UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE

Human Development and Health Division
Institute of Human Nutrition

Nutritional Screening and the Effect of Oral Nutrition Support on Clinical Outcomes:

A Randomised Trial of Oral Nutrition Supplements versus Dietary Advice in Care Homes

by

Emma Louise Parsons MNutr RD

Thesis for the degree of Doctor of Philosophy

April 2012

Emma Louise Parsons

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF MEDICINE

HUMAN DEVELOPMENT AND HEALTH DIVISION

Doctor of Philosophy

NUTRITIONAL SCREENING AND THE EFFECT OF ORAL NUTRITION SUPPORT ON CLINICAL OUTCOMES: A RANDOMISED TRIAL OF ORAL NUTRITION SUPPLEMENTS VERSUS DIETARY ADVICE IN CARE HOMES

By Emma Louise Parsons

The prevalence of malnutrition and the evidence for the use of oral nutrition support in UK care homes has not been established fully. The aim of this thesis was to establish the prevalence of malnutrition and to examine the effect of oral nutritional interventions on clinical, functional and healthcare outcomes in care homes.

An audit of nutritional care (use of weighing scales, nutrition screening tools (NST's), dietetic services) and malnutrition risk (Malnutrition Universal Screening Tool) was conducted in Hampshire care homes (August 2007-December 2009). 63 care homes and 1322 residents participated. A systematic review of oral nutrition support assessed the evidence for the use of oral nutritional supplements (ONS), food fortification (FF) and dietary advice (DA) in care homes. A 12 week randomised controlled trial (RCT) of ONS vs. DA measured quality of life (QoL) and a range of clinical, functional and healthcare use outcomes in 104 malnourished residents. A cost-utility analysis was performed using the data on QoL and healthcare use.

37% of residents were at risk of malnutrition. The prevalence varied according to type of care, age and health conditions. Use of ONS was limited (8%). Only 0.3% of residents were seen by a dietitian. Nutritional practice varied according to type of care home. The systematic review found limited good quality evidence for oral nutrition support (27 studies (12 ONS vs. control trials, 8 FF vs. control trials, 2 ONS vs. ONS trials and 5 FF vs. ONS trials). The RCT comparing the use of ONS with DA found that ONS were more effective than DA in improving QoL (EQ-5D TTO: 0.58 ± 0.02 vs. 0.48 ± 0.02, p=0.002) and nutritional intake (1645 ± 74.8kcal vs. 1218 ± 88.4kcal, p=0.001). The intervention was cost effective (mean cost/QALY (TTO): £10,698; 92% likelihood that ONS would produce incremental net benefit for willingness to pay of £30,000).

The thesis addressed some key research questions in relation to nutrition support in care homes. Given the prevalence of malnutrition and the variable use of NST's, there is a need to ensure all care homes screen for malnutrition, and implement and review nutritional care plans. The RCT of ONS versus DA has suggested that ONS may be more effective at improving quality of life, and that ONS are a cost-effective intervention. Further good quality nutrition support trials in care homes are required, using ONS, FF, DA or a combination of these interventions and measuring a wider range of outcomes in order to further assess the effectiveness of these nutritional interventions in malnourished care home residents.

Contents

List of figures

List of tables

Emma Louise Parsons

DECLARATION OF AUTHORSHIP

I, Emma Louise Parsons

declare that the thesis entitled

Nutritional Screening and the Effect of Oral Nutrition Support on Clinical Outcomes: A Randomised Trial of Oral Nutrition Supplements versus Dietary Advice in Care Homes

and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- none of this work has been published before submission, or [delete as appropriate] parts of this work have been published as: [please list references]

Signed: ……..

Date:…….

Acknowledgements

I would like to thank Professor Marinos Elia and Dr Rebecca Stratton for their excellent supervision, encouragement and support.

I would also like to express my gratitude to other members of the Institute of Human Nutrition and Southampton General Hospital with whom I have worked. I would especially like to thank Dr Abbie Cawood, Hilary Warwick, Dr Trevor Smith, Peter Collins, Caroline Anderson and John Jackson for their advice and encouragement throughout my PhD. I also wish to thank Abbie Scott and Andrea Ralph for their assistance with the care home visits.

This project would not have been possible without the participation of the care homes in Hampshire. I would like to express my sincere gratitude to all care home managers, nursing and care staff, residents and their families for their participation in the audit of nutritional care and the nutrition intervention trial.

I would also like to thank Professor Peter Emery and colleagues at King's College London for their patience and support whilst I completed my thesis.

My particular thanks have to go to those nearest and dearest to me; my Mum, Dad and brother Chris. Thanks also to all my friends for their encouragement over the last four years, especially to Tom Lunn, Katy Littlewood, Anna Bruce, Claire Heath and Emma Reeves for always being there for me.

Finally, I would like to dedicate my thesis to my best friend, Joanna Thomas, who sadly lost her battle with cancer during the course of my PhD candidature. A truely inspiring woman, who always encouraged me to do my best and to follow my dreams.

Abbreviations

ACBS	Advisory Committee on Borderline Substances
ADL	Activities of Daily Living
AMC	Arm Muscle Circumference
ANOVA	Analysis of Variance
ANCOVA	Analysis of Co-variance
BAPEN	British Association for Parenteral and Enteral Nutrition
BDA	British Dietetic Association
BMI	Body Mass Index
BS	Bootstrap
CCT	Controlled Clinical Trial (non randomised)
CEA	Cost-Effectiveness Analysis
CEAC	Cost-Effectiveness Acceptability Curve
CH	Care Home
CHO	Carbohydrate
CI	Confidence Interval
CLT	Central Limit Theorem
COPD	Chronic Obstructive Pulmonary Disease
CQC	Care Quality Commission
CSCI	Commission for Social Care Inspection
CT	Clinical Trial
DA	Dietary Advice
DALY	Disability Adjusted Life Years
DRV	Dietary Reference Value
EI	Energy Intake
EIF	Energy Intake from Food
EQ-5D	EuroQol
ESPEN	European Society for Clinical Nutrition and Metabolism

ETF	Enteral Tube Feeding
FF	Food Fortification
FL	Free Living
FSMP	Dietary Foods for Special Medical Purposes
HCP	Healthcare Professional
HUI	Health Utilities Index
ICER	Incremental Cost-Effectiveness Ratio
IMD	Index of Multiple Deprivation
INB	Incremental Net Benefit
LSOA	Lower Layer Super Output Area
LTCF	Long Term Care Facility
M	Malnourished
MAMC	Mid Arm Muscle Circumference
MHRA	Medicines and Healthcare products Regulatory Agency
MNA	Mini Nutritional Assessment
MST	Malnutrition Screening Tool
MUAC	Mid Upper Arm Circumference
'MUST'	'Malnutrition Universal Screening Tool'
NDNS	National Diet and Nutrition Survey
NH	Nursing Home
NI	Nutritional Intake
NICE	National Institute for Health and Clinical Excellence
NM	Non Malnourished
NRS	Nutrition Risk Score
NST	Nutrition Screening Tool
NSW	Nutrition Screening Week
ONS	Oral Nutritional Supplement
PEG	Percutaneous Endoscopic Gastrostomy

PI	Protein Intake
QALY	Quality Adjusted Life Years
QoL	Quality of Life
RCT	Randomised Controlled Trial
RH	Residential Home
SCIE	Social Care Institute for Excellence
SD	Standard Deviation
SE	Standard Error
SNAQ	Simple Nutrition Assessment Questionnaire
TEI	Total Energy Intake
TSF	Triceps skinfold
TTO	Time Trade Off
US	Unsupplemented
VAS	Visual Analogue Scale
Wt	Weight

Chapter One: Background

1.1 The population of older people in the UK

With the proportion of older people in the UK rising, the requirement for health and social care services is increasing as the number of people dependent on services increases. There is a drive to ensure that people remain independent in their own living environment for as long as possible, however despite this, there is still a large number of older people that require residential and nursing home places. In 2006, it was estimated that there were 441,958 places in care homes in England, with 262,826 residential places and 178,888 nursing places [1]. With the shift to ensuring people stay in their own homes for longer, this is resulting in residential and nursing home residents being much older, potentially more dependent and with greater care needs.

Currently in the UK there are more people aged over 80 years than there are aged under 16 years [1]. Over the next 45 years, the population of older people is expected to rise from 16% to 25% [1]. The average life expectancy of a person in the UK is now in their mid 80's with the gap in life expectancy between men and women declining [1]. Currently, 90% of the older population lives independently in their own homes, with the remainder requiring care in the community, either in care homes or assistance at home. This therefore sets a challenge to society in how the care of older people is managed in this growing older population.

As people get older, there are many physiological, psychological and social changes that occur, and their needs associated with these changes in health and social circumstances should be important considerations in assessing any care they may require. This sets huge challenges for the public health agenda of older people. Many agencies and societies have produced guidelines on the 'best' ways to care for older people, but within a changing political and economic climate, changes to the way in which we care for older people are likely to occur over coming years.

