reflect the evidence base; to integrate good nutritional care into guidelines for specific diseases (e.g. nutritional support as part of cancer care guidelines); and to ensure that these guidelines are recognised and established as a credible and essential basis for good patient care.
- Translation of "academic guidelines" into practical advice for healthcare professionals is needed to achieve both improved patient outcomes and to ensure appropriate use of resources.
- Sustained effort is needed to implement guidelines in practice; the link between guidelines, practical advice and individual care plans is critical and should be regularly audited and evaluated to identify challenges and successes which should be acted upon and shared.

Examples

Evidence-based guidelines for the nutritional management of patients with a variety of conditions are listed. This list is not exhaustive and other existing and newly developed national and professional guidelines should be added. Non-European guidelines have been included if available in English.

In several cases, different terminologies have been used to mean ONS, such as sip feeds and dietary supplements. To avoid confusion with vitamin and mineral food supplements, for the purposes of this report the term [ONS] has been inserted for clarification purposes.

Implementation of guidelines for good nutritional care have been shown to have positive outcomes in terms of an improvement in documentation of nutritional information, a reduction in the prevalence of malnutrition, reduced hospital length of stay, reduced hospital admissions and costs.

3.1 Examples of key national and professional guidelines

General

Table 3.1 Summary of some examples of evidence-based national and professional guidelines referring to ONS as an integral part of patient and disease management - General (parts of guidelines relevant to ONS presented here)

Country	Body	Patient Group	Title	Recommendation, guideline or standard [grade of evidence]
Denmark	The Veterinary and Food Administration, Ministry for Food, Agriculture and Fisheries (2002)	Patients in institutions	Recommendations for Food in Danish Institutions	• ONS can be used when patients require food that is easy to chew and swallow e.g. ONS can be offered as or with modified texture foods e.g. jelly or liquid type foods • ONS are needed when patients have poor oral food intake • ONS should be offered to all patients with fractured neck of femur on admission as these patients are most often elderly and malnourished • ONS should be offered to patients who need foods which are easy to chew and swallow due to mouth problems • ONS are included in the list of recommended between meal snacks **Note:** This is a summary in English of the key parts of the Danish guidelines that relate to ONS
England and Wales	National Institute for Health and Clinical Excellence (NICE) (2006)[75]	All patients in hospital and in the community	Nutrition Support for Adult Oral Nutrition Support, Enteral Tube feeding and Parenteral Nutrition	Indications for oral nutrition support: • Healthcare professionals should consider oral nutrition support[1] to improve nutritional intake for people who can swallow safely and are malnourished[2] or at risk of malnutrition[3]. [A] • Healthcare professionals should ensure that the overall nutrient intake of oral nutrition support offered contains a balanced mixture of protein, energy, fibre, electrolytes, vitamins and minerals. [D(GPP)] • Oral nutrition support should be stopped when the patient is established on adequate oral intake from normal food. [D(GPP)] **Note:** see Table 3.4 for summary of grading of recommendations

Table 3.1 continued

Country	Body	Patient Group	Title	Recommendation, guideline or standard [grade of evidence]
Finland	**Guidelines currently being developed - draft version states 'intensive nutrition treatment is needed if malnutrition or risk of malnutrition ..... the use of ONS is an essential part of nutritional treatment for these patients' DUE FOR PUBLICATION 2010**			
Norway	Norwegian Directorate for Health (2009)	All patients in hospital and in the community	National scientific guidelines for prevention and treatment of malnutrition	Offer between meal snacks and sip feeds [ONS] to patients who eat little at each meal. For some it can be easier to drink than to eat. Use of sip feeds [ONS] as between meal snacks does not necessarily affect the energy intake at the main meals.
Spain	2007	Hospital patients	Nutrition Support in Hospital Patients: update on guidelines and consensus statements	A review of key international professional guidelines on nutrition support in hospital patients. See section 3.3 for a summary of the recommendations listed under each disease area.
Sweden	The National Board of Health and Welfare (2000)	All patients within healthcare	Problems with nutrition within healthcare: prevention and treatment	Summary: Nutritionally balanced or protein rich sip feeds [ONS] have positive effects when given to patients at risk of or with manifest malnutrition. This applies for some chronic diseases, but not all; more studies are needed.
	SWESPEN		A small practical pocket handbook: Nutritional treatment within healthcare	Nutritional supplements [ONS] should be given when the need for energy and nutrients is not covered by the usual food.

Table 3.1 continued

Country	Body	Patient Group	Title	Recommendation, guideline or standard [grade of evidence]
The Netherlands	Quality Institute for Healthcare (CBO, 2007)	Surgical patients in general	Peri-operative Feeding Guidelines	Summary: guideline how to screen for and treat malnutrition before, during and after surgery (general) It is recommended to screen for malnutrition and treat malnutrition before surgery. The best way to treat serious malnutrition is to start immediately with artificial supplements [ONS] or tube feeding. Start 7-10 days before surgery [D] • If malnutrition is diagnosed, supplements [ONS] must be used instead of trying to improve the nutritional status with dietary advice [A1] • Enteral supplements are preferred above parenteral feeding when treating malnutrition prior to surgery. [C] Grading of recommendations: A1) systematic reviews of at least some A2-level clinical trials, that have shown consistent results A2) randomized, comparative clinical trials of good quality (randomized, double-blind, controlled trials) of good sample size and consistency B) randomized clinical trials of poor quality or insufficient sample size or other comparative trials (non randomized, comparative, cohort research, patient controlled research) C) non-comparative research D) Expert opinion, for example from committee members
The Netherlands	Steering Committee Malnutrition (Stuurgroep Ondervoeding, 2009)	Malnutrition in general, all lines of healthcare	Guidelines Malnutrition: screening and treatment	Summary: guidelines for all lines in healthcare about screening with screening tools and how to treat malnourished patients. A table is used to show how to treat malnourished patients with regards to their nutritional intake. • When 75-100% of the nutritional requirements are met, use protein and energy rich food, if necessary combined with ONS • When 50-75% of the nutritional requirements are met, use protein and energy rich food and combine with ONS • When < 50% of the nutritional requirements are met, use protein and energy rich food, continue ONS if possible and start with tube feeding.

Table 3.1 continued

Country	Body	Patient Group	Title	Recommendation, guideline or standard [grade of evidence]
UK	Malnutrition Advisory Group of BAPEN (2003)[4]	All	The 'MUST' Report Nutritional screening of adults: a multidisciplinary responsibility	There is substantial evidence of the beneficial clinical effects of nutritional supplements [ONS] containing a mixture of macro- and micro-nutrients in particular groups of patients in the hospital and community, and of greater benefit in individuals with a BMI < 20 kg/m^2 than > 20 kg/m^2, particularly patients in the community. [A - at least 1 RCT as part of the body of literature of overall good quality and consistency addressing the specific recommendation]
UK	British Association for Parenteral and Enteral Nutrition (BAPEN) (2000)[3]	Patients in the community	Guidelines for the detection and management of malnutrition	• Treatment typically begins with food, but may progress to the use of supplements [ONS]. In some patients it may begin with food and supplements [ONS]. • If ordinary food is ineffective in improving nutritional status and ineffective in achieving the goals set at the beginning of treatment, nutritional supplements [ONS] (mixed micro- and macronutrient supplements in solid or liquid form) can be of value. This is because they are readily available, easy to consume between meals, require little or no preparation, and are largely additive to food intake in undernourished subjects. [A - at least 1 RCT as part of the body of literature of overall good quality and consistency addressing the specific recommendation]
USA	American Medical Directors Association (2001)	With or at risk of malnutrition	Altered nutritional status	• Distribute liquid dietary supplements [ONS] during the medication pass. • Evidence suggests that liquid dietary supplements [ONS] given approximately 60 minutes before a meal does not reduce food consumption.
USA	Council for Nutritional Strategies in Long-Term Care (2000)	With or at risk of malnutrition	Nutritional management in long-term care: development of a clinical guideline	• Nutritional supplementation [ONS] can increase dietary intake and produce weight gain. • Nutritional supplementation [ONS] must be given between meals in order not to substitute for calorie intake at meals.

[1]Oral nutrition support includes any of the following methods to improve nutritional intake: fortified food with protein, carbohydrate and/or fat, plus minerals and vitamins; snacks; ONS; altered meal patterns; the provision of dietary advice.
[2]Malnourished: BMI < 18.5 kg/m^2, unintentional weight loss > 10% within the last 3-6 months, a BMI < 20 kg/m^2 and unintentional weight loss > 5% within the last 3-6 months.
[3]At risk of malnutrition: eaten little or nothing for more than 5 days and/or likely to eat little or nothing for the next 5 days or longer or poor absorptive capacity, and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism.

Older people

Table 3.2 Summary of examples of evidence-based national and professional guidelines referring to ONS as an integral part of patient and disease management - Older People (parts of the guidelines relevant to ONS presented here)

Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Europe	European Society for Clinical Nutrition and Metabolism (Volkert 2006)[153]	ESPEN Guidelines on Enteral Nutrition: Geriatrics	• In patients who are undernourished or at risk of under-nutrition use ONS to increase energy, protein and micronutrient intake, maintain or improve nutritional status, and improve survival. [A] • In frail elderly use ONS to improve or maintain nutritional status. [A] • In geriatric patients after hip fracture and orthopaedic surgery use ONS to reduce complications. [A] • In early and moderate dementia consider ONS - and occasionally tube feeding - to ensure adequate energy and nutrient supply and to prevent under-nutrition. [C] • ONS, particularly with high protein content, can reduce the risk of developing pressure ulcers. [A] • In case of nutritional risk (e.g. insufficient nutritional intake, unintended weight loss > 5% in 3 months or > 10% in 6 months, body-mass index < 20 kg/m^2) initiate ONS and/or tube feeding early. [B] **Note:** see Table 3.5 for summary of grading of recommendations
France	Haute Autorité de Santé (2007)	Strategy for the management of protein energy malnutrition in the elderly	• The nutritional management strategy should be based on the patient's nutritional status, spontaneous nutritional intake, the nature and severity of disease and associated handicaps, as well as the prognosis (e.g. swallowing disorders), the patient and carer's opinions as well as ethical considerations. Apart from when oral intake is contraindicated, it is recommended to begin with dietary advice and food fortification, if possible in collaboration with a dietitian. [C] • ONS should be considered in the event of failure of these measures or from the start in patients with severe malnutrition. [C] • It is recommended to use high energy (≥1.5 kcal/ml or g) and/or high protein (≥7.0g/100ml or 100g or 20% of total energy from protein) ONS [grade not stated]. [C - recommendations are based on low level clinical trials e.g. case studies (evidence grade III), retrospective studies, several case reports (evidence level IV)]

Table 3.2 continued

Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Australia	Developed by the Clinical Epidemiology and Health Service Evaluation Unit, Melbourne Health. Previously commissioned on behalf of the Australian Health Ministers' Advisory Council (AHMAC) by the AHMAC Care of Older Australians Working Group.	Best practice approaches to minimise functional decline in the older person across the acute, sub-acute and residential aged care settings: (This version updated by the Victorian Government Department of Human Services. Update 2007)	• There is some evidence to support the use of high-protein-containing supplements [ONS] to reduce length of stay for older people in inpatient rehabilitation and other high-risk settings. • There is good evidence to support the use of ONS (protein and energy) for reducing mortality and complications, and for improving nutritional status in undernourished hospitalised older patients and may be considered for those who would benefit from weight gain.
US	Hartford Institute for Geriatric Nursing - Academic Institution 2008	Nutrition. In: Evidence-based geriatric nursing protocols for best practice.	Provide oral supplements [ONS] Supplements [ONS] should not replace meals but rather be provided between meals but not within the hour preceding a meal and at bedtime [Level IV]. See National Collaborating Centre for Acute Care Clinical Guideline (2006) for algorithm for use of oral supplements [ONS] (See Figure 3.2 in this report, page 88).

Table 3.2 continued

Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
US	University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution 2006	Unintentional weight loss in the elderly	Management/Treatment Non-Pharmacological Therapy • Increasing nutrition through food should be the first step, prior to initiating dietary supplements [ONS]. [Strength of Recommendation: B; Quality of Evidence: Fair] • If the patient's caloric needs cannot be met with 3 meals and 3 snacks per day, high energy and nutritionally dense supplements [ONS] should be added. [Strength of Recommendation: B; Quality of Evidence: Fair/Poor] • Oral nutritional supplementation is associated with weight gain and reduced fatality. [Strength of Recommendation: A; Quality of Evidence: Good] • Protein/calorie supplements [ONS] should be given between meals and not with meals to minimize appetite suppression and compensatory decreased intake of food at meal time. [Strength of Recommendation: A; Quality of Evidence: Good] • Have the patients sample the supplements [ONS] and give them a variety. Presentation of the supplement [ONS] should also be varied. [Strength of Recommendation: B; Quality of Evidence: Fair/Poor] • A liquid supplement [ONS] in which the energy is supplied by glucose instead of fat is less likely to cause satiation. [Strength of Recommendation: B; Quality of Evidence: Fair]
US	American Dietetic Association (ADA) 2009	Unintended Weight Loss (UWL) in Older Adults Evidence-based Nutrition Practice Guideline	Indications for medical food supplements [ONS] The Registered Dietitian (RD) should recommend [ONS] for older adults who are undernourished or at risk of under-nutrition (i.e., those who are frail, those who have infection, impaired wound healing, pressure ulcers, depression, early to moderate dementia and/or after hip fracture and orthopedic surgery). Studies support [ONS] as a method to provide energy and nutrient intake, promote weight gain and maintain or improve nutritional status or prevent under-nutrition. [Strong]

Table 3.3 Summary of examples of evidence-based national and professional guidelines referring to ONS as an integral part of patient and disease management - Specific Diseases and conditions (parts of guidelines relevant to ONS presented here]

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Hip Fracture	Europe	European Society for Clinical Nutrition and Metabolism (Volkert 2006)[153]	ESPEN Guidelines on Enteral Nutrition: Geriatrics	In geriatric patients after hip fracture and orthopaedic surgery use ONS to reduce complications. [A] **Note:** see Table 3.4 for summary of grading of recommendations
	Australia	Developed by the Clinical Epidemiology and Health Service Evaluation Unit, Melbourne Health. Previously commissioned on behalf of the Australian Health Ministers' Advisory Council (AHMAC) by the AHMAC Care of Older Australians Working Group.	Best practice approaches to minimise functional decline in the older person across the acute, sub-acute and residential aged care settings: (This version updated by the Victorian Government Department of Human Services. Update 2007)	• There is good evidence to support the use of oral multi-nutrient and high-protein supplements [ONS] for the prevention of unfavourable outcomes in older people recovering from hip fracture. • There is limited evidence to support the use of resistance training, used in combination with nutrition supplementation [ONS], to improve weight gain in older, nutritionally at-risk inpatients following a lower limb fracture.
	New Zealand	New Zealand Guidelines Group (2003)	Best practice Evidence-Based Guideline: Acute management and immediate rehabilitation after hip fracture amongst people aged 65 years and over	Oral multinutrient feeds [ONS] reduce unfavourable outcome (death or post-operative complication) after hip fracture. [A] **Note:** see Table 3.4 for summary of grading of recommendations - grade A similar to NICE (except no reference to NICE Technology appraisals)

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Pressure Ulcers	Europe	European Society for Clinical Nutrition and Metabolism (Volkert 2006)[153]	ESPEN Guidelines on Enteral Nutrition: Geriatrics	• ONS, particularly with high protein content, can reduce the risk of developing pressure ulcers. [A] • Based on positive clinical experience, enteral nutrition (by means of ONS or tube feeding) is also recommended in order to improve healing of pressure ulcers. [C] **Note:** see Table 3.4 for summary of grading of recommendations
	International (Europe and US)	European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP) (2009)	Pressure Ulcer Prevention	• Offer high-protein mixed ONS and/or tube feeding, in addition to the usual diet, to individuals with nutritional risk and pressure ulcer risk because of acute or chronic diseases, or following a surgical intervention. [A] Oral nutrition (via normal feeding and/or with additional sip feeding) is the preferred route for nutrition, and should be supported whenever possible. ONS are of value because many pressure-ulcer-prone patients often cannot meet their nutritional requirements via normal oral food intake. Moreover, ONS seem to be associated with a significant reduction in pressure ulcer development, compared to routine care. Enteral (tube feeding) and parenteral (delivered outside the alimentary tract) nutrition may be necessary when oral nutrition is inadequate or not possible, based on the individual's condition and goals. • Administer ONS and/or tube feeding in between the regular meals to avoid reduction of normal food and fluid intake during regular mealtimes. [C] [A - The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the guideline statement (Level 1 studies required).] [C - The recommendation is supported by indirect evidence (e.g. studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion.]