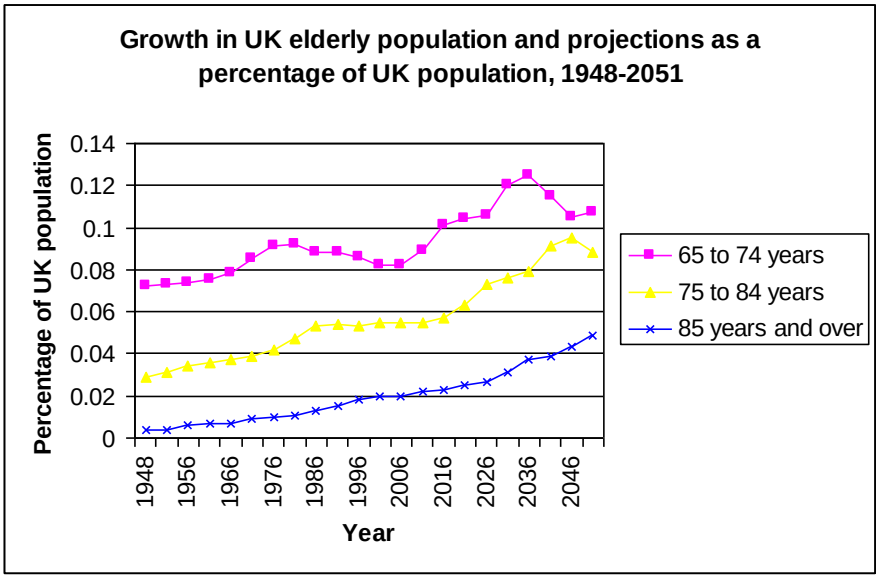


Figure 1.1 Growth in UK elderly population and projections as a proportion of the UK population, 1948–2051 [1]

1.2 Nutrition and hydration in older people

Nutrition and hydration play important roles in maintaining the health and independence of older people [2]. It has become clear that given the rising population of older people, it is just as important to ensure they remain in good health, as well as treating those who become nutritionally compromised. Due to increasing age, worsening health conditions and levels of dependency older people receiving residential or nursing care may be particularly vulnerable to nutritional inadequacies.

There is much debate as to the definition of an adequate nutritional status and also definitions of malnutrition. According to country and research groups, the definitions used to identify malnutrition vary. In the UK, an accepted definition of malnutrition is:

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

For the purpose of this review, the definition of malnutrition will be restricted to those with deficiencies or imbalances, rather than excess intake of nutrients.

1.2.1 Malnutrition risk for older people

Malnutrition is common amongst older people. A national survey of malnutrition risk in the UK has reported that approximately 1.3 million people aged over 65 years are at risk of malnutrition, according to the 'Malnutrition Universal Screening Tool' criteria [4]. In the UK, the vast majority of malnourished individuals reside in the community (93%), with only 2% in hospitals and 5% in care homes [4]. This represents approximately 13% of the population aged over 65 years, who are malnourished or at risk of malnutrition.

Similar findings were reported by a national survey of malnutrition in the Netherlands, with greater than 20% of older people being at risk of malnutrition [5]. In this survey, as with the UK survey, malnutrition risk varied according to setting with the majority of malnutrition being found in the community, affecting many frail older people.

1.3 Causes of malnutrition in the elderly

It is well documented that older people are at greater risk of malnutrition, and there are a range of factors that contribute towards malnutrition risk in this population. National nutrition surveys have shown that older people are at higher risk of malnutrition [6], and the increasing burden of chronic disease among this group may play an important role in the development of malnutrition.

In the UK, an older person may be classified as being at risk of malnutrition if they have a body mass index (BMI) less than 20kg/m^2, with or without the presence of greater than 5% weight loss in the previous three to six months, or the presence of an acute disease. Classification of malnutrition by nutrition screening tools is discussed in more detail in section 1.6. There are a range of factors affecting malnutrition risk that need to be addressed in order to prevent health problems associated with having a low BMI or recent unintentional weight loss within this population of frail older people.

Malnutrition is a multifactorial condition that occurs as a result of reduced food intake, increased nutritional requirements due to disease processes or increased losses. It is possible that a combination of processes affecting malnutrition risk can occur simultaneously, and the development of malnutrition is affected by the range of physiological, psychological and social changes that occur with aging. Physiological changes include a reduction in basal metabolic rate with increasing age, changes in gastric signalling pathways, reduced muscle function due to sarcopenia and the development of chronic disease [7]. This may then result in a reduction of food intake and weight loss, which can lead to a range of clinical and economic consequences. The

effects of conditions within these categories are not necessarily discrete and changes that occur due to one type of health condition could impact on another. This may eventually result in a reduction in food intake and body weight. Malnutrition in this age group has also been described as ‘silent malnutrition’, as many older people may appear to have BMI within normally accepted boundaries but are in fact gradually losing weight unintentionally.

Weight loss in older people tends to occur due to a reduction in total food intake, with or without the presence of an acute or chronic disease, or change in social situation. A reduction in food intake alone results in an increased likelihood of an individual not meeting their nutritional requirements. Over time, this leads to depletion of nutrient stores, as demands for nutrients continue in order to maintain essential physiological processes. Relatively simple deficiencies in nutritional intake can quickly escalate into more complex situations where an individuals’ health is affected. Catabolic processes due to the presence of disease, can in turn result in further increased energy needs. Health complications may then occur, for example, the presence of infections can lead to confusion in older people, and also affect their balance. This can lead to a person forgetting whether they have eaten a meal, resulting in a reduction in dietary intake. It could also lead to problems with their balance which can lead to falls, which in an older person with a lower bone density, could result in fractures.

In addition to deficiencies in nutrient intake, the presence of chronic conditions can affect nutritional status. With advancing chronic disease, conditions such as respiratory disorders, gastrointestinal disorders, endocrine disorders, neurological disorders and mental illnesses are all known to detrimentally affect older peoples’ nutritional status as their disease progresses and they become more dependent [8]. Physical disability, including arthritis and poor mobility are also thought to be risk factors for malnutrition as it can affect a person’s ability to access food and cook and feed themselves without assistance. Malnutrition is associated with conditions such as anaemia, pressure ulcers, sarcopenia, bone loss, hip fractures, reduced immune function, infections, cognitive impairment, functional decline and poor quality of life [7].

Body composition changes throughout age [9]. It is thought that fat mass continues to increase up to the age of approximately 75 years, after which it either remains stable or decreases. In comparison, fat free mass decreases from a much earlier age, approximately 40 years onwards [9]. The reduction in fat free mass occurs from a reduction in skeletal muscle and also bone mineral density in women. Changes in muscle mass can result in reduced function, strength and mobility. Studies have shown that in healthy individuals, a loss of 10% lean body mass results in reduced level of immunity, and increased risk of mortality [9]. It is therefore likely that a malnourished individual

would experience greater reductions in immunity, and greater risk of mortality. Sarcopenia, the loss of muscle in older people, is also known to occur in malnourished individuals. This can result in reductions in mobility and functional measures as muscle mass decreases [10]. It is thought that hormonal and cytokine activity may also play a role in development of sarcopenia [10]. Reductions in strength can have implications on an individual's mobility and ability to perform daily activities, including the preparation of meals. This may result in reduced food intake and further loss of lean tissue. Research in this area has also shown that individuals that have lost weight also find it more difficult to gain muscle mass after prolonged periods of reduced intake or illness, with any increases in body mass favouring deposition of fat rather than lean tissue.

Appetite in older people is known to vary, and there are physiological changes that occur in older people that affect their appetite. Changes in gastric signalling pathways are thought to occur with aging, resulting in anorexia and early satiation. With increasing age, it is thought that there is a reduction in the production of nitric oxide. This results in a reduction in the adaptive relaxation of the fundus of the stomach, resulting in early satiation due to more rapid antral filling. It is also thought that older people may experience reduced levels of hunger due to higher levels of cholecystokinin, a gastric peptide that induces a feeling of satiation [11]. An individual's appetite can be affected by the presence of disease.

With age, there may also be a reduction in a person's ability to taste and smell their food [9]. This is common in older people, and it is thought to be made worse by the presence of disease and drugs. The loss of these senses can reduce pleasure in eating and potentially affect food choice.

Polypharmacy; the prescription of multiple drugs to treat diseases and their side effects can put older people at higher risk of nutritional deficiencies. Drug-nutrient interactions can also occur, as well as the drugs causing gastrointestinal side effects, such as loss of appetite and nausea, or increasing an individual's metabolism [8].

Psychological factors such as confusion, dementia, depression, bereavement and anxiety can all affect malnutrition risk [9]. These conditions can cause a change in eating patterns and food preferences, resulting in a reduction in food intake, leading to a higher risk of malnutrition.

Dementia is becoming increasingly prevalent amongst older people. It affects two thirds of older people residing in care homes [12] and can have a dramatic impact on a person's nutritional status as the disease progresses. Taste changes, and alterations in food

preferences are common features of dementia. In advanced stages of dementia, people may forget how to use cutlery, and favour using their hands to feed themselves. If this occurs, using small frequent, bite size meals can help to ensure people receive an adequate diet. However, dementia can also be associated with behaviour changes, including aggressive, challenging behaviour, which can make providing people with assistance with their meals more difficult. People with dementia may also forget to eat during the day, and this omission of meals can lead to weight loss.

Anxiety, depression and bereavement can have significant effects on an individual's nutritional status. It can lead to a reduced appetite, avoidance of mealtimes and social activities associated with meals, thus resulting in a reduced nutritional intake. If this extends over a period of weeks or months, this can lead to weight loss and increased susceptibility to health problems.

Changes to peoples living environment may also affect appetite, potentially resulting in a reduced food intake and subsequent weight loss. Mowe & Bohmer, 2002 compared the appetite of older people admitted to hospital with those at home. They found that 43% of those in the hospital group reported having a reduced appetite, compared with 15% in the home living group [13]. Of those with a reduced appetite, 71% were undernourished [13].

In addition to appetite, willingness to eat can also affect nutritional intake. The association between willingness of older people residing in a care home to eat and appetite has been explored by a small scale qualitative study [14]. Their willingness was found to be associated with circumstances affecting their appetite. In this study older people reported that they found it more difficult to adjust to new surroundings, and therefore felt a loss when moving to a new environment. The feeling of loss impacted on their appetite. Those subjects with a large social network had more adequate diets than isolated individuals. Appetite was found to increase when the eating environment was more pleasant [14].

All of the above health and social conditions associated with malnutrition can impact on an individual's quality of life and wellbeing [15]. It is therefore important when assessing a malnourished individual that their quality of life is considered, in addition to other measures of health.

1.4 Consequences of malnutrition

With malnutrition being a common problem amongst older people in the UK and Europe [5, 16], it is important to consider the consequences of the condition and how they are being addressed across the nation, with emphasis on the identification and treatment of malnutrition among older people.

It is known that the consequences of malnutrition can include; increased number of GP visits, increased number of hospital admissions, increased length of stay in hospital and an increased risk of mortality [17]. These consequences can result in people becoming more dependent and result in a financial burden on the services provided by the Department of Health and social services. It has been estimated that the cost of treating the consequences of malnutrition currently stands at over £13 billion per year [16], with approximately 50% of this being spent on those aged over 65 years, including 40% being spent on older people residing in care homes [16].

Given that malnutrition can result in such a range of health and economic consequences, it is important to consider how nutritional care pathways for older people can be successfully implemented in hospitals and the community. In order to reduce the prevalence of malnutrition amongst this age group consideration needs to be given to addressing the care providers' infrastructure for nutritional screening and the implementation of evidence based nutritional interventions.

1.5 Policies addressing malnutrition in the UK

Given the prevalence of malnutrition in the community, in addition to the range of causes and consequences of malnutrition, it has become evident that a clear strategy for the identification and treatment of malnutrition, across care services is required. This has led to the publication of a number of policies and papers that have highlighted the need for improved nutrition screening and appropriate treatment in both health and social care settings [2, 18, 19].

The need for identification and treatment of malnutrition in the UK was highlighted by The Kings Fund report,1992 [18]. This was a key document highlighting that malnutrition was under-reported across care settings. It reported that health professionals were not able to recognise malnutrition as they had not been trained to identify it [18]. The report highlighted that malnutrition is multifactorial, and its presentation is not limited to gastrointestinal disorders, but can be linked to illnesses of any body system [18].

Since the publication of the King's Fund Report the Department of Health, the National Institute for Health and Clinical Excellence (NICE) and the Social Care Institute of Excellence (SCIE) have produced guidelines to improve nutritional assessment and treatment across care settings. Guidelines within 'Nutrition Support in Adults' [2] and 'Dignity in Care' [20] have attempted to change practice in both the hospital and care homes, by improving training for healthcare professionals and introducing the use of validated screening tools such as the 'Malnutrition Universal Screening Tool' ('MUST') [2, 20]. The NICE guidelines for Nutrition Support in Adults stated in Clinical Guideline 32 that all healthcare professionals should be appropriately trained to carry out screening for malnutrition [2].

In addition to these papers, guidance on nutritional screening and the appropriate management of malnutrition aimed specifically at care homes has been published, including The State of Social Care in England 2006-2007 [19], National Minimum Standards for Care Homes [21] and the Nutrition Action Plan [22]. The papers all highlighted the need for training of staff, raising awareness of good nutrition, appropriate screening and the provision of nutritious foods and drinks.

More recently, the Nutrition Action Plan, launched in October 2007, by the Department of Health agreed on five key priorities. These were to raise awareness of nutrition and good health, encourage nutritional screening, encourage provision of and access to nutrition training, and to clarify standards and strengthen inspection and regulation [22].

In order for these policies to be effective, support is required from staff at all levels, from Government to staff working in hospitals and care homes.

1.6 Identification of malnutrition; Nutrition Screening Tools

National policies on malnutrition have recommended that a nutrition screening tool should be used to identify malnutrition. The guidelines published by NICE and SCIE have recommended that the nutrition screening tool employed by healthcare workers should be suitable for use across care settings[2, 18]. However, there has been much debate as to the suitability of nutrition screening tools in the identification of malnutrition, and a variety of tools have been produced, incorporating a range of nutritional parameters. Ideally, for a nutrition screening tool to be used successfully by a range of Healthcare Professionals across care settings it needs to be valid, simple, reproducible and easy to use.

Before discussing the types of screening tools available in health and social care, it is important to differentiate between nutritional screening and nutritional assessment, which are two terms that are commonly confused. Nutritional screening refers to the initial rapid, general evaluation carried out by health professionals to detect risk of malnutrition and subsequently implement a plan of action [3]. This process is frequently confused with nutritional assessment, which refers to a more detailed process in which a more in depth, specific evaluation is made of nutritional status, so that a specific diet plan can be implemented [3]. The misuse of the two terms can result in confusion amongst healthcare staff as to whether they are carrying out screening or assessment.

Among the items included in malnutrition screening tools are body weight, body composition, anthropometry (e.g. skinfolds), changes in weight or composition, biochemical markers of nutritional status and measures of nutritional intake. There are over 50 published nutrition screening tools, varying in length and time taken to complete them. Commonly used nutrition screening tools include the 'Malnutrition Universal Screening Tool' ('MUST') [23] , the Mini Nutritional Assessment (MNA) [24] and the Nutrition Risk Score (NRS) [25].

Given the vast array of tools available, the prevalence of malnutrition can differ greatly according to the criteria used, from 10-100% [3]. The tools have been produced by a variety of organisations and focus on different factors that could affect nutritional status. Due to the variation in length and complexity of the tools, the possibility for all members of a healthcare team to use a tool could be limited. As changes in nutritional status occur over the lifespan, tools have been developed, both for whole populations and for subgroups.

Tools that are suitable for a whole population have the advantage of simplicity in that the same tool can be used for a range of settings, age groups and health conditions. However, other screening tools specific to certain care settings, age groups and health conditions may have advantages. Tools specific to people with cancer and older people have been developed in addition to broader tools, and according to location, some centres may also devise their own tool to suit their local setting. 'MUST' is designed for use in both hospital and community settings [23] and is frequently used in the UK, whereas the MNA is designed for use solely with the elderly [24] and is often used throughout Europe. Tools designed for use in one setting have limitations in their use as they cannot be transferred to a different setting, introducing limitations in their use to follow a patient's journey between care settings.

It is important to note that if sub-groups of a population are to be compared, it would be an advantage for the tool to be generalisable to the population as a whole, as well as the sub groups. Some of the variation in the classification of malnutrition could be explained by the measurement of different population groups. People of different ethnic origin may exhibit differences in body composition and disease risk. Classification may also vary according to the definitions of malnutrition and risk of malnutrition.

A number of nutrition screening tools do not include BMI, others do not include weight loss and many include disease related factors which are not directly related to nutrition. It is possible to classify an individual as malnourished without any nutritional component. This can make screening tool selection a difficult task.

A range of BMI classifications are currently used globally to define malnutrition, or risk of malnutrition. The 'MUST' tool indicates malnutrition risk if an individual's BMI is less than 20kg/m^2 [23], however the MNA uses a BMI of less than 23kg/m^2 [24]. Other tools such as the SNAQ (Simple Nutrition Assessment Questionnaire) do not include measurement of BMI, instead focusing on appetite and eating patterns [26]. This tool can be used to predict weight loss in adults residing in the community, including nursing homes.

1.6.1 UK guidance on the use of nutrition screening tools

Having reviewed the use of different nutrition screening tools, the NICE Guidelines for Nutrition Support in Adults in the UK have suggested that nutrition screening tools should be used on admission to hospital and care homes [2]. Screening should be repeated at appropriate intervals according to the care setting. The guidelines suggested that a screening tool should measure body mass index, percentage unintentional weight loss and the time period over which nutritional intake has been reduced [2]. It also suggested that a tool should be quick and simple to use, can be used on the whole population, evidence based and suitable for use across disciplines. 'MUST' was the only nutrition screening tool that NICE suggested could be used to do this [2].

Following guidance by NICE, the use of nutrition screening tools has been implemented across a range of settings, including hospitals, sheltered housing and care homes, and the prevalence of malnutrition has varied according to setting. In the UK the commonest nutrition screening tool used in hospitals and care homes is 'MUST'. The British Association for Parenteral and Enteral Nutrition (BAPEN) has carried out three national nutrition surveys in hospitals, care homes and mental health units since 2007 [4, 27, 28]. The 2010 survey reported that 68.1% of participating care homes were using 'MUST'. The collation of information on malnutrition risk across the UK has allowed comparisons regarding the prevalence of malnutrition risk across care settings to be made, with the

surveys highlighting that the prevalence of malnutrition risk is higher in care homes (30-42%) than hospitals (28-34%) and mental health units (19%) [4, 27, 28]. The survey in care homes did have some limitations, in that it only included residents admitted to care homes in the six months prior to the survey, therefore potentially excluding many older, frail residents from the surveys. The data was collected by multiple observers, based in the individual care homes, and analysed according to the type of care home rather than the type of care individual residents received.

1.7 Dietary intake and requirements among older people

Having identified malnutrition risk, it is important for a further, more detailed assessment to occur. Guidance on the assessment of nutritional status recommends that assessment should include food intake, nutritional requirements and barriers to eating and drinking [29].

In the UK, older peoples' requirements for carbohydrate, protein, fat and dietary fibre are the same as younger adults. There is some debate as to whether the requirements for protein in older people should be lower due to their decreasing lean body mass, or higher due to chronic disease processes. Older peoples' requirements for micronutrients are also the same as younger adults in the UK, with the exception of Vitamin D. It is assumed that older people have a lower exposure to sunlight and are less efficient at producing vitamin D. Therefore, the reference nutrient intake (RNI) for this age group is 10mg/day. However it is well documented that older people may require supplementation in order achieve such levels.