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Pressure Ulcer	International (Europe and US)	European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP) (2010)	Pressure Ulcer Treatment	• Provide enhanced foods and/or ONS between meals if needed [B] [B - The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)]
	England	National Institute for Health and Clinical Excellence (NICE) (2005)[154]	The prevention and treatment of pressure ulcers	Nutritional support should be given to patients with an identified nutritional deficiency. [C] † Nutritional support/supplementation for the treatment of patients with pressure ulcers should be based on: [D] • nutritional assessment (using a recognised tool, e.g.'MUST' Tool) • general health status • patient preference, and • expert input supporting decision-making (dietitian or specialists) † The link between correcting this deficiency and its causal relationship with pressure ulcer healing has not been clearly established **Note:** see Table 3.4 for summary of grading of recommendations
Patients undergoing radiotherapy and patients with upper gastro-intestinal cancer	Europe	European Society for Clinical Nutrition and Metabolism (Arends 2006)[155]	ESPEN Guidelines on Enteral Nutrition: Non-surgical oncology	Use intensive dietary advice and ONS to increase dietary intake and to prevent therapy-associated weight loss and interruption of radiation therapy. [A] **Note:** see Table 3.4 for summary of grading of recommendations
	England and Wales	NHS Executive (2001)	Guidance on Commissioning Cancer Services: Improving Outcomes in Upper Gastro-Intestinal Cancers	Nutritional supplements [ONS] are likely to be appropriate, both for patients who have undergone surgery and for poorly nourished patients

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Patients with cancer in hospital and the community	Norway	National Council for Nutrition (1997)	Nutritional Treatment and Dietary Counselling for Cancer Patients, Report No. 4	The recommendations include: 1. optimising regular food/hospital food intake if the gastrointestinal tract is functioning 2. **using ONS in addition to step 1** 3. tube feeding 4. total parenteral Nutrition Further guidelines are currently being developed
Head and Neck Cancer	USA	American Dietetic Association (ADA) 2007	ADA Oncology Evidence-based Nutrition Practice Guideline	**Head and neck cancer: Medical food supplements [ONS] and Radiation** Dietitians should consider use of [ONS] to improve protein and calorie intake for patients with head and neck cancer undergoing radiation therapy. Use of [ONS] may be associated with fewer treatment interruptions, a reduction of mucosal damage, and may minimize weight loss.
Patients with cancer	Spain	2008	Consensus document on Nutrition in Cancer (Nutr Hosp Suplementos. 2008;1(1):13)	• Nutritional care should be provided early and should be part of the overall treatment plan for oncology patients • The cancer patient's diet should be in line with healthy nutrition guidelines (balanced, varied, desirable and sufficient to meet needs) • When dietary advice is not enough, nutritional support should be given • Symptoms such as anorexia, nausea and vomiting as a result of the cancer or its treatment make it difficult for patients to meet their nutritional needs • Cancer patients may need artificial nutrition (same indications as non-cancer patients) but with an appropriate formula to meet their particular needs • The effectiveness of nutritional support must be balanced with the risk of its use **Note:** summary in English of section on Nutritional Intervention Criteria: Goals, directions and evidence

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Chronic Obstructive Pulmonary Disease (COPD)	Europe	European Society for Clinical Nutrition and Metabolism (Anker 2006)[156]	ESPEN Guidelines on Enteral Nutrition: Cardiology and Pulmonology	Frequent small amounts of ONS are preferred to avoid postprandial dyspnoea and satiety and to improve compliance. [B] **Note:** see Table 3.4 for summary of grading of recommendations
	International (Europe and US)	American Respiratory Society and European Respiratory Society (2004)[157]	Standards for the Diagnosis and Treatment of Patients with COPD: A Summary of the ATS/ERS Position Paper	Nutritional therapy may only be effective in combination with exercise or other anabolic stimuli.
	England and Wales	National Institute for Health & Clinical Excellence (NICE) (2004)[158] Currently being updated due for publication June 2010	Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care	If the BMI is low, patients should also be given nutritional supplements [ONS] to increase their total calorific intake, and be encouraged to take exercise to augment the effects of nutritional supplementation.
	International	Global Initiative for Chronic Obstructive Lung Disease (2009)[159]	Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease	Present evidence suggests that nutritional supplementation [ONS] alone may not be a sufficient strategy. Increased calorie intake is best accompanied by exercise regimens that have a non-specific anabolic action, and there is some evidence this also helps even in those patients without severe nutritional depletion. Nutritional supplements (e.g. creatine) do not augment the substantial training effect of multidisciplinary pulmonary rehabilitation for patients with COPD.

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Chronic Obstructive Pulmonary Disease (COPD)	USA	American Dietetic Association (ADA) 2008	Chronic Obstructive Pulmonary Disease (COPD) Evidence Based Nutrition Practice Guideline	**Macronutrient composition of medical food supplements [ONS]** Registered dietitians should advise that the selection of [ONS] for individuals with COPD should be influenced more by patient preference than the percentage of fat or carbohydrate. There is limited evidence to support consumption of a particular macronutrient composition of [ONS]. [Fair] **COPD: Frequent small amounts of [ONS]** Registered dietitians should recommend frequent small amounts of [ONS] for individuals with COPD. Studies report that frequent small amounts of [ONS] are preferred to avoid post-prandial dyspnea and satiety and to improve compliance. [Fair] **COPD: [ONS] for inpatients** For inpatients with COPD who have low BMI (under 20 kg/m^2), unintentional weight loss, reduced oral intake or who are at nutritional risk, registered dietitians should initiate provision of [ONS]. Studies report that [ONS] for seven to 12 days results in increased energy intake in the inpatient setting. [Fair] **COPD: [ONS] for outpatients** For outpatients with COPD who have low BMI (less than 20 kg/m^2), unintentional weight loss, reduced oral intake or who are at nutritional risk, registered dietitians should recommend consumption of [ONS]. In the outpatient setting, studies report that [ONS] results in increased energy intake, with weight gain more likely when combined with exercise. [Fair]

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Acute or chronic pancreatitis	Europe	European Society for Clinical Nutrition and Metabolism (Meier 2006)[160]	ESPEN Guidelines on Enteral Nutrition: Pancreas	**Acute pancreatitis** • Oral feeding (normal food and/or ONS) can be progressively attempted once gastric and outlet obstruction has resolved, provided it does not result in pain, and complications are under control. [C] **Chronic pancreatitis** • 10-15% of all patients require ONS. [C] **Note:** see Table 3.4 for summary of grading of recommendations
Liver disease	Europe	European Society for Clinical Nutrition and Metabolism (Plauth 2006)[161]	ESPEN Guidelines on Enteral Nutrition: Liver Disease	**Alcoholic steatohepatitis** • In general, ONS are recommended. [B] **Liver cirrhosis** • If patients are not able to maintain adequate oral intake from normal food, use ONS. [C] **Note:** see Table 3.4 for summary of grading of recommendations
HIV and chronic infectious diseases	Europe	European Society for Clinical Nutrition and Metabolism (Ockenga 2006)[162]	ESPEN Guidelines on Enteral Nutrition: Wasting in HIV and other Chronic Infectious Diseases	**HIV** • Diarrhoea does not prevent a positive effect of ONS on nutritional status. [A] • Nutritional counselling with ONS, or counselling alone, are equally effective at the beginning of nutritional support and/or for preserving nutritional status. [B] • In settings where qualified nutritional counselling cannot be provided, ONS may be indicated in addition to normal food but this should be limited in time. [C] **Infectious diseases** • Nutritional support should be given to patients with under-nutrition resulting from infectious diseases - prefer ONS. [B] **Note:** see Table 3.4 for summary of grading of recommendations

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Renal disease	Europe	European Society for Clinical Nutrition and Metabolism (Cano 2006)[163]	ESPEN Guidelines on Enteral Nutrition: Adult Renal Failure	**Acute Renal Failure (ARF)** • In uncomplicated ARF, when spontaneous alimentation is insufficient, ONS may be useful to meet estimated requirements. [C] **Patients on maintenance haemodialysis (HD) therapy** • Use ONS to improve nutritional status. [A] • ONS should be the preferred route in conscious HD patients. **Note:** see Table 3.4 for summary of grading of recommendations
Gastro-intestinal disease	Europe	European Society for Clinical Nutrition and Metabolism (Lochs 2006)[164]	ESPEN Guidelines on Enteral Nutrition: Gastroenterology	**Crohn's disease** • In case of persistent intestinal inflammation (e.g. steroid-dependent patients) use ONS. [B] • Use ONS in addition to normal food to improve nutritional status and to eliminate consequences of under-nutrition such as growth retardation. [A] • Using ONS, a supplementary intake of up to 600 kcal/day can be achieved in addition to normal food. [A] **Short bowel syndrome** • Use ONS or tube feeding if normal nutritional status cannot be maintained by normal food alone. [C] **Note:** see Table 3.4 for summary of grading of recommendations
Surgical patients	Europe	European Society for Clinical Nutrition and Metabolism (Weimann 2006)[165]	ESPEN Guidelines on Enteral Nutrition: Surgery including Organ Transplantation	• Encourage patients who do not meet their energy needs from normal food to take ONS during the preoperative period. [C] • Before transplantation, in under-nutrition, use additional ONS. [C] **Note:** see Table 3.4 for summary of grading of recommendations

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Surgical patients	Europe	European Society for Clinical Nutrition and Metabolism (2005)[166]	Enhanced Recovery after Surgery: A Consensus Review of Clinical Care for Patients undergoing Colonic Resection	**Post operative nutritional care** • Patients should be encouraged to commence oral food intake 4 hours after surgery. ONS should be taken (approximately 400 ml energy-dense ONS) from the day of surgery until a normal level of food intake is achieved. Continuation of ONS at home is recommended for nutritionally depleted patients.
	England and Wales	National Institute for Health and Clinical Excellence (NICE) (2006)[75]	Nutrition Support for Adults Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition	**Oral nutrition support for surgical patients** • Peri-operative oral nutrition support would be considered for surgical patients who can swallow safely and are malnourished. [B] **Note:** see Table 3.4 for summary of grading of recommendations
Stroke patients	England and Wales	National Institute for Health & Clinical Excellence (NICE) (2008)[167]	National Clinical Guideline for Diagnosis and Initial Management of Acute Stroke and Transient Ischaemic Attack (TIA)	Nutritional support should be initiated for people with stroke who are at risk of malnutrition. This may include ONS, specialist dietary advice and/or tube feeding.
	Australia	National Stroke Foundation 2007	Clinical Guidelines for Acute Stroke Management (currently being reviewed)	Nutritional supplementation [ONS] should be offered to people whose nutritional status is poor or deteriorating [A] [A - Body of evidence can be trusted to guide practice]

Table 3.3 continued

Patient Group	Country	Body	Title	Recommendation, guideline or standard [grade of evidence]
Spinal Cord Injury	USA	American Dietetic Association (ADA) 2009	Spinal Cord Injury (SCI) Evidence-Based Nutrition Practice Guideline	**Nutrition intervention to prevent development of pressure ulcers** If a patient with spinal cord injury is at risk of pressure ulcer development as indicated by biochemical, anthropometric and lifestyle factors, the registered dietitian should implement aggressive nutrition support measures. The range of options may include medical food supplements [ONS] and enteral and parenteral nutrition. Research suggests that improved nutrition intake, body weight and biochemical parameters may be associated with reduced risk of pressure ulcer development. [Strong Conditional] **Nutrition prescription for SCI persons with pressure ulcers** A nutrition prescription should be formulated as part of the nutrition intervention for persons with spinal cord injury (SCI) and pressure ulcers, which includes the energy, protein, fluid and micronutrient requirements. Evidence suggests that additional energy and protein is needed for optimal healing of pressure ulcers. Fluid and micronutrient needs will vary depending on the person's status. See the Assessment of Nutritional Needs for Pressure Ulcers for determining levels of each of these. [Consensus Imperative]

Table 3.4 NICE Guidelines: Grading of recommendations (adapted from NICE 2006[75])

Grade	Evidence
A	• At least one meta-analysis, systematic review, or RCT rated as 1++ (i.e. high quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias), and directly applicable to the target population, or • A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ (i.e. well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias), directly applicable to the target population, and demonstrating overall consistency of results • Evidence drawn from a NICE technology appraisal
B	• A body of evidence including studies rated as 2++ (i.e. high quality systematic reviews of case-control or cohort studies, high-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal) directly applicable to the target population, and demonstrating overall consistency of results, or • Extrapolated evidence from studies rated as 1++ or 1+
C	• A body of evidence including studies rated as 2+ (i.e. well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal), directly applicable to the target population and demonstrating overall consistency of results, or • Extrapolated evidence from studies rated as 2++
D	• Evidence level 3 (i.e. non-analytic studies e.g. case reports, case series) or 4 (i.e. expert opinion), or • Extrapolated evidence from studies rated as 2+, or • Formal consensus
D (GPP)	• A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group

Table 3.5 ESPEN Guidelines: Grading of recommendations (adapted from Schutz 2006[168])

Grade	Level of evidence	Requirement
A	Ia Ib	• Meta-analysis of randomized controlled trials • At least one randomized controlled trial
B	IIa IIb III	• At least one well-designed controlled trial without randomization • At least one other type of well-designed, quasi-experimental study • Well-designed non-experimental descriptive studies such as comparative studies, correlation studies, case-control studies
C	IV	• Expert opinions and/or clinical experience of respected authorities

3.2 Guidelines: Theory to practice for enhanced patient care

Practical guidance for healthcare professionals about when to use ONS is essential and should be a key component of many guidelines.

- Practical advice on the use of ONS in clinical practice has been formulated by Stratton and Elia (2007) in a recent review of reviews on the evidence base for ONS across different patient groups (Figure 3.1)[169].

- The method of nutrition support included in these practical guides should be carefully considered and should take account of the evidence base, condition of the patient (both clinical and nutritional), their prognosis and preferences. Food fortification is often recommended as the first line approach; with ONS reserved for if/when this strategy is not successful. Care must be taken to review patients on a regular basis and to quickly identify if nutritional goals are not being met so that an alternative strategy can be used e.g. ONS. NICE (2006) highlight that oral nutrition support strategies are not exclusive and can be used in combination[75].

- Examples include an Oral Nutrition Support Algorithm in the UK NICE guideline (Figure 3.2) and a table with information about grade of risk of malnutrition and contribution of spontaneous food intake in the Haute Autorité de Santé recommendations in France (Table 3.6).

- These practical guides allow healthcare professionals to make decisions about the appropriate use of ONS.

Figure 3.1 Recommendations for use of ONS in clinical practice (adapted from Stratton and Elia 2007)[169]

- Identify malnutrition or risk of malnutrition using routine screening across healthcare settings with a valid, evidence-based tool such as 'MUST'. Implement appropriate nutritional treatment as part of a care plan for malnutrition as soon as possible.
- Consider ONS as part of the care plan for the treatment of malnutrition*:
  - ONS can be used if improvements in energy, protein and micronutrient intakes are required. ONS tend not to suppress appetite or voluntary food intake. ONS can be particularly effective at improving total nutritional intake in acutely ill, elderly and post-surgical patients
  - For patients requiring longer-term oral nutritional support, often in the community, it is likely that a variety of types of ONS (e.g. flavours, textures, consistencies) and encouragement to comply with ONS would be beneficial to maintain improvements in nutritional intake
  - ONS can be used to attenuate weight loss in the acutely ill patient or aid weight gain in chronically ill patients. Improvements in weight (> 2 kg), especially in the underweight, are associated with improvements in function in the chronically ill
  - ONS (~250-600 kcal/d) can be used to help improve clinical outcome in hospitalised patients, acutely ill elderly, patients undergoing GI surgery and in hip fracture patients
  - Consider high protein ONS to reduce the risk of development of pressure ulcers in high-risk groups (frail elderly, hip fracture, poor mobility) and to help improve outcome in hip fracture
- When providing ONS, consider patients needs for energy, protein and micronutrients. Any specific identifiable nutrient deficiencies (trace elements, minerals, vitamins) should be corrected where possible.
- The goal(s) of treatment with ONS should be identified for an individual patient at the start of treatment. Thereafter, regular and frequent monitoring of patients receiving ONS should be undertaken to:
  - Assess ONS acceptability
  - Monitor ONS effectiveness by monitoring the patients' progress towards the treatment goal(s). These could include measures of energy and nutritional intake, appetite, nutritional status, functional measures, clinically relevant outcomes (pressure ulcer size, infection, quality of life)
  - Encourage compliance with ONS where appropriate
  - Assess whether ONS are still required or if other forms of nutritional support (e.g. tube feeding) are warranted
  - Monitor changes in clinical and nutritional status

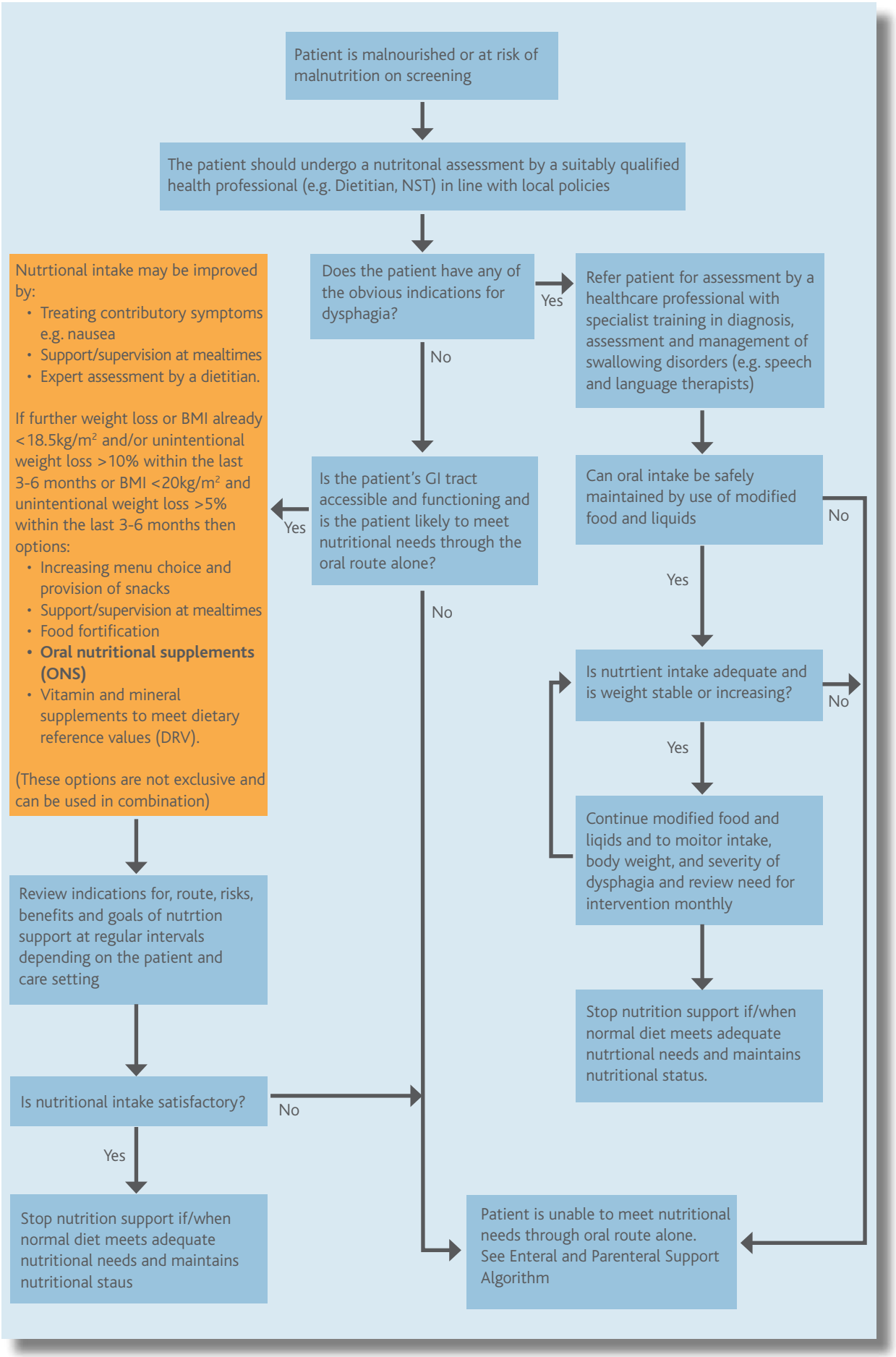
*The care plan, including when to refer to a dietitian or nutrition support team, should be devised by a multidisciplinary team, according to local policy and resources

Table 3.6 Example of a nutritional management strategy detailing when to use ONS for older people (adapted from Haute Autorité de Santé, France)

Nutritional Status:		Normal	Malnourished	Severely malnourished
Contribution of spontaneous food intake	**Normal**	• Monitor	• Dietary advice • Food fortification • Reassess* after 1 month	• Dietary advice • Food fortification • **ONS** • Reassess* after 15 days
	Reduced, but greater than 50% of usual intake	• Dietary advice • Food fortification • Reassess* after 1 month	• Dietary advice • Food fortification • Reassess* after 15 days, if no improvement: use **ONS**	• Dietary advice • Food fortification • **ONS** • Reassess* after 1 week, if no improvement: use Enteral Nutrition
	Very reduced, less than 50% of usual intake	• Dietary advice • Food fortification • Reassess* after 1 week, if no improvement: use **ONS**	• Dietary advice • Food fortification and **ONS** • Reassess* after 1 week, if no improvement: use Enteral Nutrition i.e. tube feeding	• Dietary advice • Food fortification and start Enteral Nutrition • Reassess* after 1 week

*Reassessment should include: Weight and nutritional status, clinical condition and prognosis, estimation of spontaneous food intake, tolerance and compliance with treatment

Figure 3.2 Oral Nutrition Support Algorithm (adapted from NICE, 2006)[75]



3.3 Guideline implementation: Benefits for patients and healthcare systems

ONS are recognised as a key component of care across a wide variety of patient groups. The implementation of guidelines in practice that include the use of ONS have been shown to positively influence clinical practice and patient outcome, for example in the prevention and management of pressure ulcers, in surgical patients and patients with hip fracture.