Dehydration is common amongst older people, especially amongst the oldest old and those living in care homes [30]. The World Health Organisation has sited many reasons for dehydration in older people. These include reduced fluid intake and increased fluid loss. Reduced fluid intake can be due to people feeling less thirsty, or the presence of conditions such as dementia, swallowing problems, laxative abuse and incontinence. Increased fluid losses within this age group can occur due to older adults being less able than younger adults to concentrate urine, resulting in higher minimum urine outputs.

It is known that in care homes the food provided and consumed can affect malnutrition risk and the quality of life for older people [21]. With the differing nutritional requirements in older people due to the physiological and psychological changes that occur with aging, it is important to ensure that food provided in care homes meet their nutritional needs and preferences. The Department of Health guidelines for the nutritional

requirements of older people recommends a healthy, balanced diet, containing an appropriate mix of the food groups [31]. The National Minimum Standards for Care Homes [21] addressed the standard of food provided by care homes in Standard 15, stating that;

'The registered person ensures that service users receive a varied, appealing, wholesome and nutritious diet, which is suited to individual assessed and recorded requirements, and that meals are taken in a congenial setting and at flexible times.'

However, despite this guidance, nutritional needs for older people are not always being met. The National Diet and Nutrition Survey (NDNS) for people aged over 65 years captured information related to the food and nutrient intake, dental and oral health of older people living both in their own homes and care homes [31]. The survey found that people living in care homes had significantly lower than average intakes of energy, protein, carbohydrates, fibre and some vitamins and minerals [31]. As a group, people over 65 years tended to have higher intakes of saturated fat, non-milk extrinsic sugars and too little fibre. Vitamin D and folate levels were frequently lower in this age group, particularly in the care home population and people aged over 85 years. The survey also found that individuals living in care homes were likely to frequently consume sugar, preserves, buns, cakes and cereal based milk puddings [31]. In addition to the NDNS, an example of a care home not meeting nutritional standards was reported by a small scale study in a care home in Glasgow which assessed the nutritional content of meals provided to residents [32]. It found that the energy provision of meals was found to meet current dietary guidelines [32], however, the quantity of the meals consumed by the residents meant that energy intakes did not meet current estimated average requirement [33] by 24% for men and 22% for women [32]. They also found that micronutrient intakes were also below the recommended Dietary Reference Value (DRV), with the exception of iron and vitamin C [32].

A report by CSCI, published in 2006, found that approximately 88% of care homes met Standard 15 of the National Minimum Standards, however, approximately 2,000 care homes in England did not meet standard 15 [19]. The report highlighted the need for good nutrition and hydration to be provided at mealtimes, within a pleasant environment, in order to improve health and wellbeing of older people [19]. The large number of homes that did not meet standard 15 suggests that further work is necessary in order for homes to improve the quality and environment in which meals are provided.

1.8 Treatment of malnutrition

Following the identification of malnutrition risk with a nutrition screening tool, it has been recommended that appropriate pathways need to be put in place across care settings to monitor and treat patients identified as being at risk [2], however, local policies can vary considerably. Treatment of malnutrition commonly includes the use of nutritional interventions such as dietary advice and oral nutrition supplements, although it is unclear which may offer most benefit to malnourished individuals. This aim of using such interventions is to improve an individual's nutritional status by increasing their dietary intake of a range of nutrients. A range of outcomes may be considered in studies related to nutrition support, including quality of life, mortality, morbidity, weight change, dietary intake and healthcare use. Nutrition support strategies in the community will be discussed in this chapter, with further consideration given to specific nutritional interventions in care homes in chapter three, as a formal review of the literature has never been conducted.

1.8.1 Dietary Advice

Dietary advice is a common first line treatment of malnutrition, routinely provided by dietitians [29]. This involves people being advised to choose energy dense foods and nourishing drinks. Where possible, people are advised to fortify their foods, commonly with dairy products. The evidence base to support dietary advice is extremely limited. Although it is supported as being a first line treatment by the British Dietetic Association (BDA), the literature supporting this treatment is scarce, relying more often upon clinical judgement.

A systematic review of the benefits of dietary advice on nutritional intake in adults with disease related malnutrition assessed whether dietary advice improved mortality, morbidity, weight and energy intake [34]. A total of 24 trials were included in the review, however, there was insufficient evidence to support the use of dietary advice in the management of malnutrition. There were no significant improvements in any of the outcome measures of study participants (n=2135) that had received dietary advice.

In a further systematic review by Baldwin et al., 2007, only seven studies were identified that compared dietary advice with no advice in both hospital and community [35]. The studies identified were of small size and did not result in significant differences between groups in terms of mortality, hospital admission and weight change with three months intervention. Only two studies within the systematic review could detect significant changes, with one study finding a significant weight change at six months[36] and the

other identified a change in hand grip strength[37]. Only four studies identified within the review [38-41] found significant increases in energy intake and body weight in the groups that received oral nutritional supplements for three months compared with groups that received dietary advice.

1.8.2 Oral Nutrition Supplements

Oral nutritional supplements (ONS) are 'Dietary Foods for Special Medical Purposes' (FSMP), classified under the EC Directive 1999/21/EC[42]. They are defined as foods for particular nutritional uses that are specially processed or formulated and intended for the dietary management of patients. Disease-related malnutrition is one of the main prescribable indications for oral nutritional supplements [43]. They contain a range of macronutrients (energy, protein, carbohydrate and fat) and micronutrients (vitamins, minerals and trace elements). They can be nutritionally complete, incomplete or modular (containing one or two energy sources).

Nutritionally complete ONS can be advantageous in the treatment of malnutrition, as malnourished individuals tend to have a reduced intake of both macro and micronutrients. They therefore require supplementation with a range of nutrients in order to improve their nutritional status, increase stores, prevent infections and in the presence of wounds, aid healing.

ONS are commonly prescribed by general practitioners and healthcare professionals across care settings, expenditure on which was £99million in England in 2007 [44]. This represented 1.2% of the total prescribing expenditure in England. The use of ONS as a treatment for disease related malnutrition has been included in guidelines produced by many bodies, both in the UK and Europe. These include the National Institute for Health and Clinical Excellence (NICE) [2], British Association for Parenteral and Enteral Nutrition (BAPEN) [45] and European Society for Clinical Nutrition and Metabolism (ESPEN) [46].

A recent review of systematic reviews assessed the use of ONS across patient groups has clearly shown that there is substantial evidence to support the use of ONS in a wide range of people at risk of malnutrition [47]. The review suggested that there can be a reduction in mortality and complications when ONS usage is compared with routine care across patient groups [47]. This difference was particularly marked in acute illness and older patients. Similar to studies investigating the use of dietary advice, most studies were conducted in the hospital setting. The paper also suggested that ONS can reduce the length of hospital stay and reduce complications [47]. It has been shown that ONS do not suppress appetite and can be an effective treatment in those with a poor appetite [48].

A further review of protein and energy supplementation in older people supported the review by Stratton and Elia, 2007 suggesting that the use of ONS can reduce the risk of mortality, but limits this effect to those prescribed ONS in hospital, due to the small size of studies that have been published in the community setting [49]. The paper suggested that ONS may reduce mortality in those who are undernourished at baseline, are 75 years of age or older and are offered high energy ONS. A total of 15 studies within the meta-analysis reported using a variety of quality of life tools, however only two studies reported statistically significant improvements between groups from baseline to the end of follow up [49]. Prescription of ONS was found to provide a small, but consistent increase in body weight and mid arm muscle circumference.

The prescription of ONS to elderly patients for eight weeks post discharge from hospital was investigated by Edington et al., 2004 with patients being reviewed over a 24 week period. A total of 100 people participated, with 51 receiving ONS and 49 in the control group. The study measured height, weight, BMI, mid-arm circumference, triceps skinfold thickness, handgrip, quality of life using the EuroQol questionnaire (EQ-5D), dietary intake, healthcare visits and hospital admissions. ONS intakes of 600-1000kcal/day were prescribed, with the mean ONS intake being 342 ± 193kcal, 15.8 ± 8.8g protein during the 8 week intervention. Although ONS were prescribed for eight weeks, participants were encouraged to continue with ONS after this period if there was a clinical need, resulting in a mean duration of supplementation of 99.4 days (range 6-169). In 24 weeks, there were significant increases in weight, BMI and triceps skinfold thickness in the ONS group, however this difference was not significant when compared with the control group that had only received routine care [50]. No significant changes were seen in mid arm circumference in either group, or between groups. Handgrip increased significantly within ONS group during the eight week intervention period, however this was not significant between groups, though there was a trend towards significance ($p=0.055$). This increase was also not sustained to 24 weeks. The EuroQol questionnaire and visual analogue scale were completed throughout the study, with there being significantly less problems within the mobility domain when comparing the ONS group with the control group at 24 weeks (ONS group; 32.4% no problems, 67.6% some problems, Control group; 7.7% no problems, 92.3% some problems ($p=0.022$)). There were no significant differences between groups in terms of healthcare use or hospital admissions; however hospital admissions did decrease significantly in both groups during the 24 week study period compared with the 24 weeks prior to the study.

1.9 Summary

The population of older people is set to rise in the UK in coming years, posing challenges to health and social care services. Older people have complex nutritional needs due to physiological, psychological and social changes that occur with increasing age. Those with the greatest needs may take the decision to move to a care home in order to ensure their health and social care needs are met, including the provision of adequate nutritional care.