Screening and use of ONS more frequent in patients with pressure ulcers (hospital and community)

- A cross-sectional survey of 363 institutions and homecare settings in The Netherlands, Germany and the UK (hospitals 46.9%, nursing homes 25.8% and home care 21.6%) showed that 66.1% of organisations had implemented the European Pressure Ulcer Advisory Panel Guidelines for Pressure Ulcer Prevention and Treatment[170].

  - Nutritional screening in pressure ulcer care was conducted significantly more frequently in organisations where the nutritional guideline was used compared with institutions and organisations not using the guidelines (18.3% 'never' performed screening vs 3.0% $p = 0.001$)[170]
  - ONS were used more frequently in guideline-using organisations, whereas tube feeding was used equally in the two groups. Parenteral nutrition was given less frequently in the group using the guidelines[170]

Improved clinical outcomes in surgical patients (hospital)

- Clinical benefits were observed in a study of older patients (n = 117, median age 67 years, range 60-85) who received a multidisciplinary protocol of peri-operative care established by the ACERTO project (n = 75) (included early instead of delayed postoperative feeding and preoperative nutrition support for malnourished patients) compared with patients who received traditional care (n = 42). The number of hours of pre-operative fasting decreased and patients were fed one day earlier after the introduction of the new protocol[171].

  - Surgical site infection was significantly reduced (9/42; 28.1% vs 2/75; 2.6%; OR = 9.9 95% CI 2.0 - 48.6; $p < 0.01$)
  - Overall post-operative morbidity diminished (16/42; 38.1% vs 16/75; 21.3%; OR = 2.2, 95% CI 0.98 - 5.2; $p = 0.05$)
  - Both total length of stay (10[2-44]) vs 4[2-140] days) and post-operative stay (6[1-43] vs 2[1-99] days $p < 0.01$) reduced

Better energy intake and reduced pressure ulcers in patients with hip fracture (hospital)

- A pre- and post-test comparison group study of patients with hip fracture (n = 100, mean age 81 years) showed that the use of nutritional guidelines (including pre-operative carbohydrate loading and post-operative ONS) compared with standard hospital food and regular nutrition support according to doctors and nurses knowledge and goodwill significantly increased energy intake ($p < 0.001$). In addition, five days post-operatively fewer patients in the intervention group developed pressure ulcers (18%) compared with the control group (36%) ($p = 0.043$)[172].

Screening guidelines: benefits of implementation

A key aspect of many of the guidelines listed in Tables 3.1 to 3.3 is the correct targeting of nutritional support, including the use of ONS, at patients who have been identified as malnourished or at risk of malnutrition. It is clear that appropriate use of nutritional support is a key part of the wider task of identifying patients at nutritional risk and implementing timely and appropriate care plans to address their needs. Nutritional screening has become mandatory in some countries (Scotland, The Netherlands and Denmark) although this is not yet widespread across Europe. Evidence is beginning to emerge that screening may reduce the prevalence of malnutrition (see country example The Netherlands) and that the use of screening programmes that include intervention and care planning can contribute to improved outcomes, although more work is needed in this area.

Implementation of screening guidelines in the hospital setting

- In a study investigating the prevalence of under-nutrition in Swiss hospitals the proportion of patients found to be at risk of under-nutrition remained constant (1 in 5), however the proportion of nutritional interventions increased from 63% (in year 1) to 72% (in year 2) to 78% (in year 3) ($p < 0.05$ by analysis of variance) providing a promising indication that participating hospitals became more aware over the course of the study[44].

- In a study of orthopaedic surgery hospital in-patients (n = 98), weekly screening by nurses using the NRS-2002 tool was used to help implement a preventative nutrition policy (patients with an NRS Score ≥3 were referred to the Clinical Nutrition Unit for nutritional assessment and intervention). Data was collected at three time points; group A = baseline, Group B = 6 months after implementation of NRS-2002, Group C = at 3 years[173].

  - Proportion of patients with weight loss > 5% reduced significantly (58% vs 33% vs 29%, $p < 0.05$)
  - Proportion of patients referred to the Clinical Nutrition Unit significantly increased (16% vs 63% vs 82%, $p < 0.05$)
  - Hospital length of stay was reduced in Group C (50 ±47 days) compared with Group A (72 ± 52) ($p < 0.05$)

- In a group pre- and post-test study in patients aged > 65 years admitted to sub-acute geriatric and rehabilitation wards the use of nutritional screening and an early intervention program (referral to a dietitian, nutritional assessment and nutrition care plan) led to significantly increased energy ($p = 0.0001$) and protein intake ($p = 0.01$) and improvements in health-related quality of life ($p < 0.05$)[174].

Implementation of screening guidelines in the community setting

- A study of the implementation of a written food and meal policy, systematic screening (using the MNA Short Form) and nutrition care planning (including energy and protein drinks, small meals and snacks) in nursing home residents (n = 20, time series design i.e. residents used as their own controls, quarterly measurements from December 2004 to December 2005) showed[175]:

  - A significant increase in the proportion of weight-stable residents over the study (52.6% at baseline vs 87.7% at the end of the study, $p < 0.01$)
  - A significant reduction in the proportion of residents losing weight (42% to 13.3%, $p < 0.01$)

- Implementation of screening using 'MUST' in line with NICE guidelines[75] in six care homes in the UK (n = 208 residents, median age 86 (37-105) years, data collected on the same residents before and after implementation for three months) showed[176]:

- A significant increase in documentation of nutritional information (height 43-100%, weight 75-100% and proportion screened using 'MUST' 57-100% ($p < 0.001$))
- A 32% increase in the use of nutritional care plans
- A 31% reduction in hospital admissions (13% vs 9%) (27% reduction in emergency admissions, 11% vs 8%) although this was not significant
- A significant reduction in length of hospital stay (58%, mean length of stay reduced from 2.67 days ±11.48 to 1.13 days ±4.74, $p < 0.005$) and hospital costs (mean saving £599 per resident over three months)

Nutritional screening as part of a programme of nutritional care

A review of the evidence for the impact of improving nutritional care on nutritional and clinical outcomes and cost suggested that screening alone may be insufficient to achieve beneficial effects with the following implications for practice[122]:

- Consensus on screening suggests that adequately validated and reliable screening tools are a useful way of identifying patients at risk of malnutrition
- Nutritional screening together with appropriate intervention may confer benefits to patients in terms of outcome. Nutrition screening alone is unlikely to result in measurable benefits
- Provision of optimal nutritional care encompasses not only screening and assessment but also food service provision, eating environment, feeding assistance, recognition of individual needs and preferences, monitoring and documentation
- Such improvements are likely to benefit from a multidisciplinary approach, with input from senior managers and clinicians

Implementation in practice: A National Example - Scotland

- Nutritional screening is mandatory in Scottish hospitals. Under the terms of the Scotland Act 1998 the devolved administration in Scotland has the power to pass laws on a range of issues including health
- Figure 3.3 provides an overview of some of the key milestones in the evolution of strategies to improve nutritional care in NHS Scotland over the past decade.

The introduction of mandatory government standards for Food, Fluid and Nutritional Care in Hospitals in Scotland in 2003 ensured that under-nutrition was highlighted as a key issue at NHS Board level in every locality (see Table 3.7 for a summary of the standards).

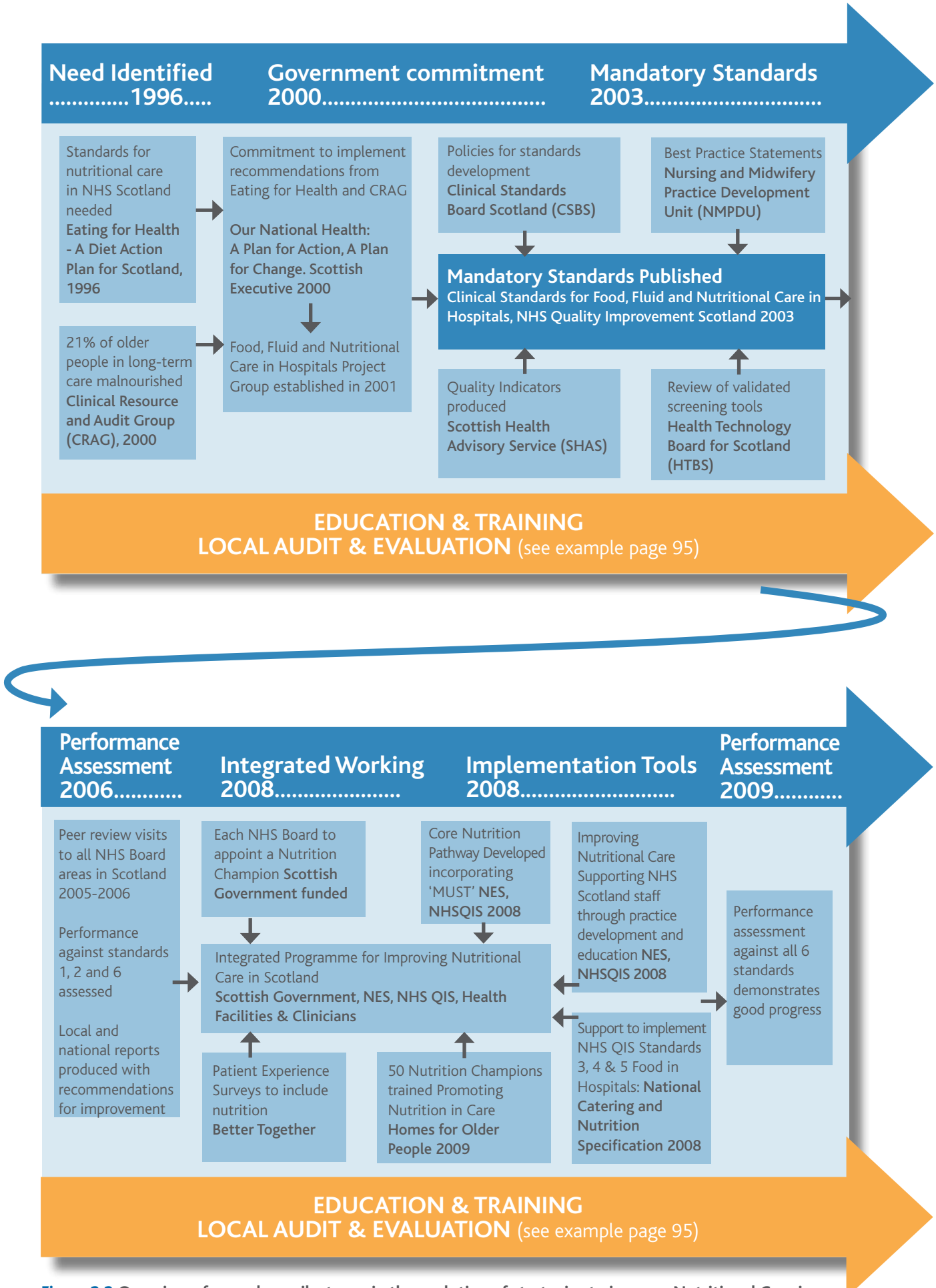


Figure 3.3 Overview of some key milestones in the evolution of strategies to improve Nutritional Care in NHS Scotland

Table 3.7 Summary of Clinical Standards for Food, Fluid and Nutritional Care in Hospitals, NHS Quality Improvement Scotland 2003

Standard	Standard statement
1. Policy and Strategy	Each NHS Board has a policy, and a strategic and co-ordinated approach, to ensure that all patients in hospitals have food and fluid delivered effectively and receive a high quality of nutritional care.
2. Assessment, Screening and Care Planning	When a person is admitted to hospital, an assessment is carried out. Screening for risk of undernutrition is undertaken, both on admission and on an ongoing basis. A care plan is developed, implemented and evaluated.
3. Planning and Delivery of Food and Fluid to Patients	There are formalised structures and processes in place to plan the provision and delivery of food and fluid.
4. Provision of Food and Fluid to Patients	Food and fluid are provided in a way that is acceptable to patients.
5. Patient Information and Communication	Patients have the opportunity to discuss, and are given information about, their nutritional care, food and fluid. Patient views are sought and inform decisions made about the nutritional care, food and fluid provided.
6. Education and Training for Staff	Staff are given appropriate education and training about nutritional care, food and fluid.

- Performance assessments of standards 1, 2 and 6 in 2005-2006 revealed that work had begun with many NHS Boards having made progress with implementing screening. Work was still needed especially education and training. A local example is described on page 95.

- A range of new innovative strategies has been developed to help NHS Boards implement the guidelines. A multi-agency Integrated Programme for Improving Nutritional Care in Scotland has been established, funding for Nutrition Champions made available by the Scottish Government, a Core Nutrition Pathway (Figure 3.4) and Education Framework for Nutritional Care have been developed and patients' views are being sought.

- In 2009 each NHS Board undertook a local self assessment followed by an external peer review visit to assess performance against standards 1, 2 and 6 and a full report against standards 3, 4 and 5. The national overview and local reports are available at http://www.nhshealthquality.org/nhsqis/controller?p_service=Content.show&p_applic=CCC&pMenuId=0&pElementID=0&pContentID=7510. The National Overview report also includes examples of good practice.

- After the first review (2006) five challenges were set for NHS boards and progress against these, as described in the National Report is listed below:

  - Implementation of nutritional assessment, screening and care planning by 2009: this has been achieved by almost every NHS board in Scotland
  - Planning and implementation of improved care for patients with complex nutritional needs: this has been achieved by most NHS boards, although some organisations find it challenging to formalise access to all key members of the complex nutritional care team
  - Including nutritional care in job/personal development plans (as appropriate): this has been achieved across Scotland
  - Demonstrating leadership commitment and reporting to the Board: this has been achieved in every NHS board
  - Ensure budgets and resources are allocated to underpin improvement: nutritional care is clearly funded across NHS Scotland. However, while it is relatively straightforward to budget for catering and supplement requirements, it is less easy to define and cost clinical requirements

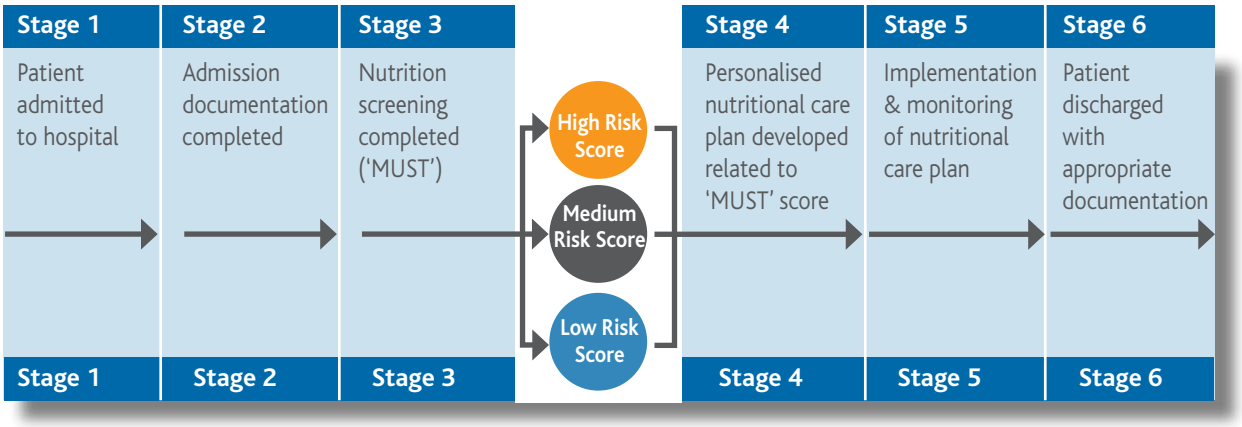


Figure 3.4 The Core Nutrition Pathway (adapted from NHS Education for Scotland, NHS Quality Improvement Scotland 2008)

Implementation in practice: A Local Example - NHS Fife

Hospitals in Scotland must demonstrate that they meet the Food, Fluid and Nutritional Care standards. To help them do so, some hospitals undertook baseline audits to help inform the development of their nutritional policy and strategy and to provide baseline data against which they could compare future audits to objectively demonstrate improvements. The example below describes such an audit undertaken by NHS Fife.

Title: Risk of malnutrition in a sample of acute and long-stay NHS Fife in-patients: an audit (Ruxton 2008)[177]

Guideline:
Clinical Standards: Food, Fluid and Nutritional Care in Hospitals, NHS Quality Improvement Scotland 2003

Aims:
To audit current practices in NHS Fife hospitals in order to provide baseline data with which to evaluate progress

Method/Intervention:
One hundred and fifty in-patients were recruited from wards likely to yield those with a high risk of malnutrition. Using patient records and anthropometry, data were collected on:

- Weight
- Height
- Weight change
- BMI
- Mid-arm muscle circumference (MUAC)
- Dietetic referral
- Therapeutic diets
- Patients' perceptions of nutritional status

The data required to complete 'MUST' was not routinely collected therefore malnutrition risk was estimated by comparing BMI with

- The Scottish Intercollegiate Guideline Network (SIGN) classification of $< 18.5\ kg/m^2$ = under weight
- Step 1 'MUST' classification of $> 20\ kg/m^2$, $18.5\text{-}20\ kg/m^2$ and $< 18.5\ kg/m^2$ = low, medium and high risk respectively

Where data was available weight change within the previous 3-6 months was compared with

- Step 2 'MUST' classification of < 5% weight loss, 5-10% weight loss and > 10% weight loss = low, medium and high risk respectively

MUAC was used as a substitute for BMI and was classified using the BAPEN classification:

- MUAC < 23.5 cm BMI likely to be $< 20\ kg/m^2$
- MUAC > 32.0 cm BMI likely to be $> 30\ kg/m^2$ (low risk of malnutrition)

Continued

Results:
The minimum risk of malnutrition varied from 14 to 25%:

- Using the SIGN criteria for BMI 14.3% of patients were classified as underweight
- Using 'MUST' step 1 classification 24.6% had a BMI of < 20 kg/m^2 and were classified as 'at risk', reducing to 21.5% when patients with conditions likely to affect weight (e.g. oedema, amputation etc.) were excluded
- Using 'MUST' stage 2 was possible in only 42 patients due to lack of data and on excluding patients with conditions likely to affect weight only two were classified as 'at risk'
- Using MUAC 21.2% of patients were classified as 'at-risk'

Around half of patients received a special diet. The most common method of nutritional support was ONS. 32% of patients were referred to a dietitian.

Weight was recorded for 87% of patients; eating and drinking problems were recorded in 32% of cases.

Conclusion:

- The prevalence of malnutrition risk was lower than expected (14-25%), but this should be considered as a conservative estimate as it was not possible to weigh some patients.
- Although screening and referral procedures were generally found to be working well, the authors concluded that the use of 'MUST' as the preferred screening tool may be of benefit in acute wards (i.e. less reliance on subjective assessments).

Recommendation:

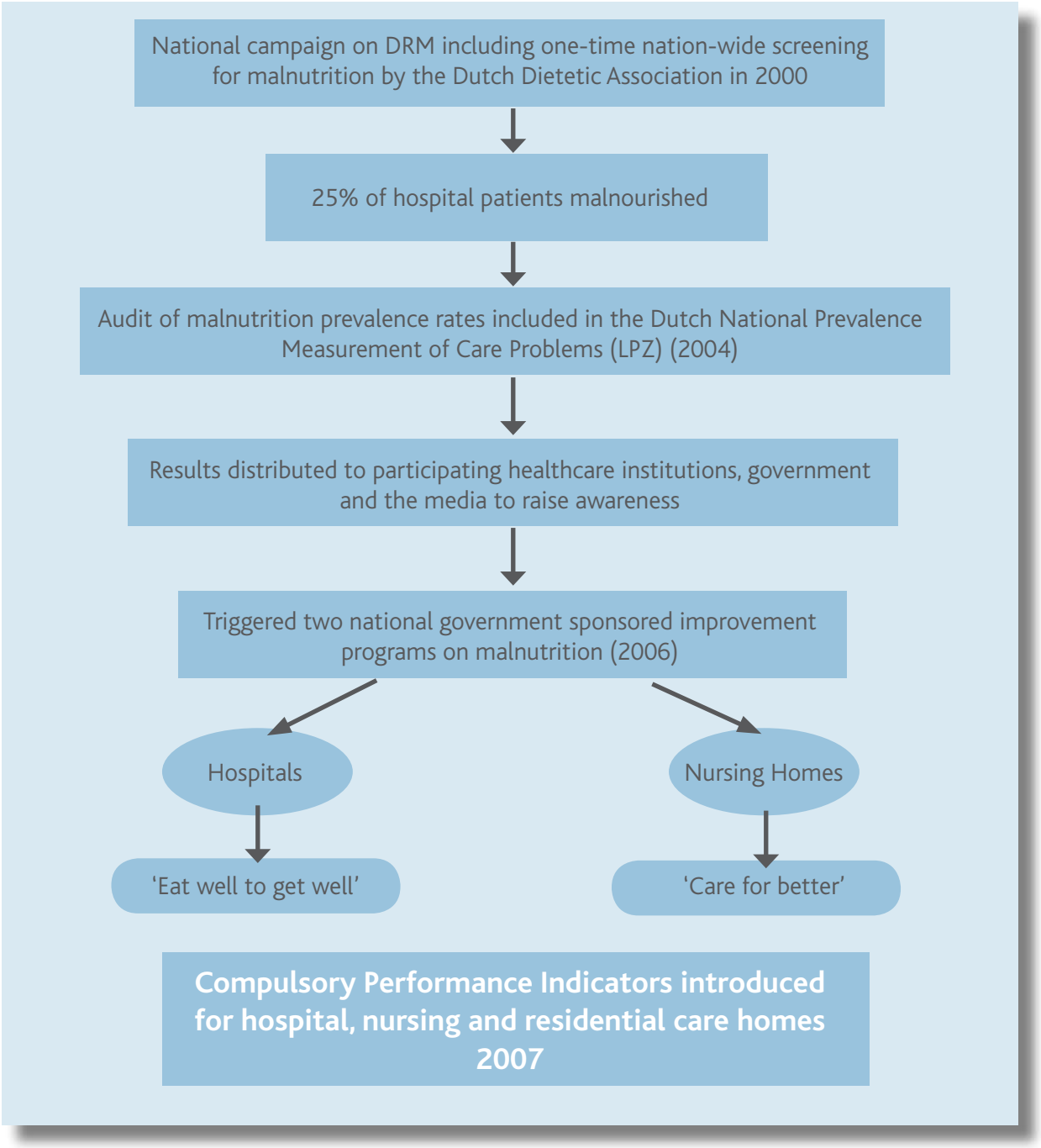
- The impact of changes in response to implementation of the NHS QIS standards should be evaluated in the future using the results from this audit as a baseline.

Implementation in practice: A National Example - The Netherlands

- In The Netherlands screening for malnutrition became mandatory in 2007 in hospitals and in nursing and residential homes. Figure 3.5 illustrates the events that led to this change.

- An analysis of the results from national audits conducted in The Netherlands from 2004 to 2007 showed that the prevalence of malnutrition tended to decrease in hospitals and home care over the years. Furthermore, the more often hospitals and home care organisations participated in the annual audits, the lower the prevalence of malnutrition ($p < 0.001$). Participation in the national improvement programs also resulted in lower prevalence rates ($p = 0.027$) (Figure 3.6). This data suggests that increasing awareness and actively working toward improvement could be important in lowering the rate of malnutrition[152].

Figure 3.5 Evolution of strategies to tackle malnutrition in The Netherlands[152]
(LPZ, Landelijke Prevalentiemeting Zorgproblemen)



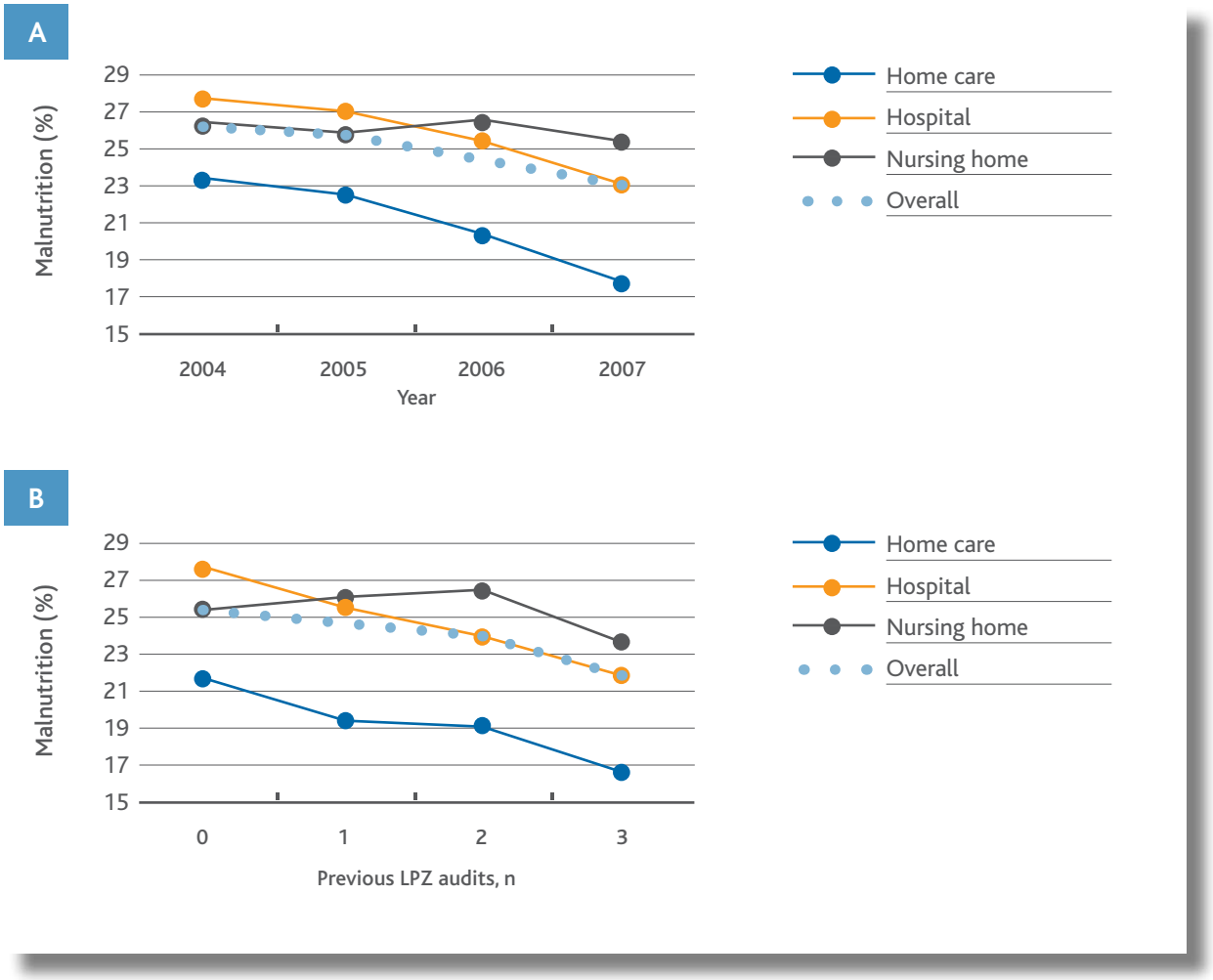


Figure 3.6 Malnutrition prevalence rates from 2004 to 2007 (A) and malnutrition prevalence rates against the number of previous LPZ audits (B) in hospitals, nursing homes, and home care institutions.
(adapted from Meijers 2009)[152]

SECTION 4

Nutritional care: good practice examples

Summary

Evidence based guidelines can only improve patient care if implemented successfully in practice. There are some good examples of where theory has been put into practice. However, it is often difficult to identify examples either because gaps still exist between guidelines that are in place but are not yet fully implemented or because the good practice has not been documented and shared. Few examples of good practice were available in the literature or from a search for unpublished work. This does not mean they do not exist; efforts need to focus on encouraging the sharing of experience and good practice. Healthcare professionals need the time, the right skills and resources, and the right forum in which to do so. Consideration should be given to innovative ways to facilitate the sharing of good practice at local, national and European level.

"Translating evidence and guidelines into best practice is a key to ensuring that people who require nutrition support receive the right intervention at the right time in the course of their illness, irrespective of the healthcare setting."

Prof. Olle Ljungqvist (2007)#

Key Messages

- A few key examples of good practice exist and show that implementation of nutritional guidelines and protocols can have positive effects for patients and healthcare providers.
- Healthcare professionals need the resources, skills and opportunity to share good practice more widely.

Examples

In the following pages some examples of good practice are described to illustrate how ONS as part of evidence-based protocols lead to better patient management and better clinical outcomes. A brief overview of each project is provided with an illustration of the patient-centre protocol or treatment pathways (where available) used in the project that includes ONS.

- Implementation of screening using 'MUST' improved nutritional care, improved appropriate use of care plans and reduced hospital stay and costs (Table 4.1)[176].
- Use of dietetic assistants to provide intensive feeding support, including ONS (as recommended by the Welsh Assembly Government guidelines), in older women with hip fracture significantly increased energy intake and reduced mortality both in the acute trauma ward and at 4 month follow-up (Table 4.2)[111].

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- Implementation of a nutritional care protocol for patients with cancer in a Spanish hospital led to attenuation of weight loss in 60% of patients and weight gain in 17% of patients (Table 4.3)[178].

- Implementation of a nutritional care programme for older people in a Belgian hospital led to a significant reduction in length of hospital stay (Table 4.4) (Figures 4.1 and 4.2)[179].

- Use of an intensive nutrition intervention protocol for medical nutrition therapy in oncology patients undergoing radiotherapy led to improvements in nutrition-related outcomes (Table 4.5)[180].

- In the UK NICE has developed an extensive implementation programme to support the NHS, local authorities and the private and voluntary sector to implement NICE guidance. The programme includes implementation tools such as costing tools, slide sets, educational tools and audit support materials. NICE has developed Good Practice Awards, a Shared Learning initiative (either submit or search for good practice or innovations) and a team of Implementation Consultants (see http://www.nice.org.uk/usingguidance/). To help support the implementation of the NICE Nutrition Support Guidelines for Adults, BAPEN has joined with NICE in their Shared Learning initiative by inviting applicants to submit their example of good practice for discussion at the BAPEN Annual Conference and for publication on the BAPEN and NICE websites.

4.1 Examples of good practice

Table 4.1 Effectiveness of implementing 'MUST' into care homes within Peterborough Primary Care Trust, England (adapted from Cawood 2009)[176]

Country: UK	**Setting:** Care homes	**Patient Group:** Care home residents

Guideline:
National Institute for Health and Clinical Excellence (NICE) Nutrition support in adults Clinical Guideline 32 (2006)[75]

Aim:
To investigate the effect of implementation of nutritional screening using 'MUST' in care homes on nutritional care and hospital admissions

Method/Intervention:
The implementation programme included education on malnutrition and management, practical training sessions using 'MUST', standardised care plans and on-going follow-up support.

The programme was implemented in six care homes (n = 208 residents; median age 86 years (range 37-105 years); 75% female).

Staff satisfaction was assessed using a questionnaire.

The effectiveness of the programme was assessed by collecting information on the same residents for three months before and after the implementation. Documentation of nutritional information (e.g. weight, height), use of screening and nutrition care plans and number and duration of hospital admissions was collected.

Results:
Implementation of the nutritional screening programme resulted in:

- A significant increase in documentation of nutritional information (height 43-100%, weight 75-100% and proportion screened using 'MUST' 57-100% ($p < 0.001$))
- A 32% increase in the use of nutritional care plans
- A 31% reduction in hospital admissions (13% vs 9%) (27% reduction in emergency admissions, 11% vs 8%) although this was not significant
- A significant reduction in length of hospital stay (58%, mean length of stay reduced from 2.67 days ±11.48 to 1.13 days ±4.74, $p < 0.005$) and hospital costs (mean saving £599 per resident over three months)
- Overall satisfaction with the programme was high (mean 100%)

Conclusion:
'In accordance with national guidelines, implementing 'MUST' in care homes improved appropriate use of nutrition care plans, significantly reduced hospital stay and costs, and significantly improved nutritional care.'

Table 4.1 continued

Further information

- The implementation programme followed an earlier cross sectional study of nutritional care in 19 care homes (n = 703 residents) in the Peterborough Primary Care Trust which showed that 32% of residents were at risk of malnutrition (13% medium risk, 19% high risk). In that survey 64% of residents at high risk of malnutrition were not receiving any form of nutritional support whereas 9% of residents at low risk were receiving nutritional intervention such as ONS, dietetic care or food fortification[32].

- This project has been included in the NICE Shared Learning Database accessible at www.nice.org.uk (go to the Shared Learning Implementing NICE Guidance, search examples of implementation).

- This project has been included in 'Appropriate Use of Oral Nutritional Supplements in Older People: Good Practice Examples and Recommendations for Practical Implementation' compiled by an expert panel and endorsed by key healthcare professional organisations in the UK (access at http://manage.nutricia.com/uploads/documents/ONS_Guide.pdf). Includes summary details of the nutrition care plan for risk categories including guidance on use of ONS.

Table 4.2 **Using dietetic assistants to improve the outcome of hip fracture: a randomised controlled trial of nutritional support in an acute trauma ward**[111]

Country: UK	**Setting:** Hospital	**Patient Group:** Hip fracture

Guideline:
Welsh Assembly Government. National Service Framework for Older People in Wales (2006) (recommends that all hip fracture patients receive ONS)

Aim:
To assess the effect of intensive feeding support provided by dietetic assistants on postoperative clinical outcome in hospitalised older women with hip fracture (with or without cognitive impairment)

Method/Intervention:
Subjects randomised to receive either conventional care (usual nurse and dietitian-led care with ONS for all patients) or to receive conventional care plus the personal attention of the dietetic assistant.

The role of the dietetic assistant was to ensure that patients received appropriate help in meeting their nutritional needs including:

- Checking food preferences
- Co-ordinating appropriate meal orders with catering
- Ordering ONS
- Provision of feeding aids
- Assistance with food choice, portion size and positioning at mealtimes
- Providing encouragement or assistance with feeding for the frailest of patients
- Collecting data to assist the dietitian with nutritional assessment

Primary outcome measure: post-operative mortality in the acute trauma unit.
Secondary outcome measures: post-operative mortality at 4 months after hip fracture, length of hospital stay, energy intake and nutritional status.