Information on the prevalence and treatment of malnutrition in care homes is limited. National surveys have reported that malnutrition is a common condition in older people, particularly for those residing in residential and nursing care facilities, however the national surveys only took into account those residents admitted to the care homes in the six months prior to the surveys.

The National Institute for Health and Clinical Excellence and the Social Care Institute for Excellence have recommended that nutritional screening and appropriate nutrition interventions be implemented for those at risk of malnutrition. However the extent to which this guidance is followed in care homes is unclear. Given that older people are at greater risk of malnutrition and the magnitude of the health and economic costs of treating malnutrition there is a need to explore this area further. The routine nutritional care practice in care homes needs to be evaluated in order to ensure adequate infrastructure is in place to identify and treat malnutrition. This includes the use of nutrition screening tools and investigation of parameters affecting malnutrition prevalence in this setting. This will help to ensure that in settings such as care homes, malnutrition is identified amongst this group of older people, with the results of malnutrition screening being linked to individualised nutritional care plans.

Although national guidance recommends that nutritional interventions should be implemented for those at risk of malnutrition, currently the evidence to support the use of nutritional interventions such as dietary advice, food fortification and oral nutritional supplements in the community is limited. Information on the effectiveness of nutritional interventions in care homes is lacking and presently no formal review of the evidence to support the use of nutritional interventions in residential and nursing care facilities has taken place. These issues are addressed in subsequent sections of this thesis. The next chapter assesses the routine nutritional care and the use of nutritional interventions in care homes. Before continuing to the next chapter, the aims of this thesis are presented here.

1.10 Thesis Aims

The aim of this thesis was to establish the prevalence of malnutrition risk in care homes and to examine the effect of oral nutritional interventions on clinical, functional and healthcare outcomes.

In order to address the main aim of the thesis, the following specific aims were considered:

1. To assess the routine nutritional care provided by care homes in Hampshire, and the prevalence of malnutrition risk in these care homes
2. To conduct a systematic review of the literature for the use of oral nutritional interventions in care homes
3. To conduct a randomised controlled trial of oral nutritional supplements versus dietary advice in malnourished care home residents, to assess their effects on quality of life, clinical, functional and healthcare use outcomes
4. To conduct a cost-utility analysis of the cost-effectiveness of the randomized controlled trial of oral nutritional supplements versus dietary advice.

Chapter Two: Nutritional screening and the use of nutritional interventions in care homes

2.1 Introduction

Malnutrition is frequently under-detected and under-treated across care settings [3]. Much is known regarding the prevalence of malnutrition in UK hospitals, however, very few surveys of malnutrition have been conducted in UK care homes despite reports suggesting that the majority of malnutrition exists in the community [4]. With approximately 460,000 people residing in care homes, there is a great need to assess malnutrition risk and the use of nutritional interventions amongst this population of older people.

Surveys of care home residents' malnutrition risk have taken place in the UK, and other countries. Such surveys have taken place using a variety of nutrition screening tools, from 'MUST' to the MNA or SGA. The prevalence of malnutrition amongst this frail elderly population has ranged from 10 to 100% [3]. However, some caution must be applied when interpreting the prevalence of malnutrition in countries beyond the UK, as the structure of care home systems varies between countries. In the UK, care homes include residential and nursing homes of varying case mix and size, from less than ten residents up to over 100 residents. In other countries, such as Sweden and the USA care homes may refer to large nursing institutions with greater than 100 residents and multiple units within each centre.

Three recent UK surveys have suggested that the prevalence of malnutrition in UK care homes ranges from 30% to 42% [27, 28, 51], however there are limitations with these surveys. The first survey, completed in Peterborough, screened 703 care home residents (54% residential, 46% nursing) using 'MUST'. The survey reported that 32% of residents were at risk of malnutrition, however only preliminary data from this survey has been published [51]. The further two surveys, conducted by BAPEN in 2007 and 2008 included residents in residential and nursing homes [27, 28]. In these surveys, residents were screened by the staff in care homes using the 'MUST'. The surveys only included residents admitted in the six months prior to the survey, and residents already receiving nutritional interventions, such as oral nutritional supplements, were excluded from the surveys. They also did not utilise a representative sample of care homes due to self-selection of participating homes. This therefore suggests that there is a need to explore the

prevalence of malnutrition within UK care homes, without excluding those already receiving ONS, and including both residential and nursing care facilities.

When assessing the prevalence of malnutrition risk in care homes, it would also be important to consider the factors that may affect residents' malnutrition risk. The surveys conducted by BAPEN indicated trends for malnutrition risk to vary according to age, gender, diagnosis and type of care, however the surveys did not indicate whether the locality of the care home affected malnutrition risk [27, 28]. Given the association between malnutrition and deprivation that has been reported in hospitals [52] and outpatients with chronic obstructive pulmonary disease [53], it would be useful for a survey of malnutrition in care homes to explore this association.

It is also important to consider the parameters that are being measured and the accuracy of the tools used when assessing the provision of nutritional care in care homes. If measures such as body weight are included in nutrition screening tools, it is important to be aware of the precision of these measures. Little is known regarding the types of weighing scales used in care homes in the UK. Preliminary data from the survey in Peterborough in 2007 reported that 74% of the 19 care homes surveyed were using sitting and/or hoist scales, and 21% used standing scales only [51]. Since the Peterborough survey, the Department of Health issued a directive for weighing scales in 2008, stating that only medical grade three or four scales should be used in hospitals and the community [54]. It is clear that the precision of the weighing scales would determine the accuracy of the measurement of body mass index (BMI), and subsequently the assignment of a BMI risk score, if a tool such as 'MUST' were used.

Having assessed resident's weight and completed a nutrition screening tool, national guidance recommends that those at high risk of malnutrition should receive nutritional interventions, such as oral nutritional supplements (ONS), and where possible, should be referred to a dietitian for dietary counselling [2]. As discussed in the previous chapter, there is a range of evidence to support the use of ONS, particularly in the acute setting, however there is a need to review the literature regarding the use of nutritional interventions in care homes (Chapter 3), as currently the evidence to support their use in care homes is more limited. Prescription of ONS is thought to vary according to local prescribing policy, and some surveys conducted by prescribing dietitians have suggested that prescription of ONS may, at times, be inappropriate[55]. In addition to the prescription of ONS varying according to locality, it is thought that the provision of dietetic services to care homes may vary according to locality, due to the relatively small number of community dietitians in the UK. However, such information is generally lacking. It needs to be established so that appropriate changes in the organisational infrastructure of nutrition support services can be implemented.

2.2 Aims

The overall aim of the study presented in this chapter was two-fold:

A) To determine if appropriate nutritional screening procedures and treatments were used in conjunction with appropriate operational infrastructure.
B) To determine the prevalence of malnutrition in Hampshire care homes.

The specific aims of this survey were;

1. To determine the nutritional screening practice within residential and nursing care, including routine weight measurements of residents and use of nutrition screening tools.
2. To establish the use of oral nutrition supplements and access to dietetic services in Hampshire, and whether the use of oral nutritional supplements was linked to malnutrition risk and the use of nutrition screening tools.
3. To establish the prevalence of malnutrition in the care home residents and explore relationships according to age, gender, health problems, type of care and duration of stay (less than and more than six months), deprivation score of the locality of the care homes.
4. To compare the prevalence of malnutrition risk in Hampshire care home residents with the results of the national nutrition screening surveys (BAPEN Nutrition Screening Weeks 2007 & 2008).

2.3 Methods

2.3.1 Selection of care homes

Care homes were selected using a convenience sample, using details from a database of care homes in Hampshire (n=633). The database was produced using information from the Hampshire County Council website and care home search websites, including the CSCI website, which preceded the Care Quality Commission. Care homes with less than ten beds, those on the peripheries of the county, those with residents with advanced dementia, learning disabilities, drug dependence and those solely for people aged less than 50 years were not included. The study took place from August 2007 to December 2009.

From the database of eligible care homes (n=359), 255 care homes (71%) were contacted by telephone, letter and email, and invited to participate in the survey. Meetings to assess the feasibility of conducting the survey were carried out with 87 care homes, and 62 care homes participated in the survey assessing routine nutritional screening practice (18% of eligible care homes) (32 Residential, 22 nursing, 8 dual registered), and 53 care homes (15% of eligible care homes) participated in the survey assessing residents' malnutrition risk.

Reasons for non-participation are shown in Figure 2.1. Common reasons for non-participation included non-response to initial contact (20%), and being owned by Hampshire County Council (16%). Care homes owned by Hampshire County Council were excluded, due to the local council not wishing to participate in the survey, as they already had their own processes for nutrition support in place in their care homes.