Results:

- Patients who received the care of a dietetic assistant had significantly reduced postoperative mortality both on the acute ward (4.1 vs 10.1%, $p = 0.048$) and at four months (13.1 vs 22.9%, $p = 0.036$) compared with the patients who received conventional care.

- Mean daily energy intake was significantly better in dietetic assistant supported patients (1,105 kcal vs 756 kcal/24 hours, 95% CI 259-440 kcal/24 hours, $p < 0.001$).

- There was no significant difference in energy intake from conventional food between the two groups, however, the dietetic assistant supported patients consumed significantly more energy from ONS compared with the patients who received conventional care (123 kcal vs 409 kcal/24 hours, 95% CI 232-339, $p < 0.001$).

- A significantly smaller reduction in mid-arm circumference was observed in dietetic assistant supported patients (0.39 cm, $p = 0.002$) but no other significant differences were observed in nutritional status between the two groups.

Conclusion:
The use of dietetic assistants to deliver intensive feeding support, including ONS, significantly reduced mortality in the acute trauma ward and this effect persisted at 4 month follow-up.

Table 4.2 continued

Further information

- This project has been included in 'Appropriate Use of Oral Nutritional Supplements in Older People: Good Practice Examples and Recommendations for Practical Implementation' compiled by an expert panel and endorsed by key healthcare professional organisations in the UK (access at http://manage.nutricia.com/uploads/documents/ONS_Guide.pdf). Includes summary details of the nutrition care plan for risk categories including guidance on use of ONS.

- Winner of the 2006 British Dietetic Association Rose Simmonds Award for published scientific work.

Table 4.3 Overview of a nutritional care programme for patients with cancer in Spain (adapted from Caro 2008)[178]

Country: Spain	**Setting:** Outpatients	**Patient Group:** Cancer

Supported by:
Sociedad Espanola de Nutricion Basica y Aplicada (SENBA)

Aim:
To develop strategies to improve the quality of nutritional intervention in cancer patients

Method/Intervention:
A multidisciplinary group developed a protocol describing nutritional assessment and intervention in the form of algorithms based on literature and personal experience. Patients were classified in a three step process:

1. Type of cancer treatment (curative or palliative)
2. Nutritional risk associated with the anti-cancer treatment (low, medium or high risk)
3. Nutritional risk assessed by a patient-generated Subjective Global Assessment

Patients were classified as

A. Adequate nutritional state
B. Malnutrition or risk of malnutrition
C. Severe malnutrition

The protocol was used over a one-year period in 226 randomly selected patients aged > 18 years of age.

Results:

- 64% of patients were suffering from malnutrition, increasing up to 81% in patients undergoing palliative treatment. Most patients were treated curatively (83%) and received oncology treatment with moderate or high nutritional risk (69%). 68% of patients were affected by some feeding difficulty.
- Mean percentage weight loss was 6.64% (± 0.87, range 0-33%). More than half of the patients required nutritional counselling to control symptoms which made food intake difficult. One third of patients needed ONS.
- Following the nutritional intervention weight maintenance was observed in about 60% of patients and weight gain was seen in one sixth of patients.

Conclusion:

- The application of the protocol was useful, easy and helped in the detection of malnutrition in patients with cancer.
- It provided the opportunity to select patients who could benefit from a specific nutritional intervention.
- Nutrition support proved effective for most patients.

Recommendation:

- The application of the protocol should be started immediately after diagnosis of cancer.

Table 4.4 Overview of a nutritional care programme for older people in hospital in Belgium (adapted from Pepersack 2005)[179]

Country: Belgium	**Setting:** Hospital	**Patient Group:** Older people

Supported by:
Belgian Ministry of Social Affairs, Public Health and the Environment

Aim:

a) To assess the quality of care concerning nutrition among Belgian geriatric units
b) To include more routine nutritional assessments and interventions in comprehensive geriatric assessment
c) To assess the impact of nutritional recommendations on nutritional status and on the length of hospitalisation

Method/Intervention:
A prospective observational and interventional 6-month trial. For the first 3 months, the nutritional status of patients was assessed (Mini-Nutritional Assessment (MNA) and prealbumin (PAB)) on admission and discharge without particular recommendations for nutritional intervention (observational study - phase 1).

A standardised nutritional intervention was implemented for the last 3 months (Intervention study - phase 2).

Nutritional intervention was started when MNA was < 23.5 and/or PAB < 0.2 g/L. Treatable causes of malnutrition were identified using the 'meals on wheels' approach (Figure 4.1) and caloric supplementation commenced in line with the algorithm in Figure 4.2.

Results:

- 1139 consecutive patients were admitted during the study, mean age 82.9 ± 7.3 years, 70% of the patients were women. MNA was measurable in 73% of cases with a median value of 18.5 points (range 9-29), mean admission PAB concentration was 18.5 ± 7.6 mg/100 ml, and CRP was 5.3 ± 7.5 mg/100 ml.
- The proportion of patients receiving caloric supplementation significantly increased during the interventional period (20% vs 25% of patients; $p < 0.01$).
- Length of hospital stay was significantly shorter during phase 2 than during phase 1 (21.7 ± 15.1 vs 27.1 ± 21.9 days, $p < 0.001$).

Conclusion:

- Nutritional assessment should be part of routine clinical practice in older hospitalised patients.

Recommendation:

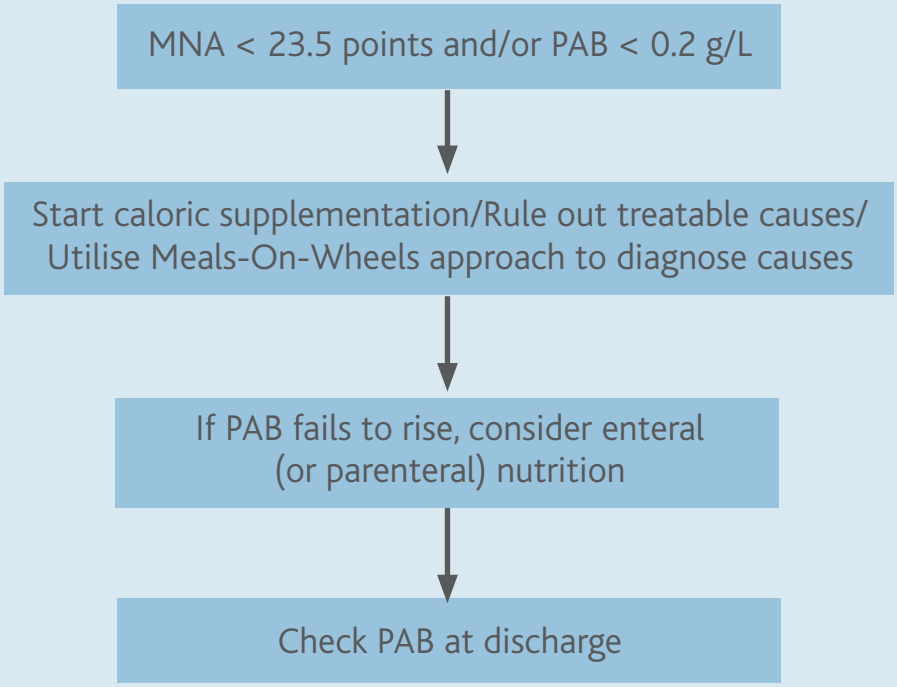
- The experience from this project should be extended to other hospital wards, as malnutrition is common in patient groups other than older people.

Medications
Emotional problems (depression)
Anorexia nervosa (tardive) and abnormal attitudes to food
Late life paranoia
Swallowing problems

Oral problems
No money

Wandering and other dementia-behaviours
Hyperthyroidism, hyperparathyroidism
Entry problems (malabsorption)
Eating problems (physical and cognitive)
Low salt, low cholesterol diets
Shopping (food availability)

Figure 4.1 The "Meals-On-Wheels" approach to diagnosing treatable causes of malnutrition used in the nutritional care programme in geriatric units in Belgium (adapted from Pepersack 2005)[179]



[Note: MNA = Mini Nutritional Assessment; PAB - serum prealbumin.]

Figure 4.2 Flowchart suggesting a rational approach to the management of malnutrition used in the nutritional care programme in geriatric units in Belgium (adapted from Pepersack 2005)[179]

Table 4.5 Nutrition support using the American Dietetic Association Medical Nutrition Therapy Protocol for radiation oncology patients improves dietary intake compared with standard practice
(adapted from Isenring 2007)[180].

Country: Australia	**Setting:** Outpatients	**Patient Group:** Cancer

Guideline:
American Dietetic Association Medical Nutrition Therapy Protocol (ADA MNT)

Aim:
To determine the impact of nutrition intervention compared with standard practice on dietary intake in outpatients receiving radiotherapy.

Method/Intervention:
Patients randomly assigned to receive either nutrition intervention (n = 29) (nutrition counselling following the ADA MNT) or standard practice (n = 31) (general nutrition and booklet). Dietary intake assessed at baseline and at 4, 8 and 12 weeks after starting radiotherapy.

Results:
- The nutrition intervention group had higher mean total energy ($p = 0.029$) and protein intake ($p < 0.001$) compared with the standard practice group.
- Mean intake per kilogram of body weight for the nutrition intervention group ranged from 28 - 31 kcal/kg/day compared with 25 - 29 kcal/kg/d for the standard practice group ($p = 0.022$).
- The nutrition intervention group had a higher mean protein intake (1.1 - 1.3 g/kg/d) compared with the standard practice group (1.0 - 1.1 g/kg/d) ($p = 0.001$).
- During treatment more patients in the nutrition intervention group (than in the standard practice group) were assessed as well-nourished and less assessed as malnourished according to PG-SGA global rating, significant at 8 weeks ($p = 0.020$) and approached significance at 12 weeks ($p = 0.065$).
- The nutrition intervention group had a significantly smaller decrease and faster recovery in global quality of life ($p = 0.0009$) and physical function ($p = 0.012$) over time compared with the standard practice group.

Conclusion:
- Intensive nutrition intervention following the ADA MNT protocol results in improved dietary intake compared with standard practice and seems to beneficially impact nutrition-related outcomes previously observed in oncology outpatients receiving radiotherapy.

Recommendation:
- The ADA MNT for radiation oncology patients is a useful guide to the level of nutrition support required.
- If insufficient dietetic resources are available, nutrition screening and triage systems should be implemented to ensure those clients in most need of care receive a level that demonstrates outcomes.

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Appendix I

Prevalence of malnutrition - Tables A1.1 to A1.7

Table A1.1 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - hospital (general)

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening /assessment)	Prevalence % (risk category)	Method and details of risk category where reported
Bosnia Herzegovina	Vanis (2008)[181]	Randomly chosen hospitalised patients	2200	Hospital (during hospital stay)	**58.3** **52** **55.3**	Malnutrition Universal Screening Tool ('MUST') (no further details given) Nutrition Risk Screening 2002 (NRS 2002) (no further details given) Mini Nutritional Assessment (MNA) (no further details given)
Denmark	Rasmussen (2004)[49]	> 14 years of age	590	Hospital - internal medicine, gastro and orthopaedic surgery (hospitalised patients on the specific day of investigation)	**39.9**	NRS 2002 but note no adjustment made for age
Denmark	Kondrup (2002)[48]	> 15 years of age	740	Hospital - university, regional & local (on admission)	**22**	**Nutritionally at risk = score ≥3**. Severe malnutrition = score 3 (Body Mass Index (BMI) < 18.5 kg/m^2, recent weight loss > 5% in the last month, or an intake of 0-25% of requirement). Moderate malnutrition = score 2 (BMI 18.5-20.5 kg/m^2, recent weight loss > 5% in the last 2 months, or an intake of 25-50% of requirement). Slight malnutrition = score 1 (recent weight loss > 5% in the last 3 months, or an intake of 50-75% of requirement). Patients' general condition and disease severity also taken into account

Table A1.1 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening /assessment)	Prevalence % (risk category)	Method and details of risk category where reported
Germany	Pirlich (2006)[24]	> 18 years of age	1886	Hospital - community, teaching & university (on day of admission)	**27.4** (17.6 + 9.8)	Subjective Global Assessment (SGA) (**moderate + severe**)
Germany	Pirlich (2003)[35]	> 18 years of age	502	Hospital - university & district (on day of admission)	**24.2**	SGA (**moderate + severe**). Not reported separately
Hungary	Lelovics (2008)[147]	All adult patients	1266	Hospital (on admission)	**41** (13 + 28)	'MUST' (**medium + high**)
Italy	Lucchin (2009)[45]	Adults aged > 18 years of age	1284	Regional hospitals with > 400 beds (within 36 hours of admission)	**28.6**	NRS-2002. '**At-risk**' of malnutrition = Score 3
Portugal	Amaral (2007)[182]	> 18 years of age	469	Hospital (on admission)	**42**	NRS 2002 (based on BMI, % recent weight loss, recent change in food intake and disease severity). Mild/slight = score 1, moderate = score 2, severe = score 3. For patients > 70 years of age one point was added to the score. Patients with a total score of **≥3 were considered nutritionally-at-risk**, patients with a score < 3 were not considered nutritionally-at-risk
Spain	Martinez Olmos (2005)[42]	> 18 years of age	360	Hospital (stratified, random sample of hospitalised patients on specified days)	**46.9** (37.2 + 9.7)	SGA (**moderate + severe**)

Table A1.1 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening /assessment)	Prevalence % (risk category)	Method and details of risk category where reported
Spain	Planas (2004)[93]	Adult patients	400	Hospital - university affiliated (within 48 hours of admission)	**26.7** (anthropometry) **46** (SGA)	Anthropometry (classification as undernourished = BMI <18.5, or BMI < 20 and TSF or Arm Muscle Circumference <15th percentile) Subject Global Assessment (SGA) (**moderate + severe**). Not reported separately
Spain	Pablo (2003)[22]	> 18 years of age	60	Hospital - public general (within 48 hours of admission)	**63.3** (36.7, 18.3 + 8.3) SGA **90** (6.7, 60 + 23.3) NRI **80** (20, 15 + 45) INA **78.3** Combined Index	SGA (**mild, moderate + severe**) Nutritional Risk Index (NRI = 1.519 x serum albumin (g/l) + 41.7 x (present/usual weight)) (mild = NRI 97.5-100, moderate = NRI 83.5 to < 97.5, severe = NRI < 83.5 Instant Nutritional Assessment (INA) = **1st degree** (serum albumin ≥3.5 g/dl; blood lymphocyte count < 1500 cells/mm^3), **2nd degree** (serum albumin < 3.5 g/dl; blood lymphocyte count < 1500 cells/mm^3), **3rd degree** (serum albumin < 3.5 g/dl; blood lymphocyte count ≥1500 cells/mm^3), **4th degree** (serum albumin < 3.5 g/dl; blood lymphocyte count < 1500 cells/mm^3)
Sweden	Westergren (2009)[183]	> 18 years of age	1197 824 370	Large hospitals > 500 beds Medium hospitals 200-500 beds Small hospitals < 200 beds (point prevalence, data collected on hospitalised patients on a single day)	**34** (26.4 + 7.6) **26.2** (21.1 + 5.1) **21.6** (17.7 + 3.9)	**Moderate/high** risk of under-nutrition defined as the occurrence of at least two of: involuntary weight loss, BMI below limit (BMI < 20 if ≤ 69 years, BMI < 22 if ≥ 70 yrs), eating difficulties according to Minimal Eating Observation Form - Version II

Table A1.1 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening /assessment)	Prevalence % (risk category)	Method and details of risk category where reported
Sweden	Westergren (2008)[69]	All persons	874	Hospitals (hospitalised patients, timing not specified)	**27**	At risk of under-nutrition if 2-3 of following 3 criteria fulfilled: (1) involuntary weight loss (irrespective of time and amount), (2) BMI below limit (< 20 kg/m^2 if ≤ 69 years, < 22 kg/m^2 if ≥ 70 years) and (3) the presence of eating difficulties. Little risk = 1 criterion fulfilled, **moderate risk** = 2 criterion fulfilled, **high risk** = 3 criteria fulfilled. Not reported separately
Switzerland	Imoberdorf (2010)[44]	All adult medical admissions	32837	Hospital (on day of admission)	**18.2** (range 13-20% across 7 participating hospitals)	NRS-2002. **Severe under-nutrition or high risk for developing under-nutrition** = score ≥3
Switzerland	Venzin (2009)[184]	All medical admissions	430	Hospital - medium sized general teaching (MNA within 24 hours of admission, Physician's assessment on admission)	**30.5** (20.1 + 10.4) **14**	MNA, at risk of malnutrition = score of 17-23.5, frank malnutrition score of < 17 Physician's assessment (judgement based on patient history, physical examination and laboratory results)
Switzerland	Kyle (2002)[43]	All adult medical/ surgical admissions	995	Hospital (within 3 hours of admission)	**61.4** (38.3 + 23.1)	SGA (**moderate + severe**)
The Netherlands	Meijers (2009)[185]	≥18 years of age	8028	Hospital (cross-sectional, point prevalence on specified day)	**23.8**	Malnutrition defined according to one of the three following criteria: (1) BMI < 18.5 kg/m^2 (2) unintentional weight loss (6 kg in previous 6 months or 3 kg in the previous month) or (3) BMI 18.5-20 kg/m^2 in combination with no nutritional intake for 3 d or reduced intake for > 10 d

Table A1.1 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening /assessment)	Prevalence % (risk category)	Method and details of risk category where reported
The Netherlands	Bavelaar (2008)[50]	All newly admitted patients	395	Hospital general medical wards (within 72 hours of admission)	**31.9** (31.1 + 0.8)	BMI and/or SNAQ score (**severe** = BMI < 18.5 kg/m^2 and/ or SNAQ score ≥ 3 points + **moderate** = BMI 18.5-20.0 kg/ m^2 and/or SNAQ score ≥ 2 points)
The Netherlands	Kruizenga (2003)[19]	> 18 years of age	6150	Hospital (convenience sample, timing not clear)	**26** (13 + 13)	Involuntary weight loss (**at risk** = 5-10% unintentional weight loss during the past 6 months + **malnourished** = unintentional weight loss > 10% during the past 6 months)
Turkey	Nursal (2005)[186]	All adult patients admitted to wards	2211	University referral centre (within 48 hours of admission)	**11** **15.6**	SGA (**moderate + severe**). Not reported separately Combination criteria: diagnosed with malnutrition if positive for at least two of the following six criteria: (1) > 10% weight loss during the past 6 months; (2) BMI < 20 kg/m^2; (3) Triceps Skin Fold no higher than the 5th percentile; (4) Mid Arm Muscle Circumference no higher than the 5th percentile; (5) serum albumin level < 3 g/dl; and (6) serum pre-albumin level < 0.2 g/dl
UK	Lamb (2009)[51]	Adult inpatients ≥16 years of age	328 226	Hospital - general medicine, general surgery, orthopaedics and critical care (all patients assessed on a single day, 1st May 2007)	**43.9** (11.9 + 32) **32.7** (19 + 13.7)	'MUST' (**medium + high**) Northumbria Nutrition Score Chart (NNSC) validated for reproducibility and ease of use only. Patients scored according to psychological state, BMI, weight loss, ability to swallow and co-morbid medical illness, 0-3 = low risk of malnutrition, 4-5 = **moderate** risk, ≥ 6 **high risk**
UK	Russell (2009)[15]	Adults ≥18 years of age	5089	Hospital (within 72 hours of admission)	**28** (6 + 22)	'MUST' (**medium + high**)
UK	Russell (2009)[21]	Adults ≥18 years of age	9336	Hospital (within 72 hours of admission)	**28** (6 + 22)	'MUST' (**medium + high**)

Table A1.2 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - hospital (older people)

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence % (risk category)	Method and details of risk category where reported
Italy	Orsitto (2009)[47]	> 65 years of age	588	Hospital - geriatric ward (on admission)	**82** (58 + 24)	MNA (**at risk + malnourished**)
Portugal	Cansado (2009)[23]	≥ 65 years of age	341	Hospital - surgery (within 48 hours of hospital admission and 24 hours of discharge)	**93.3** (0.0 + 93.3) admission **61.5** (8.2 + 53.3) discharge	'MUST' (**medium + high**)
					77.9 (26.6 + 51.3) admission **77.1** (33.7 + 43.4) discharge	MNA (**at risk + undernourished**)
			190	Hospital - medicine (within 48 hours of hospital admission and 24 hours of discharge)	**92.6** (0.0 + 92.6) admission **50.9** (15.2 + 35.7) discharge	'MUST' (**medium + high**)
					91.5 (48.9 + 42.6) admission **95.7** (44.7 + 51.0) discharge	MNA (**at risk + undernourished**)
Spain	de Luis (2006)[94]	> 70 years of age	213	Hospital internal medicine departments (randomly selected hospitalised patients)	**74.1** (23.9 + 50.2)	MNA (**malnourished** = score < 17 points + **at risk** = score 17-23.5)
UK	Stratton (2006)[91]	Acutely ill older people	150	Hospital elderly care wards (within 48-72 hours of admission)	**58** (17 + 41)	'MUST' (**medium + high**)

Table A1.3 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - outpatients

Country	Author (year)	Study population	Patients (n)	Healthcare setting†	Prevalence % (risk category)	Method and details of risk category where reported
Italy	Bozzetti (2009)[27]	Adults with cancer	1000	Outpatients	**33.8** **39.7**	NRS-2002. Score ≥3 = **malnourished** Significant weight loss (≥10%)
The Netherlands	Leistra (2009)[25]	> 18 years of age	2288	General outpatient departments in 9 hospitals	**7.1** (2 + 5.1) Wide variation depending on type of department see Figure 1.3	**Moderate malnutrition** = BMI ≥18.5 kg/m² with 5-10% unintentional weight loss in the last 6 months. **Severe malnutrition** = one or more of the following present: BMI < 18.5 kg/m² and/or intentional weight loss of > 5% in the last 1 month or > 10% in the last 6 months
The Netherlands	Neelemaat (2008)[26]	Adults aged > 18 years	705 979	General outpatients Preoperative outpatients	**12** (7 + 5) **17** (9 + 8)	SNAQ, 3 questions: 'Did you lose weight unintentionally > 6 kg in the last 6 months and/or > 3 kg in the last 1 month)?; Did you use supplemental drinks or tube feeding over the last month?; Did you experience difficulties when eating and drinking over the last month? (**moderate** = score of ≥ 2 and **severe** = score ≥ 3)
The Netherlands	Vermeeren (2006)[30]	Adults aged 40-75 years with COPD	389	Outpatients in 39 centres	**27**	Nutritional depletion defined as BMI ≤ 21 kg/m² and or Fat-Free Mass Index (FFMI) ≤15 (females) or ≤16 (males) kg/m²
Turkey	Halil (2009)[187]	Older people aged ≥ 65 years	2327	Geriatric medicine outpatient clinic	**28**	MNA Short form. **Malnutrition risk** = MNA ≤11 points
UK	Collins (2010)[29]	Adults with COPD	425	Outpatients (overall) Mild disease Moderate disease Severe disease	**21** (7 + 14) **13** **12** **26**	'MUST' (**medium + high risk**)
UK	Rust (2010)[188]	Adults	321	General hospital outpatients	**15.9** (10.9 + 5)	'MUST' (**medium + high risk**)

Table A1.3 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting†	Prevalence % (risk category)	Method and details of risk category where reported
UK	Renshaw (2008)[28]	Adults with cancer	207	Medical oncology outpatients	**83** (Upper gastrointestinal) **76** (Lung/ mesothelioma) **73** (Gynaecological) **60** (Breast) **50** (Colorectal) **45** (Urological)	Nutritional risk determined using local trust validated Nutrition Screening Tool (includes questions on unintentional weight loss, appetite reduction in previous 3-6 months, height, usual and current weight and BMI). Details of validation not given
UK	Stratton (2004)[31]	Adults	50	Gastroenterology outpatients	**30** (18 + 12)	'MUST' (**medium + high risk**)

†Timing not specified in studies; assume on attendance during the period of the study.

Table A1.4 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - care homes (majority of participants were older people)

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
Austria	van Nie-Visser (2009)[53]	Residents of care homes (age not reported)	221	Care homes (on admission)	**28**	**Malnutrition** prevalence measured by assessing BMI, undesired weight loss and nutritional intake (no further details given)
Denmark	Beck (2002)[189]	> 65 years of age	180	Nursing homes (not specified)	**33** (22)	BMI < 20 kg/m^2 (BMI < 18.5 kg/m^2)
Finland	Suominen (2009)[190]	Older people	1043	Long-term elderly care facilities (all patients during two weeks in Sept 2003)	**97.4** (40.7 + 56.7) **15.2**	**At risk** MNA 17-23.5 points, **malnourished** MNA < 17 points Nurses assessment using **BMI**

Table A1.4 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
France	Bourdel-Marchasson (2009)[191]	Older people	517	Nursing homes† (random sample of 15 residents from each home at the time of the interview visit)	**54.9** (13.1)	**At risk** MNA-SF score ≤ 11 (of whom were **malnourished** MNA score < 17)
			84	Long-term care homes† (random sample of 15 residents from each home at the time of the interview visit)	**90.4** (42.9)	**At risk** MNA-SF score ≤ 11 (of whom were **malnourished** MNA score < 17)
Germany	Smoliner (2009)[192]	Older people	114	Nursing home (not specified)	**80.7** (57.9 + 22.8)	**At risk** MNA 17-23.5 points, **malnourished** < 17 points
Germany	van Nie-Visser (2009)[53]	Residents of care homes (age not reported)	2444	Care homes (on admission)	**26**	Malnutrition prevalence measured by assessing BMI, undesired weight loss and nutritional intake (no further details given)
Germany and Austria	Valentini (2009)[70]	> 50 years age	2137	Nursing homes (one-day cross-sectional audit on 22nd Feb 2007)	**16.7** (13.9) **9.2** (14.3)	Malnourished = BMI < 20 kg/m^2 (**at risk of malnutrition** = BMI 20-21.9 kg/m^2) Subjectively assessed by staff **Malnourished** (**at risk of malnutrition**)
Hungary	Lelovics (2009)[193]	Older people > 60 years	1381	Nursing homes (unclear)	**38.1** (8.0 + 30.1)	'MUST' (**medium + high**)
Italy	Cereda (2009)[194]	Older people	241	Long-term care for older people (not specified)	**51.8** (39 + 12.8) **56.8** (36.1 + 20.7)	**At risk** MNA 17-23.5 points, **malnourished** < 17 points Geriatric Nutritional Risk Index (GNRI) moderate risk = GNRI 92-98, high risk GNRI < 92
Italy	Pezzana (2009)[195]	Older people	738	Nursing homes (not specified)	**78**	MNA Short form (no further details given)

Table A1.4 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
Sweden	Westergren (2008)[69]	All persons*	1726	Special accommodation - nursing home-type setting (not specified)	**27**	At risk of under-nutrition if 2-3 of following 3 criteria fulfilled (1) involuntary weight loss (irrespective of time and amount), (2) BMI below limit (< 20 kg/m^2 if ≤ 69 years, < 22 kg/m^2 if ≥ 70 years) and (3) the presence of eating difficulties. Little risk = 1 criterion fulfilled, **moderate risk** = 2 criterion fulfilled, **high risk** = 3 criteria fulfilled. Not reported separately
The Netherlands	Meijers (2009)[185]	≥18 years of age*	2061	Nursing homes (cross-sectional, point prevalence on specified days)	**19.2**	Malnutrition defined according to one of the three following criteria (1) BMI < 18.5 kg/m^2 (2) unintentional weight loss (6 kg in previous 6 months or 3 kg in the previous month) or (3) BMI 18.5-20 kg/m^2 in combination with no nutritional intake for 3 d or reduced intake for > 10 d
The Netherlands	van Nie-Visser (2009)[53]	Residents of care homes (age not reported)	583	Care homes (on admission)	**27**	**Malnutrition** prevalence measured by assessing BMI, undesired weight loss and nutritional intake (no further details given)
The Netherlands	Kruizenga (2003)[19]	> 18 years of age*	808	Nursing home (convenience sample, timing not clear)	**18** (12 + 6)	**At risk of malnutrition** = 5-10% unintentional weight loss during the past 6 months , malnourished = unintentional weight loss > 10% during the past 6 months
UK	Parsons (2010)[54]	Residents of care homes*	1176	Care homes - overall (not specified)	**39** (14 + 25)	'MUST' (**medium + high**)
UK	Parsons (2009)[196]	Residents of care homes*	1176	Nursing homes Residential homes (cross-sectional survey)	**40** **36**	'MUST' (**medium + high**)

Table A1.4 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
UK	Russell (2009)[15]	> 18 years of age*	581	Care homes (overall) Nursing home only Elderly mentally ill homes only Residential homes only Other homes (restricted to adults admitted within the previous 6 months)	**42** (11 + 30)** **46** **59** **36** **43**	'MUST' (**medium + high**)
UK	Russell (2008)[21]	> 18 years of age*	1610	Care homes (overall) Nursing homes only Residential homes only Other (restricted to adults admitted within the previous 6 months)	**30** (10 + 20) **35** **22** **32**	'MUST' (**medium + high**)
UK	Elia (2005)[41]	> 65 years of age	202	Institution (secondary analysis of the National Diet and Nutrition Survey)	**20.8** (8.9 + 11.9)	'MUST' type criteria applied i.e. a score of current weight status added to the weight loss score (**medium + high**)

†In France, long-term care homes receive older people with functional impairment and severe disease requiring continuous medical care; in contrast nursing homes do not provide continuous presence of nurses

*Participants' age in years mean (± SD): special accommodations 85.4 (± 7.7)[69], Nursing homes 80.3 (± 10.0)[185], Nursing home well nourished 80 (± 11), at risk 81 (± 11), malnourished 83 (± 9)[19], care homes 86.5 (± 8.7)[54;196], 84.2 (± 8.4)[15], care homes 83.3 (± 9.5)[21].

**Figures rounded to the nearest 1%.

Table A1.5 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - sheltered accommodation (majority of participants were older people)

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
Sweden	Odlund Olin (2008)[197]	Frail older people	49	Serviced flats (before and after intervention with additional meal)	**90** (27 + 63) (baseline)	MNA (**malnourished** = score < 17 + **at risk of malnutrition** score = 17-23.5)
UK	Ralph (2010)[34]	Individuals in sheltered housing*	1353	Sheltered housing schemes (overall) > 80 years of age < 80 years of age (individuals screened during invited coffee mornings over 6 month period)	**12** (7 + 5) **14** **9**	'MUST' (**medium + high**)
UK	Elia (2009)[198]	Older people (not specified)	335	Sheltered accommodation (not specified)	**14** (5 + 9)	'MUST' (**medium + high**)
UK	Harris (2007)[199]	> 65 years of age	100	Sheltered accommodation (not specified)	**10** **12** **17**	Dietitians assessment 'MUST' (**medium + high risk**). Not reported separately MNA (screening score < 12)

* Participants' age in years mean (± SD): 78 (±10.4)[34].

Table A1.6 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - free living (majority of participants were older people)

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
Denmark	Beck (2002)[189]	> 65 years of age	200	Home care districts (not specified)	**30** (12)	BMI < 20 kg/m^2 (BMI < 18.5 kg/m^2)
Ireland	O'Dwyer (2009)[33]	Older people	63	Meals on wheels recipients (not specified)	**36.5** (27 + 9.5)	**At risk** MNA 17 to 23.5, **malnourished** MNA score < 17
Spain	Cuervo (2008)[40]	> 65 years of age	22007	Community dwelling (cross-sectional survey)	**29.7** (25.4 + 4.3)	**At risk** MNA ≥17 to ≤23.5, **malnourished** MNA score < 17
Sweden	Johansson (2009)[200]	Older people	579	Home-living: - Baseline - At follow-up 1-4 (between 2001 and 2006) (prospective study, assessed at baseline and follow-up as above)	**14.5** Between 7.6 - 16.2	**At risk** MNA 17 to 23.5, **malnourished** MNA score < 17
The Netherlands	Meijers (2009)[185]	18 years of age*	2794	Home care (cross-sectional, point prevalence)	**21.7**	**Malnutrition** defined according to one of the three following criteria (1) BMI < 18.5 kg/m^2 (2) unintentional weight loss (6 kg in previous 6 months or 3 kg in the previous month) or (3) BMI 18.5-20 kg/m^2 in combination with no nutritional intake for 3 d or reduced intake for > 10 d
The Netherlands	Kruizenga (2003)[19]	> 18 years of age*	533	Home care (convenience sample, timing not clear)	**13** (7 + 6)	**At risk of malnutrition** = 5-10% unintentional weight loss during the past 6 months , **malnourished** = unintentional weight loss > 10% during the past 6 months

Table A1.6 continued

Country	Author (year)	Study population	Patients (n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
UK	Skinner (2010)[201]	Older people (not specified)	111	Meals on wheels recipients	**31** (16 + 15)	'MUST' (**medium + high**)
UK (2005)[41]	Elia of age	> 65 years	953	Free living (secondary analysis of the National Diet and Nutrition Survey)	**12.5** (6.6 + 5.9)	'MUST' type criteria applied i.e. a score of current weight status added to the weight loss score (**medium + high**)

*Participants' age in years mean (± SD): home care 76.2 (± 12.0)[185], home care well nourished 59 (± 20), at risk 64 (± 23), malnourished 66 (± 23)[19].

Table A1.7 Prevalence of malnutrition or risk of malnutrition in some examples of studies reported after 2002 according to country and healthcare setting - other care settings

Country	Author (year)	Study population	(n)	Healthcare setting (and timing of nutritional screening/assessment)	Prevalence (%) (risk category)	Method and details of risk category where reported
The Netherlands	Poels (2006)[202]	Stroke patients > 18 years of age*	69	Stroke rehabilitation centre (on admission)	**35** (primary criteria) **73** (if malnutrition defined by the presence of at least one of the primary or secondary criteria)	Malnutrition assessed by a dietitian. **Primary criteria** for malnutrition was an unintentional weight loss of > 5% in 1 month or > 10% in 6 months or a BMI < 18 (< 65 years) or < 22 (≥ 65 years). Secondary criteria for malnutrition (1) serum albumin < 25 g/l, (2) FFM ≤16 kg/m^2 (men), 15 kg/m2 (women), (3) TSF < 90% of 12.5 mm (men) or 16.5 mm (women), (4) MAMC < 90% of 25.3 cm (men) or 23.3 cm (women)
UK	Russell (2009)[15]	Adults ≥ 18 years of age*	185	Mental health units (restricted to adults admitted within the previous 6 months)	**20** (5 + 15)	'MUST' (**medium + high**)
UK	Russell (2008)[21]	Adults ≥ 18 years of age*	332	Mental Health Units (restricted to adults admitted within the previous 6 months)	**19** (7 + 12)	'MUST' (**medium + high**)

* Participants' age in years mean (± SD): stroke rehabilitation centre 56.7 (± 11.0)[202], mental health units 66.4 (±20.1)[15], mental health units 59.2 (± 20.0)[21].