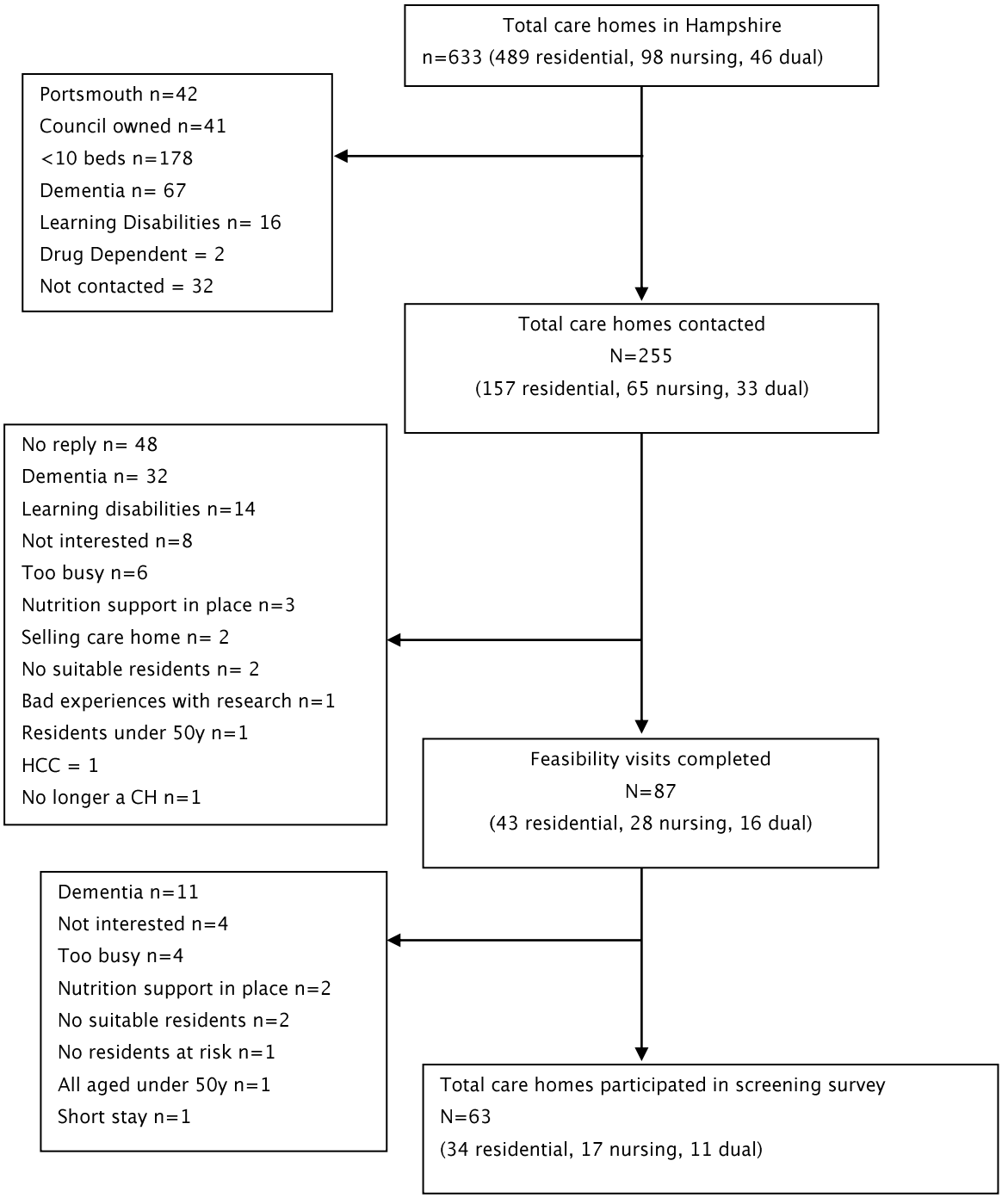


Figure 2.1Number of participating care homes, and reasons for non participation

2.3.2 Part A – Determining the operational infrastructure

The first survey assessing routine nutrition screening practice in the care homes was completed with care home managers or senior care staff. The pre-set questionnaire asked questions regarding the routine weighing of their residents, including the type of scales they used, how often they weighed them, whether they used a nutrition screening tool and which tool they used (Appendix Two).

2.3.3 Part B – Determining the prevalence of malnutrition and use of nutritional interventions

The second survey assessing the prevalence of malnutrition risk was completed for all residents (n=1322) (See Appendix Three). The questionnaire also included sections covering residents age, sex, date and source of admission, type of care, diagnoses and 'MUST'. Diagnoses were classified according to the body systems they affected. In addition to conditions affecting particular body systems, the presence of cancer, dementia, confusion, chronic obstructive pulmonary disease (COPD) and diabetes were also recorded. The 'MUST' was completed as described in Section 2.3.4. The questionnaire was completed by a registered dietitian and a trained assistant. The characteristics of the care home residents are shown in Table 2.6 and 2.7. The postcodes of the care homes were used to assess the deprivation of the localities of the care homes (section 2.3.7).

Following the survey of malnutrition risk for individual residents the dietitian and trained assistant asked care home managers and senior care staff to identify those residents that were prescribed oral nutritional supplements at the time of the survey, and those that were under the care of a dietitian for nutrition support.

2.3.4 Screening for malnutrition using the 'Malnutrition Universal Screening Tool' ('MUST')

The 'MUST' is a validated nutrition screening tool that is validated for use across care settings [23] (Appendix Three). NICE guidance for Nutrition Support for Adults has recommended its use as it is simple to use and includes a score for body mass index (BMI), percentage weight loss and the presence of any acute disease [2]. From these three sections an overall score can be calculated.

2.3.4.1 'MUST'; Step 1

The first step of the tool is to calculate BMI (kg/m^2). This was calculated using a subject's weight in kilograms and height in metres.

$$\text{Body Mass Index (kg/m}^2\text{)} = \frac{\text{Weight (kg)}}{\text{Height}^2\ (\text{m}^2)}$$

Using their BMI, a score was recorded according to their BMI (Table 2.1). Ideally, actual weight (Section 2.3.5.1) and standing height (Section 2.3.6.1) were used in order to calculate BMI. However, this was not always possible. If the resident's current weight had not been recorded, recalled weight or estimation of weight was used. Due to the age of the residents being studied, they frequently had conditions such as kyphosis and arthritis. The presence of these conditions made standing height less accurate. In these instances, self-reported height was recorded, and converted from imperial measurements to metric where necessary. If residents could not recall their height, then ulna measurements (Section 2.3.6.2) were taken. Where BMI could not be calculated, mid upper arm circumference (MUAC) (Section 4.3.9.4.1) provided an indication of BMI. This was also used to confirm estimations of height and weight. If an individual's MUAC was less than 23.5cm then they were likely to have a BMI of less than 20kg/m^2.

Table 2.1 Scores for Step One of 'MUST', according to BMI category

BMI range (kg/m^2)	SCORE
<18.5	2
18.5-20	1
20-25	0
25-30	0
>30	0

2.3.4.2 'MUST'; Step 2

The second step of 'MUST' assessed recent unplanned weight loss over the last three to six months. It uses this time period as it is deemed a good indicator of recent weight loss and metabolic changes. It is calculated by

$$\text{Percentage weight loss (\%)} = \frac{\text{(usual weight (kg) - current weight (kg))}}{\text{usual weight (kg)}} \times 100$$

Table 2.2 shows the designated weight loss scores. If an individual had gained weight, or had lost weight intentionally, through methods such as a weight reducing diet they received a score of zero.

If a previous weight could not be obtained from care plan notes or from recall from the resident, questions regarding their weight history were asked. These included whether their clothes and jewellery felt looser than they used to, and the period over which this had occurred. They were also asked whether they had been intentionally trying to lose weight. If this unintentional weight loss had occurred within the last 3-6 months, then a score for weight loss was recorded.

Table 2.2 Scores for step two of 'MUST', according to categories of percentage unintentional weight loss

Percentage unintentional weight loss	Score
0-5	0
5-10	1
>10	2

2.3.4.3 'MUST'; Step 3

The third step addressed the presence of any acute disease. If an individual had been acutely ill and there was no nutritional intake for more than five days, a score was recorded (Table 2.3). Acute disease included critical illness, swallowing difficulties (e.g. after stroke), head injuries and any form of gastrointestinal surgery.

Table 2.3 Scores for step three of 'MUST', according to the presence of an acute disease effect

	SCORE
No nutritional intake for >5 days	2
All others	0

2.3.4.4 Calculation of 'MUST' score

This established the overall risk of malnutrition. The sum of steps one to three produced the final score. A score of zero indicated a low risk of malnutrition, one indicated a medium risk, and a score of two or greater indicated a high risk.

2.3.5 Measuring residents' weight

Standing weight was measured using University of Southampton scales (Hanson HCL 700). If the resident was unable to stand up safely, care home hoist or sitting scales were used, if available. If this was not possible, the most recent weight from the resident's care plan notes or resident's recalled weight was used.

If it was not possible to weigh a subject at a visit, the care home scales were checked against a set of calibrated University of Southampton scales, if the care home scales were available.

2.3.5.1 Protocol for measuring standing weight

When measuring standing weight, the resident was measured barefoot and wearing light clothing, where possible. The resident stood up as straight as possible and did not lean against anything. Weight was recorded in kg, to the nearest one decimal place. The type of scales used was recorded at each visit.

2.3.6 Measuring residents' height

Height was recorded at baseline in order to calculate BMI. Standing height was measured. If the resident could not stand up, resident's recalled height was recorded. If the resident could not recall their height, the forearm (ulna) length was measured and converted to height using a conversion table.

2.3.6.1 Protocol for measuring standing height

The resident was measured barefoot where possible. The stadiometer was placed against a wall to aid stability. The resident stood upright, feet flat, heels against the wall. The resident looked forward, with their head being horizontal in the Frankfort Plane. Height was recorded in metres, to the nearest centimetre.

2.3.6.2 Protocol for measuring forearm (ulna) length

If it was not possible to measure standing height, due to residents not being able to stand safely then ulna length was measured, as a surrogate measure of height.

To measure ulna length, the subject bent their arm, preferably the right arm, with their palm across their chest and fingers pointing to their opposite shoulder (Figure 2.2). Using a tape measure, the length of the forearm, between the olecranon and the styloid process was measured (Figure 2.2). The measurement was taken in cm, accurate to 0.5cm. A conversion table was then used to obtain the subjects height in metres (Appendix Three).

Figure 2.2 Measuring ulna length [23]

2.3.7 Deprivation

Deprivation scores were assessed using the Index of Multiple Deprivation (IMD) [56]. The IMD score is based upon seven components of deprivation; income, employment, health, education, housing, crime and living environment. The components included in the Index are thought to be independent indicators of deprivation. In order to combine the components into an IMD score, weightings were applied to each component (Table 2.4). Each of the seven domains contains a variety of indicators which measure the features of deprivation that are specific to the domain (Table 2.5).

Table 2.4 Weightings of the domains of the Index of Multiple Deprivation[56]

	Domain weight
Income deprivation	22.5 %
Employment deprivation	22.5%
Health deprivation and disability	13.5%
Education, skills and training deprivation	13.5%
Barriers to housing and services	9.3%
Crime	9.3%
Living Environment deprivation	9.3%

Using postcodes for the care homes, the IMD score and rank for the 'lower layer super output area' (LSOA) for each postcode was obtained from the Office of National Statistics website. The LSOA relates to a small area, of approximately 1000 to 1500 homes. There are 32,482 LSOA's in England. The most deprived LSOA is given the rank of one, and the least deprived LSOA is given a rank of 32,482. The ranks indicate how LSOA's compare with each other, and the score indicates the distance between each rank position.

Table 2.5 Indicators of deprivation within each of the seven domains of deprivation [56]

Domain	Indicators of Deprivation
Income	Adults and children in Income Support Households, Income-Based JSA Households or Pension Credit (Guarantee) Households Adults and children in those Working Tax Credit or Child Tax Credit Households (who are not eligible for IS, Income-Based JSA, Pension Credit or Working Tax Credit) where there are children in receipt of Child Tax Credit whose equivalised income (excluding housing benefits) is below 60 per cent of the median before housing costs National Asylum Support Service (NASS) supported asylum seekers in England in receipt of subsistence and/or accommodation
Employment	Recipients of Jobseekers Allowance (both contribution-based and income based), Incapacity Benefit, or Severe Disablement Allowance: (men aged 18-64 and women aged 18-59) Participants in the New Deal for the 18-24s and 25+ who are not in receipt of JSA Participants in the New Deal for Lone Parents
Health and Disability	Years of Potential Life Lost (YPLL) (2001 to 2005) Comparative Illness and Disability Ratio (CIDR) Measures of acute morbidity, derived from Hospital Episode Statistics The proportion of adults under 60 suffering from mood or anxiety disorders
Education, Skills and Training	**Sub Domain: Children/young people** Average test score of pupils at Key Stage 2 & 3 (2 year weighted average, 2004-2005) Best of 8 average capped points score at Key Stage 4 (inc. GCSEs and GNVQs) (2 year weighted average, 2004-2005) Proportion of young people not staying on in school or non-advanced education above the age of 16 Secondary school absence rate (2 year average 2004-2005) Proportion of those aged under 21 not entering higher education (5 year average, 2001-2005) **Sub Domain: Skills** Proportions of working age adults (aged 25-54) in the area with no or low Qualifications

Domain	Indicators of Deprivation
Barriers to Housing and Services	**Sub Domain: Wider Barriers** Household overcrowding LA level percentage of households for whom a decision on their application for assistance under the homeless provisions of housing legislation has been made, assigned to the constituent SOAs Difficulty of Access to owner-occupation **Sub Domain: Geographical Barriers** Road distance to a GP surgery, general stores or supermarket, a primary school, a Post Office or sub post office
Crime	Burglary (4 recorded crime offence types, April 2004-March 2005, Theft (5 recorded crime offence types, April 2004-March 2005) Criminal damage (10 recorded crime offence types, April 2004-March 2005 Violence (14 recorded crime offence types including Robbery, Police Force data for April 2004-March 2005
Living Environment	**Sub-Domain: The 'indoors' living environment** Social and private housing in poor condition (2003 – 2005) Houses without central heating **Sub-Domain: The 'outdoors' living environment** Air quality (2005) Road traffic accidents involving injury to pedestrians and cyclists (2003-2005)

2.4 Statistics

The Chi squared test was used to assess differences between groups (e.g. 'MUST' category, type of care). Logistic regression was used to examine binary outcomes, such as presence or absence of malnutrition, and to adjust the results for other continuous (e.g. age) and categorical (e.g. sex) variables. A p value of <0.05 (two tailed) was considered to be significant. Analysis was undertaken using SPSS version 18.0 (Chicago, USA). For the analysis of the BAPEN nutrition week surveys, the results of the two surveys were combined and analysed using unweighted means.

2.5 Results

2.5.1 Characteristics of the care home population

A total of 1413 residents were screened for malnutrition risk in 63 care homes (mean age; 86.7 ± 8.6, mean BMI; 23.0 ± 5.1kg/m^2, 76% female, 24% male), with 34% residing in residential homes, 42% in nursing homes and 23% in dual registered homes. Screening of all care home residents present in care homes (blanket screening) was conducted in 53 homes. It was not possible to carry out screening of all care home residents in a small number of homes, therefore, results are presented in this chapter for those care homes where blanket screening was carried out.

Within the 53 care homes where blanket screening of all care home residents took place (n=1322), 40% of residents received residential care and 60% nursing care. The age of the residents was not significantly affected by gender or the type of care home or the type of care provided. Further details of resident's age, gender, weight, height, BMI, percentage weight loss and duration of stay are displayed in Tables 2.6 and 2.7. The BMI of residents was significantly lower in nursing homes (22.6 ± 5.2 kg/m^2, p=0.019) than residential or dual registered homes (23.4 ± 4.8kg/m^2 and 23.1 ± 5.2kg/m^2).

Only 23.7% of residents surveyed became resident in the care homes in the six months prior to the survey (Figure 2.3). The mean duration of admission was 2.4 ± 2.8 years, however the duration of residency ranged from one day to 22.2 years (Tables 2.6 and 2.7). There were tendencies for the length of residency in care homes to vary according to gender (men; 2.0 ± 2.6 years versus women; 2.51 ± 2.8 years, p=0.064) and type of care home (residential; 2.4 ± 2.8 years, nursing; 2.2 ± 2.4 years, dual registered; 2.8 ± 3.2 years, p=0.041), but not according to the type of care residents received (residential; 2.5 ± 2.9 years versus nursing; 2.3 ± 2.7years, p=0.286).

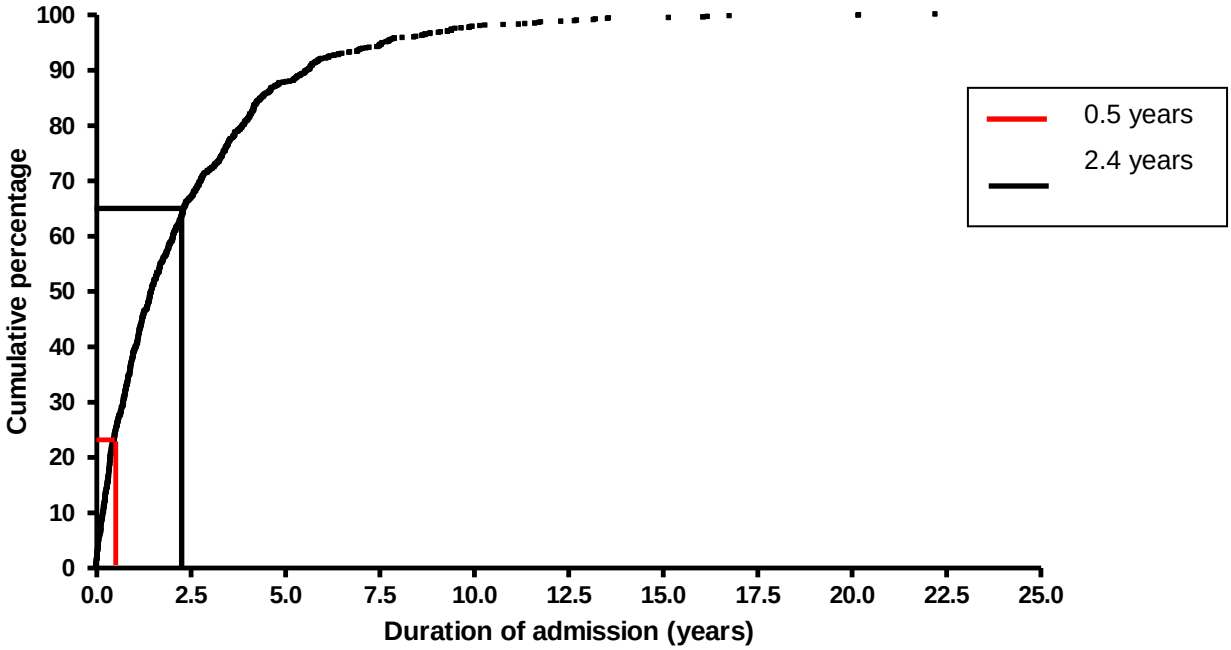


Figure 2.3 Length of residency (years) of care home residents in the Hampshire survey

Table 2.6 Characteristics of Hampshire care home residents, according to the type of care home

	Type of care home						Totals	
	N=483	Residential	N=596	Nursing	N=318	Dual registered	P value†	N=1322	Total
Age; y	434	86.4 ± 8.9	550	86.5 ± 8.7	297	87.3 ± 8.0	0.293	1281	86.7 ± 8.6
Male; %	100	21.9	121	21.8	90	28.8	0.100	311	25.3
Female; %	356	78.1	432	78.0	222	71.2		1010	76.4
Weight; kg	456	60.3 ± 13.9	550	59.8 ± 15.2	312	61.9 ± 15.8	0.143	1318	60.5 ± 14.9
Height; m	456	1.60 ± 0.09	549	1.62 ± 0.09	310	1.63 ± 0.09	0.000	1315	1.62 ± 0.09
BMI; kg/m^2	456	23.4 ± 4.8	539	22.6 ± 5.2	309	23.1 ± 5.2	0.019	1304	23.0 ± 5.1
Weight Loss; %	411	2.4 ± 4.2	506	1.9 ± 3.7	286	2.4 ± 4.2	0.159	1203	2.2 ± 4.0
Duration of stay; y	370	2.4 ± 2.8	384	2.2 ± 2.4	187	2.8 ± 3.2	0.041	941	2.4 ± 2.8