Appendix II

Functional benefits of ONS - Table A2.1

Table A2.1 Some examples of trials reported after 2002 describing improved functional outcomes with ONS in a variety of healthcare settings

Trial	Design	Subjects (setting)	Intervention (n)	Control (n)	Duration	Functional outcome
McMurdo (2009)[119]	RCT	Older people, malnourished. Community dwelling admitted to hospital with acute illness. Residents of care homes excluded. ONS provided upon discharge	ONS (126)	Control supplement (127)	4 months	• Significant improvement in hand-grip strength in ONS group compared with controls • Significantly more vector movement (objective measure of physical activity using accelerometry) in the ONS group compared with controls
Norman (2008)[107]	RCT	Adult malnourished SGA B or C, benign GI disease (post-hospital)	HP ONS + DC (38)	DC (42)	3 months	• Significant improvement in hand-grip strength and peak expiratory flow in ONS group, unchanged in DC group • Significant improvement in all 8 scales of QOL in ONS group, whereas improvement in 3 scales in DC group only. Significantly higher increases in physical functioning, role physical, vitality and general health scales in ONS group • Change in hand-grip strength correlated with the change in two physical scales (physical functioning and physical role)
Rabadi (2008)[123]	RDB Trial	Undernourished (2.5% weight loss in two weeks) patients admitted to a stroke rehabilitation unit	Intensive ONS	Standard ONS	From within 72 hours arrival on unit to discharge	• Significant improvement in the 'Intensive' ONS group in total Functional Independence Measure (FIM) score, FIM motor subscore, 2-minute walk, and 6-minute walk

Table A2.1 continued

Trial	Design	Subjects (setting)	Intervention (n)	Control (n)	Duration	Functional outcome
Gariballa (2007)[124]	RDBPCT	Acutely ill older people (hospital and post-discharge)	NHD + HP ONS (106)	NHD + Placebo (119)	6 weeks	• Significant increase in number of patients with no symptoms of depression and decrease in those with symptoms of mild or severe depression among ONS group compared with placebo group
Gariballa (2007)[125]	RDBPCT	Acutely ill older people (hospital and post-discharge)	NHD + HP ONS (106)	NHD + Placebo (119)	6 weeks	• Significantly better quality of life scores in the ONS group compared with placebo at 6 months but not at 6 weeks. Effect of supplementation was seen in higher physical function, role physical and social function scores
Persson (2007)[118]	RCT	Older acutely ill/trauma patients at risk of malnutrition MNA-SF (at hospital discharge to home/nursing home)	ONS + DC (29)	Brief written dietary advice (25)	4 months	• Treated-as-protocol analyses showed Katz Activities of Daily Living (ADL) index improved in the ONS + DC group
Price (2005)[114]	RCT	Undernourished* older people (at hospital discharge to community)	ONS (70)	Usual care (66)	8 weeks	• Improvement in hand-grip strength in both groups, but ONS group showed significantly greater increase over 12 weeks compared with controls. Intention-to-treat analysis showed a 13.9% increase in the ONS group compared with 7.2% in the control group
Edington (2004)[126]	RCT	Older malnourished** patients (community)	ONS (51)	Standard care (49)	8 weeks	• Significant improvement in hand-grip strength during supplementation, but not sustained from week 8 to week 24 • No difference between groups in QOL utility score or health status, however ONS group scored significantly higher on the mobility score at week 24 than controls, possibly indicating an improvement in strength
Payette (2002)[203]	RCT	Frail older people at high nutritional risk (community)***	ONS + DC (41)	Visited monthly, no advice/ ONS (42)	16 weeks	• When results analysed by sex, significant reduction in the mean time to execute 'up and go' test was seen in women in the ONS group, knee extensor strength increased in men in the ONS group • The number of days subjects had to stay in bed significantly increased in the control group over the course of the study as compared with baseline, in contrast no change in bed disability days seen in the ONS group

RCT - Randomised Controlled Trial, SGA - Subjective Global Assessment, GI - Gastrointestinal disease, HP - High Protein (> 20% En from protein), DC - Dietary Counselling, RDBPCT - Randomized Double Blind Placebo Controlled Trial, NHD - Normal hospital diet, MNA-SF - Mini Nutritional Assessment Short Form.

*BMI ≤ 24 kg/m^2, TSF or MAMC below the 10th centile and/or weight loss ≥ 5% during hospital stay

**(a) BMI < 20 or (b) BMI ≥20 but < 25 with documented evidence of weight loss of ≥ 10% in the 6 months prior to study period or ≥ 5% in the 3 months prior to study period

***(a) involuntary weight loss > 5% body weight in the past month, > 7.5% in the past 3 months, or > 10% in the past 6 months and BMI < 27 or (b) BMI < 24 kg/m^2

Appendix III

Summary of trials: Setting, population, intervention and outcome - Table A3.1 - A3.2

Table A3.1 Community studies

Table A3.2 Hospital and hospital to community studies

The studies listed here are key individual trials that have been mentioned within the text to illustrate specific points and therefore this list is not an exhaustive list of all trials using ONS, for example studies which have been included in key systematic reviews and meta-analyses have not been listed here.

For trials up to 2002 see Stratton (2003)[1]. Key systematic reviews and meta-analyses include: Stratton (2003)[1], Langer (2003)[138], Stratton (2005)[139], Milne (2005)[104], (2006)[105] & (2009)[11], NICE (2006)[75], Elia (2006)[110], Avenell and Handoll (2006)[129] & (2010)[130], Cawood (2007)[137] & (2008)[108] and Lidder (2009)[136].

Adverse effects/intolerance of ONS

- A review of systematic reviews concluded that 'overall, ONS can be regarded as a safe intervention as no systematic reviews or meta-analyses or individual RCTs show significant adverse effects of ONS on clinical outcome. There may be minor gastrointestinal symptoms, although the majority of trials do not thoroughly assess gastrointestinal tolerance'[169].

- A systematic review of ONS in older people at risk from malnutrition by Milne (2009) (62 trials, n = 10,187) reported that 'adverse events included nausea and diarrhoea'[11]. On further assessment it appears that adverse effects were reported in 12 trials i.e. < 20% of the total number of trials included in the review. The FOOD trial[132] dominated the analysis contributing 4023 patients, of whom 2016 received a protein energy supplement compared with 2007 controls. Twenty eight percent of patients stopped the supplement due to disliking the taste, weight gain or nausea therefore the proportion of patients with true intolerance is not known. Poor glycaemic response was indicated in 33 patients. However, compliance with ONS was actually reported to be very high (mean 76%, median 93%). Note that only 8% (n = 564) of patients included in the FOOD trial were actually malnourished at baseline. Excluding the FOOD trial, in total only 92 of 3078 patients i.e. 3% experienced adverse effects or intolerance of ONS in the review by Milne (2009), rising to 13% when patients from the FOOD trial are included, thus illustrating that actual numbers of adverse effects are low.

Table A3.1 Summary of trials: setting, population, intervention and outcome - community studies

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Bonnefoy (2003)[128]	Retirement homes	Frail older people	RCT factorial design	57	Two x 200ml daily given at 10.00 and 16.00 hours **Group 1** - ONS plus memory **Group 2** - ONS plus exercise	Placebo in identical packaging, contained no energy, protein or micronutrients **Group 3** - placebo plus exercise **Group 4** - placebo plus memory	9 months	**Nutritional** Increase in BMI at 3 and 9 months with ONS ($p = 0.004$, $p = 0.007$ respectively) Trend towards increase in FFM in ONS group and decrease in placebo group at 3 and 9 months **Functional** ONS improved muscle power at 3 months (+56.8%, $p = 0.03$) Improved 5-time chair rise with exercise at 9 months ($p = 0.014$) but no significant effect on muscle function or nutritional status at 3 or 9 months
Bunout (2001)[127]	Community dwelling (free-living)	Older people	RCT	149	Two servings soup/porridge-style supplement daily **Group 1** - ONS plus resistance exercise training **Group 2** - ONS, no training **Group 3** - no ONS, resistance exercise training	**Group 4** - no ONS and no training	18 months	**Nutritional** No change in body weight or FFM, fat mass increased in all groups. Bone mineral density decreased less in ONS groups than in trained groups ($p < 0.01$) **Functional** ADL remained constant in ONS groups and decreased in non-ONS groups. Exercise had no effect. Mini-mental scores increased in all groups, no differences among groups. No effect of ONS on walking capacity, muscle strength and maximal inspiratory pressure

Table A3.1 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Edington (2004)[126]	Community (post-discharge from hospital)	Older people, malnourished	RCT	100	Intakes between 600kcal and 1000kcal/day prescribed in order to achieve a weight gain of at least 0.5 kg/week (+ telephone contact by dietitian)	Standard care	8 weeks*	**Nutritional** Higher energy intake at week 12 (p = 0.041) Improved nutritional status (BMI, weight and triceps skinfold thickness) between baseline and 24 weeks in ONS group, but no significant difference between groups **Functional** Improvement in handgrip strength at 8 weeks in ONS group (p = 0.04) (not sustained), trend towards significance at 8 weeks between groups Fewer mobility problems in ONS vs control group at 24 weeks (p = 0.022) **Economic** No difference in health economic outcomes between groups at 24 weeks
Lauque (2004)[113]	Geriatric wards and day care centres	Older people with Alzheimer's disease, at risk of under-nutrition	RCT	91	300 - 500 kcal/day in addition to the patients' spontaneous food intake	Usual care (some patients from the control group who received ONS prescribed during the study not excluded, but ONS prescription recorded)	3 months	**Nutritional** Improved energy and protein intakes between baseline and 3 months in the intervention group leading to significant improvement in weight and FFM **Functional/clinical** No difference in dependence, cognitive function, biological markers at 3 months, or in fractures, pressure ulcers or hospitalization at 6 month follow-up

Table A3.1 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Manders (2009)[120]	Residents of care homes for older people	Older people	RDBPC, parallel	176	Two x 125ml dairy drink between meals (250 kcal/day)	Placebo drink, no energy, vitamins or minerals. Contained water, cloudifier, thickener, flavouring, colourant and non-calorific sweetener	6 months	**Nutritional** Weight gain, 1.6 kg difference in change ($p = 0.035$). Increased calf circumference 0.9 cm difference in change ($p = 0.48$). Improved plasma vitamin D, B_{12}, B_6, homo cysteine, folate and Methyl Malonic Acid ($p < 0.01$) **Functional** Better performance on language sub score of Alzheimer's Disease Assessment Scale in a subgroup with BMI < 24.4 kg/m^2 ($p = 0.01$) No significant effects on physical performance (e.g. grip strength, ADL), verbal fluency or depression score
Manders (2009)[117]	Residents of care homes for older people (homes for the elderly n = 3, nursing homes n = 3, mixed homes n = 3)	Older people	RDBPC, parallel	176	Two x 125ml dairy drink between meals (250 kcal/day) in addition to usual diet	Placebo drink, no energy, vitamins or minerals. Contained water, cloudifier, thickener, flavouring, colourant and non-calorific sweetener	6 months	**Nutritional** Increased intake of vitamins and minerals, except vitamin A ($p < 0.001$) (non-randomised sub-sample n = 66) Most vitamin deficiencies normalised, most notably vitamin D (10% vs 75% remained deficient in ONS vs placebo group) (vitamin levels also reported in Manders (2009)[120]) Non-significant positive effect on macronutrient intake and body weight. Energy intake decreased to the same extent in both groups. No effect on blood proteins or biochemical indicators of general health

Table A3.1 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
McMurdo (2009)[119]	Community dwelling (admitted to hospital with acute illness). Residents of care homes excluded	Older people, under-nourished	RCT	253	Two ONS x 200ml daily	Control supplement based on skim milk containing 200 kcal, 12.4 g protein	4 months	**Nutritional** Weight gain† mean difference of 1.17 kg (95% CI = 0.07-2.27, p = 0.04) **Functional** Hand grip strength¥ mean difference of 1.48 kg (95% CI =0.46-2.50, p = 0.005). Physical activity (accelerometry)¥ mean difference in % change in vector movement 1.71 (95% CI=0.26-3.17, p = 0.02). No change to ADL, health-related quality of life, falls, rehab input, time spent walking, death, unplanned admissions or other adverse events, trend towards improvement in sit-to-stand test in ONS group
Norman (2008)[107]	Community	Malnourished patients with gastro-intestinal disease	RCT	101	Up to three x 200ml daily. Patients advised to drink ONS slowly and in between meals (≥1 h before a meal) (+standard dietary counselling session as per control, contacted once/month)	Standard dietary counselling session (verbal advice, 45min) by a registered dietitian. Advised on improving protein and energy intake with normal food. All patients actively contacted once/month	3 month	**Nutritional** Higher energy and protein intake in ONS group vs control (p < 0.0001). **Functional** Improved handgrip strength and peak flow in ONS group vs controls (p = 0.002, p = 0.047 respectively). Body weight and BMI increased in both groups. Significantly improved QOL in 4 areas in ONS group vs controls (physical functioning, role physical, general health and vitality, p < 0.05) **Clinical** Control patients had more readmissions than ONS group (n = 20 vs n = 10, p = 0.041)

Table A3.1 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Payette (2002)[203]	Community living	Frail, older under-nourished people	RCT	83	Two x 235 ml daily. Choice of ONS, encouraged to attain max tolerable energy intake to gain 0.5 kg body weight per week. Instructed to use ONS and increase overall food intake (+nutrition counselling by phone every two weeks between visits)	Visited monthly, no advice/ONS	16 weeks	**Nutritional** ONS group had higher energy intake ($p < 0.001$) and weight gain ($p < 0.001$). No significant differences in other anthropometric indexes, muscle strength or functional measures **Clinical** Number of bed days significantly increased in control group compared with baseline ($p = 0.04$), no change in bed disability days seen in the ONS group
Persson (2007)[118]	Community (recruited in hospital, ONS at discharge)	Older people at risk of malnutrition	RCT	108	One to two x 200ml daily of a choice of either a complete or an incomplete formula (+ two individualized counselling sessions by a dietitian, telephone contact from dietitian at three time points, advised to increase fat, eat more snacks between meals)	Brief written dietary advice	4 month	**Nutritional** In both intention to treat and per protocol analyses ONS group maintained weight, while controls lost weight ($p < 0.001$) **Functional** Improved ADL in ONS group in the treated as protocol analyses ($p < 0.05$ between groups)

Table A3.1 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Price (2005)[114]	Community, at discharge from hospital (nursing home residents excluded)	Older people following acute illness	RCT	136	Two x 200ml daily	Usual care	8 weeks	**Nutritional** Higher energy intake in ONS group vs controls ($p = 0.022$) **Functional** Improved handgrip strength in ONS group v control over 12 weeks ($p = 0.02$), mean increase of 19.9% vs 6.6%; intention to treat analysis 13.9% vs 7.2%, $p = 0.055$
Wouters-Wesseling (2002)[78]	Nursing Homes	Psycho-geriatric patients	RCT	42	Two x 250 ml daily during daytime between main meals. Patients were helped and encouraged by nursing staff to drink the ONS (+ regular dietary intake)	Placebo (2 x 250ml) consisting of water, cloudifier, flavourant and non-caloric sweetener to resemble ONS in taste and appearance. No energy, no vitamins, no minerals.	3 months	**Nutritional** Improved body weight with ONS vs placebo ($p = 0.03$) Significant improvement in homocysteine, vitamins B_1, B_6, B_{12}, D, thiamine diphosphate and folic acid levels in ONS group vs placebo **Functional** No significant change in ADL

*Mean actual duration of supplementation was 99.4 days (range 6-169). †Per protocol analysis, ¥intention to treat analysis. Note that actual intake often not recorded, may differ from target level.

Table A3.2 Summary of trials: setting, population, intervention and outcome - hospital studies and hospital to community

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Bos (2001)[115]	Hospital inpatients	Malnourished older people	Controlled trial	23	Two units daily of 400 kcal, 30 g protein. Advised to consume between meals or at bedtime	No ONS, but careful nutrition attention from nursing staff (advice on finishing meals)	10 days	**Nutritional** Increased energy and protein intake, ($p < 0.005$ and $p < 0.0002$ respectively) **Functional** FFM and BMI changes between day 7 and 17 ($p < 0.02$ and $p < 0.005$ respectively) No significant effect on biological markers or hand-grip strength
Botella-Carretero (2008)[131]	Hospital (ONS started 48 hrs after surgery and continued until after discharge)	Normally nourished or mildly under-nourished older hip fracture patients	RCT (3-arm)	90	Group A - 4 x 10g packets protein powder providing 36 g protein and 152 kcal/day dissolved in water, milk or soup Group B - 2 x 200ml liquid ONS providing 37.6 g and 500kcal/day	Standard or texture modified diet		**Nutritional** No significant effects on nutritional status (albumin, prealbumin, BMI, tricipital fold or midbrachial circumference). **Functional/clinical** No differences in hospital stay, mobilization, blood transfusions, complications
Gariballa (2007)[124]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	225	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micro-nutrients and with a minimal kcal content (60 kcal))	6 weeks	**Functional** Increase in number of patients with no depressive symptoms and decrease in patients with mild or severe depression with ONS compared to placebo ($p = 0.007$)

Table A3.2 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Gariballa (2007)[125]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	225	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micro-nutrients and with a minimal kcal content (60 kcal))	6 weeks	**Functional** After adjustment for baseline QOL, age and sex, better QOL score with ONS at 6 months (physical function p = 0.04, role physical p = 0.047 and social function p = 0.05) but not at 6 weeks. Overall QOL scores better at 6 months with ONS (p = 0.003), no significant difference in cumulative change between the two groups. No difference in ADL
Gariballa (2006)[106]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	445	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micro-nutrients and with a minimal kcal content (60 kcal))	6 weeks	**Nutritional** Improved red-cell folate and plasma vitamin B_{12} in ONS group compared to decrease seen in controls. At 6 months no difference between groups in weight, BMI, MUAC, TSF or transferrin **Clinical** Reduced readmission rate (29% vs 40%, p < 0.05)
Gazzotti (2003)[112]	Hospital, continued in the community	Older people, at risk of malnutrition	RCT	80	Two x 200ml cup daily (one of each energy density to provide total of 500 kcal and 21 g protein daily) (+ standard diet)	No nutritional supplementation	2 months	**Nutritional** MNA scores higher in ONS group vs control at day 60 (p < 0.01). Spontaneous protein and energy intake higher in ONS group vs controls (p < 0.01). Mean weight loss in controls 1.23 ±2.5 kg (p = 0.01), ONS groups showed non-significant weight increase 0.28 ±3.8 kg (p = 0.6) **Clinical** No difference in LOS or discharge destination

Table A3.2 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Lauque (2004)[113]	Geriatric wards and day care centres	Older people with Alzheimer's disease, at risk of under-nutrition	RCT	91	300 - 500 kcal/day in addition to the patients' spontaneous food intake	Usual care (some patients from the control group who received ONS prescribed during the study not excluded, but ONS prescription recorded)	3 months	**Nutritional** Improved energy and protein intakes between baseline and 3 months in the intervention group leading to significant improvement in weight and FFM **Functional/clinical** No difference in dependence, cognitive function, biological markers at 3 months, or in fractures, pressure ulcers or hospitalization at 6 month follow-up
Miller (2006)[204]	Hospital, continued in the community (On discharge 52 went to rehab programme, 12 to community hospital, 16 to higher level care & 20 returned to pre-injury admission accomodation)	Older people at risk of under-nutrition with fall-related lower limb fracture	RCT	100	Supplement volumes were prescribed to meet 45% of individual estimated total energy requirements (range 580 to 800 ml/day). Four doses of equal volume administered daily +usual clinical care **Group 1** - ONS **Groups 2** - Nutrition and exercise **Group 3** - Exercise	**Group 4** -Attention control (received tri-weekly visits to match the home visits of the active intervention groups; discussions limited to general information e.g. benefits of regular exercise and nutrient-dense meals)	42 days	**Nutritional** Patients in resistance training group lost more weight than those in ONS and exercise group ($p = 0.029$) **Functional/clinical** No significant difference in quadriceps strength, gait speed, quality of life or healthcare utilization

Table A3.2 continued

Trial	Setting	Population	Design	Sample size	Intervention (ONS)	Control	Duration	Outcome
Neumann (2004)[116]	Rehabilitation hospital	Older people following hip fracture	RDB, parallel	46	At least two x 8oz (227 ml*)daily	Compared with 'standard' ONS (110 kcal and 3.9 g protein per 100ml†)	28 days	**Nutritional** Protein, fibre, calcium, vitamin K and phosphorus intake greater in high protein ONS group **Clinical** Trend towards shorter rehab LOS but not significant (23 vs 28 days p = 0.27) **Functional** No differences in functional independence measure
Rabadi (2008)[123]	Stroke Rehabilitation hospital	Under-nourished patients	RDBCT	102	120 ml dose of an 'intensive' ONS every 8 hours by mouth	Compared with 'standard' ONS (127 kcal, 5 g protein). Standard ONS contained 36 mg vitamin C compared with 90 mg in the intensive ONS	From within 72 hours arrival on unit to discharge	**Nutritional** Non significant greater increase in body weight in intensive group **Functional** Improved total functional independence measure (FIM) and motor FIM subscore ($p < 0.001$), and 2 minute and 6 minute walk test ($p < 0.001$) in the intensive ONS group vs control. Higher % returned home in the intensive group (63% vs 43% $p < 0.05$)

Table A3.2 continued

Trial	Setting	Population	Design	Sample	Intervention size	Control	Duration	Outcome
Stratton (2006)[101] Stratton (2006)[102] Stratton (2007)[103]	Hospital	Patients with fractured neck of femur, at risk of malnutrition	RCT	50	Choice of liquid ONS Ad libitum	Isoenergetic food snacks e.g. cakes, biscuits, puddings	Post operatively until discharge	**Nutritional** Significantly greater energy and protein intake with ONS vs snacks Significantly greater mean total intake of all water-soluble vitamins in ONS group vs snacks Significantly fewer patients in the ONS group had complications than in the snack group (27% vs 58%, p = 0.04) Non-significant reduction in the incidence of specific complications i.e. infections 17% vs 33% and wound-related complications (poor wound healing, pressure ulcers) 17% vs 38%

*1 fluid oz = 28.4 ml. †Calculated from the description of the ONS used in the study. Note that actual intake often not recorded, may differ from target level.

Appendix IV

Nutrient content of ONS vs typical food snacks - Table A4.1

Table A4.1 Comparison of average nutrient content of some examples of ONS with typical snack foods used with the aim of increasing nutrient intake

		Fortisip† (Nutricia)	Ensure Plus† (Abbott Nutrition)	Fresubin Energy† (Fresenius Kabi)	Clinutren 1.5/ Resource Energy† (Nestle Nutrition)	Fruit yogurt	Cheese & crackers	Chocolate cake	Mars Bar
		per 200ml	per 220ml	per 200ml	per 200ml	per 150g	per portion*	per portion**	Per 65g bar
Energy	kcal	300	330	300	300	164	299	313	307
Protein	g	12	13.75	11.2	11.2	6	11.6	3.7	2.9
Carbohydrate	g	36.8	44.44	37.6	42	26.6	9.7	33.1	50.2
Sugars	g	13.4	15.2	7.8-12.6‡	10.4	24.9	0.1	22.3	43
Fat	g	11.6	10.82	11.6	10	4.5	24	19.3	11.9
Saturates	g	1.2	1.06	0.8	1.4	3	14.6	N/A	6.7
Dietary fibre	g	0¥	0¥	0¥	< 0.5¥	0	0.4	1	0.3
Sodium	mg	180	202	160	160	87	435	273	98
Potassium	mg	318	352	270	340	255	50	91	163
Chloride	mg	174	242	200	300	269	632	299	195
Calcium	mg	182	264	270	160	183	313	38	62
Phosphorus	mg	156	220	160	160	144	220	104	72
Magnesium	mg	46	66	42	60	20	15	23	21
Iron	mg	4.8	4.6	4	3.4	0.18	0.36	0.98	0.78
Zinc	mg	3.6	4.0	3	3	0.6	1.75	0.59	0.46
Copper	µg	540	396	0.6	0.3	0	0.04	0.2	0.20
Manganese	mg	1	1.1	0.8	0.6	0	0.01	0.1	0
Fluoride	mg	0.3	0	0.4	0.3	N/A	N/A	N/A	N/A
Molybdenum	µg	30	35	30	22	N/A	N/A	N/A	N/A
Selenium	µg	17.2	18	20	15	3	3	3	1
Chromium	µg	20	17	20	15	N/A	N/A	N/A	N/A
Iodine	µg	40	48	60	30	41	18	19	0
Vitamin A	µg RE	246 (600µg carotenoids)	257	240 (beta-carotene 600µg)	260	54	241 (117 µg carotene)	0	20 µg retinol (26 µg carotene)
Vitamin D	µg	2.2	4.4	4	3	0.15	0.21	1.83	0.2
Vitamin E	mg-α-TE	3.8	4.7	6	4	0.27	0.57	1.96	0.31
Vitamin K	µg	16	26	33.4	16.6	0	2.62	0	3.12
Thiamin B1	mg	0.46	0.44	0.46	0.36	0.18	0.04	0.05	0.03
Riboflavin B2	mg	0.48	0.59	0.64	0.4	0.24	0.17	0.06	0.13
Niacin B3	mg NE	5.4	5.7	6	3.6	0.15	0.28	0.26	0.13
Pantothenic acid B5	mg	1.6	2.4	2.4	1.5	0.6	0.25	0.26	0.59
Vitamin B6	mg	0.52	0.59	0.66	0.52	0.02	0.08	0.03	0.02
Folic acid	µg	80	88	100	72	15	15	6	3
Vitamin B12	µg	0.64	1.2	1.2	1.1	0.45	0.99	0.65	0
Biotin	µg	12	13	15	9	1.7	2.1	3.9	1.3
Vitamin C	mg	30	26	30	30	1.5	0	0	0
Choline	mg	110	121	53.4	0	N/A	N/A	N/A	N/A
Data Source		www.nutricia.com. Accessed 26.04.10	Provided by Abbott Nutrition 30.04.10	www2.fresenius-kabi.com. Accessed 26.04.10	www.nestlenutrition.com. Accessed 26.04.10	McCance and Widdowson The Composition of Foods[205]			

†Required to comply with the minimum and maximum values for vitamins, minerals and trace elements within Commission Directive 1999/21/EC on dietary foods for special medical purposes. *Portion = 2 crackers, 40g cheddar cheese & 10g butter, **portion = 65g chocolate cake with butter icing. ‡Depending on flavour. ¥Fibre variants available. N/A, not available.

Appendix V

Summary of trials: Type, regimen and duration of ONS used -

Tables A5.1 - A5.2

Table A5.1 Community studies

Table A5.2 Hospital and hospital to community studies

- A variety of different ONS were used in the trials discussed, but in general liquid multi-nutrient ONS were used.
- The duration of supplementation with ONS ranged from 10 days to 18 months (not specified in some trials).
- The energy density ranged from 0.85 - 2.5 kcal/ml and protein content ranged from 3.4 - 13g/100ml.
- Energy intakes from ONS ranged from 400 - 1000 kcal per day and 17- 50 g of protein/day.

Table A5.1 Summary of trials: Type, regimen and duration of ONS used - community studies

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Bonnefoy (2003)[128]	Retirement homes	Frail older people	RCT factorial design	57	1 kcal/ml	Two x 200ml daily given at 10.00 and 16.00 hours **Group 1** - ONS plus memory **Group 2** - ONS plus exercise	100	7.5	ONS provided 50% of RDA for vitamins and minerals	Placebo in identical packaging, contained no energy, protein or micronutrients **Group 3** - placebo plus exercise **Group 4** - placebo plus memory	9 months
Bunout (2001)[127]	Community dwelling (free-living)	Older people	RCT	149	N/R	Two servings soup/porridge-style supplement daily **Group 1** - ONS plus resistance exercise training **Group 2** - ONS, no training	400 (per 100g)	13 (per 100g)	Contained 25% of daily vitamin and mineral requirements	**Group 3** - no ONS, resistance exercise training **Group 4** - no ONS and no training	18 months
Edington (2004)[126]	Community (post-discharge from hospital)	Older people, mal-nourished	RCT	100	Various - N/R	Intakes between 600kcal and 1000kcal/day prescribed in order to achieve a weight gain of at least 0.5 kg/week (+ telephone contact by	Choice offered. Variety of different energy/protein contents - N/R		N/R. Some known to be nutritionally complete	Standard care	8 weeks*

Table A5.1 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Lauque (2004)[113]	Geriatric wards and day care centres	Older people with Alzheimer's disease, at risk of under-nutrition	RCT	91	Various (1-1.5 kcal/ml)	300 - 500 kcal/ day in addition to the patients spontaneous food intake	100 - 150	5 - 8	Enriched with vitamins and minerals	Usual care (some patients from the control group who received ONS prescribed during the study not excluded, but ONS prescription recorded)	3 months
Manders (2009)[120]	Residents of care homes for older people	Older people	RDBPC, parallel	176	1 kcal/ml	Two x 125ml dairy drink between meals (250 kcal/ day)	100	3.5	Added vitamins, minerals & trace elements (25-175% of U.S. RDA, enhanced levels of antioxidants)	Placebo drink, no energy, vitamins or minerals. Contained water, cloudifier, thickener, flavouring, colourant and non-calorific sweetener	6 months
Manders (2009)[117]	Residents of care homes for older people (homes for the elderly n = 3, nursing homes n = 3, mixed homes n = 3)	Older people	RDBPC, parallel	176	1 kcal/ml	Two x 125ml dairy drink between meals (250 kcal/ day) in addition to usual diet	100	3.5	Added vitamins, minerals & trace elements (25-175% of Dutch RDA, with added antioxidants)	Placebo drink, no energy, vitamins or minerals. Contained water, cloudifier, thickener, flavouring, colourant and non-calorific sweetener	6 months

Table A5.1 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
McMurdo (2009)[119]	Community dwelling (admitted to hospital with acute illness). Residents of care homes excluded	Older people, under-nourished	RCT	253	1.5 kcal/ml	Two x 200ml daily	150	10	Nutritionally complete	Control supplement based on skim milk containing 200 kcal, 12.4 g protein	4 months
Norman (2008)[107]	Community	Mal-nourished patients with gastro-intestinal disease	RCT	101	1.5 kcal/ml, High protein**	Up to three x 200ml daily. Patients advised to drink ONS slowly and in between meals (1 h before a meal) (+standard dietary counselling session as per control, contacted once/month)	150	10	Nutritionally complete	Standard dietary counselling session (verbal advice, 45 min) by a registered dietitian. Advised on improving protein and energy intake with normal food. All patients actively contacted once/month.	3 month

Table A5.1 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Payette (2002)[203]	Community living	Frail, older under-nourished people	RCT	83	Various - N/R	Two x 235 ml daily. Choice of ONS, encouraged to attain max tolerable energy intake to gain 0.5 kg body weight per week. Instructed to use ONS and increase overall food intake (+nutrition counselling by phone every two weeks between visits)	Choice offered. Variety of different energy/protein contents - N/R		N/R. Some known to be nutritionally complete	Visited monthly, no advice/ONS	16 weeks
Persson (2007)[118]	Community (recruited in hospital, ONS at discharge)	Older people at risk of mal-nutrition	RCT	108	1.2 kcal/ml or 0.85 kcal/ml	One to two x 200ml daily of a choice of either a complete or an incomplete formula (+ two individualized counselling sessions by a dietitian, telephone contact from dietitian at three time points, advised to increase fat, eat more snacks between meals)	120 (complete) 85 (in-complete)	5 4	Vitamins D, B_6, B_{12}, Folacin, Mg, Ca, Zn + multi vitamin supplement (nutrients as above except Mg, Ca)	Brief written dietary advice	4 months

Table A5.1 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Price (2005)[114]	Community, at discharge from hospital (nursing home residents excluded)	Older people following acute illness	RCT	136	1.5 kcal/ml	Two x 200ml daily	150	12	N/R. Known to be nutritionally complete	Usual care	8 weeks
Wouters-Wesseling (2002)[78]	Nursing Homes	Physo-geriatric patients	RCT	42	1.1 kcal/ml	Two x 250 ml daily during daytime between main meals. Patients were helped and encouraged by nursing staff to drink the ONS (+ regular dietary intake)	109†	3.4†	Contained a range of vitamins and minerals	Placebo (2 x 250ml) consisting of water, cloudifier, flavourant and non-caloric sweetener to resemble ONS in taste and appearance. No energy, no vitamins, no minerals.	3 months

N/R Not reported. *Mean actual duration of supplementation was 99.4 days (range 6-169). **High protein 20% Energy from protein[2]. †Calculated from the description of the ONS used in the study. Note that actual intake often not recorded, may differ from target level.

Table A5.2 Summary of trials: Type, regimen and duration of ONS used - hospital studies and hospital to community

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Bos (2001)[115]	Hospital inpatients	Mal-nourished older people	Controlled trial	23	N/R	Two units daily providing total of 400 kcal, 30 g protein. Advised to consume between meals or at bedtime	N/R	N/R	Contained a range of vitamins and minerals	No ONS, but careful nutrition attention from nursing staff (advice on finishing meals)	10 days
Botella-Carretero (2008)[131]	Hospital (ONS started 48 hrs after surgery and continued until after discharge)	Normally nourished or mildly under-nourished older hip fracture patients	RCT (3-arm)	90	N/R 1.25 kcal/ml	**Group A** - 4 x 10g packets protein powder providing 36 g protein and 152 kcal/day dissolved in water, milk or soup **Group B** - 2 x 200ml liquid ONS providing 37.6 g and 500kcal/day	N/R 125	N/R 9.4	N/R N/R	Standard or texture modified diet	
Gariballa (2007)[124]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	225	2.5 kcal/ml, High protein†	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	249*	12.4*	100% RNI for vitamins & minerals for healthy older person	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micronutrients and with a minimal kcal content (60 kcal))	6 weeks

Table A5.2 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Gariballa (2007)[125]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	225	2.5 kcal/ml, High protein†	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	249*	12.4*	100% RNI for vitamins & minerals for healthy older person	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micronutrients and with a minimal kcal content (60 kcal))	6 weeks
Gariballa (2006)[106]	Hospital, continued in the community	Older people with acute illness	RDBPC Trial	445	2.5 kcal/ml, High protein†	Two bottles x 200ml daily at 8.00 am and 12 noon (+ normal hospital diet)	249*	12.4*	100% RNI for vitamins & minerals for healthy older person	Normal hospital diet plus placebo (identical to the supplement but contained no protein or micronutrients and with a minimal kcal content (60 kcal))	6 weeks
Gazzotti (2003)[112]	Hospital, continued in the community	Older people, at risk of mal-nutrition	RCT	80	1 kcal/ml 1.5 kcal/ml	Two x 200ml cup daily (one of each energy density to provide total of 500 kcal and 21 g protein daily) (+ standard diet)	100	N/R	N/R - ? Nutritionally Complete	No nutritional supplementation	2 months
Lauque (2004)[113]	Geriatric wards and day care centres	Older people with Alzheimer's disease, at risk of under-nutrition	RCT	91	Various (1-1.5 kcal/ml)	300 - 500 kcal/day in addition to the patients' spontaneous food intake	100 - 150	5 - 8	Enriched with vitamins and minerals	Usual care (some patients from the control group who received ONS prescribed during the study not excluded, but ONS prescription recorded)	3 months

Table A5.2 continued

Trial	Setting	Population	Design	Sample size	Intervention					Control	Duration
					ONS Type	ONS regimen (+ other care, if provided)	Energy (kcal) per 100ml	Protein (g) per 100ml	Micronutrients		
Miller (2006)[204]	Hospital, continued in the community (On discharge 52 went to rehab programme, 12 to community hospital, 16 to higher level care & 20 returned to pre-injury admission accomodation)	Older people at risk of under-nutrition with fall-related lower limb fracture	RCT	100	1.5 kcal/ml	Supplement volumes were prescribed to meet 45% of individual estimated total energy requirements (range 580 to 800 ml/day). Four doses of equal volume administered daily +usual clinical care **Group 1** - ONS **Groups 2** - Nutrition and exercise	150	6*	Complete	**Group 3** - Exercise **Group 4** -Attention control (received tri-weekly visits to match the home visits of the active intervention groups; discussions limited to general information e.g. benefits of regular exercise and nutrient-dense meals)	42 days
Neumann (2004)[116]	Rehabilitation hospital following hip fracture	Older people	RDB, parallel High protein	46	1.1 kcal/ml	At least two x 8oz (227 ml¥) daily	106*	6.6	Contains vitamins and minerals	Compared with 'standard' ONS (110 kcal and 3.9 g protein per 100ml*)	28 days
Rabadi (2008)[123]	Stroke Rehabilitation hospital	Under-nourished patients	RDBCT	102	N/R	120 ml dose of an 'intensive' ONS every 8 hours by mouth	240 kcal per?	11g protein per?	Accompanied by multi-vitamin with minerals. ONS Nutritionally complete	Compared with 'standard' ONS (127 kcal, 5 g protein). Standard ONS contained 36 mg vitamin C compared with 90 mg in the intensive ONS	From within 72 hours arrival on unit to discharge
Stratton (2006) [101-103]	Hospital	Patients with fractured neck of femur, at risk of mal-nutrition	RCT	50	1.5 kcal/ml	Choice of liquid ONS Ad libitum	150	various	Contained vitamins and minerals	Isoenergetic food snacks e.g. cakes, biscuits, puddings	Post operatively until discharge

N/R Not reported. †High protein 20% Energy from protein[2]. *Calculated from the description of the ONS used in the study.
¥1 fluid oz = 28.4 ml. Note that actual intake often not recorded, may differ from target level.

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