†ANOVA for the three types of care homes

Table 2.7 Characteristics of Hampshire care home residents, according to the type of care residents received

	Type of Care					Totals	
	N=556	Residential	N=857	Nursing	P value†	N=1322	Total
Age; y	502	86.8 ± 8.6	779	86.5 ± 8.6	0.552	1281	86.7 ± 8.6
Sex							
Male; %	128	24.4	183	22.9	0.596	311	23.6
Female; %	396	75.6	798	76.9		1010	76.4
Weight; kg	524	61.0 ± 14.4	794	60.1 ± 15.3	0.269	1318	60.5 ± 14.9
Height; m	523	1.61 ± 0.10	792	1.62 ± 0.09	0.005	1315	1.62 ± 0.09
BMI; kg/m^2	522	23.5 ± 4.7	782	22.7 ± 5.2	0.004	1304	23.0 ± 5.1
Weight Loss; %	471	2.3 ± 4.1	732	2.1 ± 3.9	0.659	1203	2.2 ± 4.0
Duration of stay; y	417	2.5 ± 2.9	524	2.3 ± 2.7	0.348	941	2.4 ± 2.8

†ANOVA for the two types of care for residents

2.5.2 Operational infrastructure for detecting and managing malnutrition

2.5.2.1 Use of weighing scales

Almost all of the care homes used weighing scales (97%), with the majority of residential homes using bathroom scales (87.5%), and the majority of nursing homes (72.7%) and dual registered homes (62.5%) using sit on scales (Table 2.8). Monthly weights were recorded by 96% of care homes, with two residential care homes not routinely weighing residents, and one nursing home weighing residents as and when possible (Table 2.9).

Table 2.8 Types of weighing scales used in care homes in Hampshire

	Types of scales used			
Care home type	Bathroom	Sit On	Sit On and Hoist	No Scales
Residential; %, (n)	87.5 (28/32)	6.3 (2/32)	0 (0/32)	6.3 (2/32)
Nursing; %, (n)	9.1 (2/22)	72.7 (16/22)	18.2 (4/22)	0 (0/22)
Dual; %, (n)	12.5 (1/8)	62.5 (5/8)	25.0 (2/8)	0 (0/8)

Table 2.9 Frequency of routine weights being recorded for care home residents, according to care home type

	Frequency of routine weights		
Care home type	Monthly	As and when	Do not routinely weigh
Residential; %, (n)	90.6 (29/32)	3.1 (1/32)	6.3 (2/32)
Nursing; %, (n)	95.5 (21/22)	4.5 (1/22)	0
Dual; %, (n)	100 (8/8)	0	0

2.5.2.2 Routine use of nutrition screening tools

The use of nutrition screening tools varied considerably between the types of care home (Table 2.10). Only 12.5% of residential homes reported using any form of nutrition screening tool, compared with 45.5% of nursing homes and 87.5% of dual registered homes. In all types of care home, 'MUST' was chosen by the majority of care homes (85.7%) followed by the care homes own tool (9.5%) and MNA (4.8%) (Table 2.11). Using the data from individual residents risk of malnutrition, there were no significant

differences in malnutrition risk between care homes that did (38%) and did not (37%) use a screening tool.

Table 2.10 The use of a nutrition screening tool, according to type of care home

Care home type	Is a nutrition screening tool used?	
	Yes	No
Residential; %, (n)	12.5 (4/32)	87.5 (28/32)
Nursing; %, (n)	45.5 (10/22)	55.5 (12/22)
Dual; %, (n)	87.5 (7/8)	12.5 (1/8)

Table 2.11 Specific nutrition screening tools, according to the type of care home

Care home type	Which nutrition screening tool is used?			
	'MUST'*	MNA^	None	Homes own tool
Residential; %, (n)	9.4 (3/32)	3.1 (1/32)	87.5 (28/32)	0 (0/32)
Nursing; %, (n)	40.9 (9/22)	0	54.5 (12/22)	4.5 (1/22)
Dual; %, (n)	75 (6/8)	0	12.5 (1/8)	12.5 (1/8)
Total	18/62	1/62	41/62	2/62

* 'MUST' – Malnutrition Universal Screening Tool

^MNA – Mini Nutritional Assessment

2.5.2.3 Access to Dietetic Services in Hampshire

The access to dietetic services within the care homes in Hampshire that were included in this survey was extremely limited. Only 0.3% of residents were under the care of a dietitian at the time of the survey, despite 37% of residents being at risk of malnutrition. Only small proportions of residents receiving oral (2%) or enteral nutrition (8%) were seen by a dietitian. None of the residents that were at risk of malnutrition, but were not receiving oral or enteral nutrition support were seen by a dietitian.

2.5.2.4 Use of nutritional interventions in Hampshire care homes

Eight percent of the care home population received ONS and 2% received PEG feeding. The prescription of ONS varied according to the type of care home, with the majority of residents that received ONS residing in nursing homes (61%). ONS were prescribed to a lesser extent in residential homes (10%) and dual registered homes (29%). All residents

that received nutrition via a percutaneous endoscopic gastrostomy (PEG) tube resided in nursing homes.

The use of ONS also differed significantly according to whether a nutrition screening tool was routinely used, with 13.4% of residents receiving ONS in care homes where nutrition screening tools were used compared to 4.7% of residents in care homes where a nutrition screening tool was not routinely used ($p<0.001$). Further information on their use in association with residents' risk of malnutrition is discussed in Section 2.5.7.

2.5.3 Prevalence of malnutrition risk

2.5.3.1 Overall prevalence of malnutrition

37.2% of residents were at risk of malnutrition, with 14% being at medium risk and 23% being at high risk of malnutrition (Figure 2.5).

2.5.3.2 Malnutrition according to source of admission

Analysis of a subset of residents where data was collected on source of admission, found that malnutrition risk was higher amongst those admitted from another care home (41.1%) than those admitted from hospital (36.4%) or home (35.2%), however this was not significant.

2.5.3.3 Deprivation and malnutrition risk in care homes

IMD rank ranged from 4,837–32,374 (mean 24,440 ± 6499; median 26930). The prevalence of malnutrition in individual care homes ranged from 10–78% (mean 38 ± 12.7%; median 37%). There was no significant association between deprivation rank of the care home and the prevalence of malnutrition risk in the residence, either before ($r=0.177$; $p=0.214$) or after adjustment for care home type (residential, nursing) ($r=0.185$; $p=0.179$) (Figure 2.4). None of the individual components of deprivation were significantly associated with the prevalence of malnutrition.

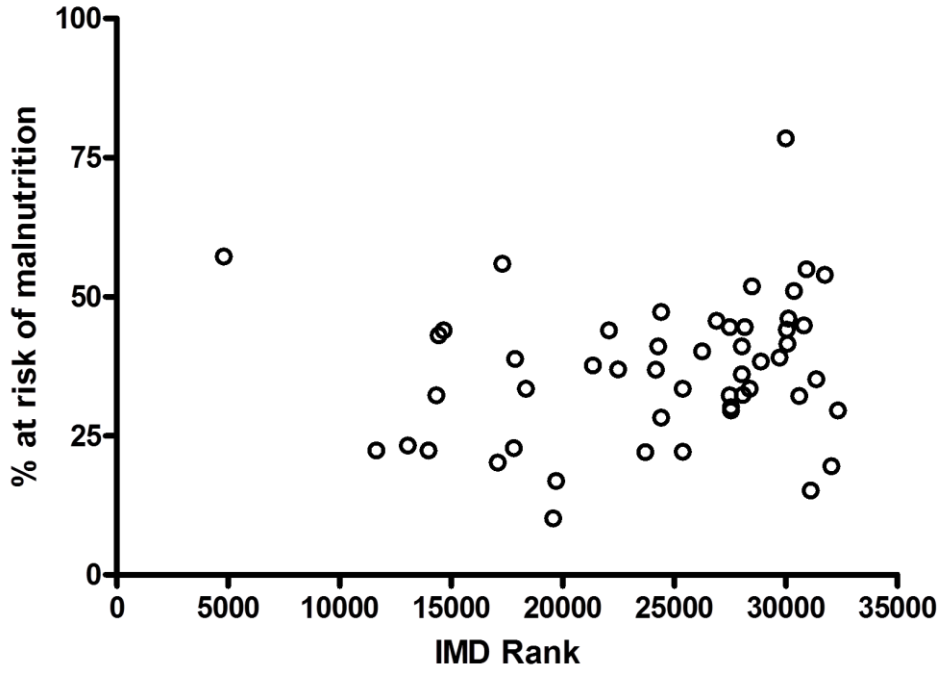


Figure 2.4 Deprivation Ranks (Index of Multiple Deprivation (IMD)) of care homes were not associated with malnutrition risk

2.5.3.4 Malnutrition according to type of care received

There were no significant differences in malnutrition risk according to type of care home (Residential; 35.5%, Nursing; 39.2%, Dual registered; 36.2%, p=0.450) or type of care individual residents received (Residential; 35.1%, Nursing; 38.6%, p=0.200) (Figure 2.5).

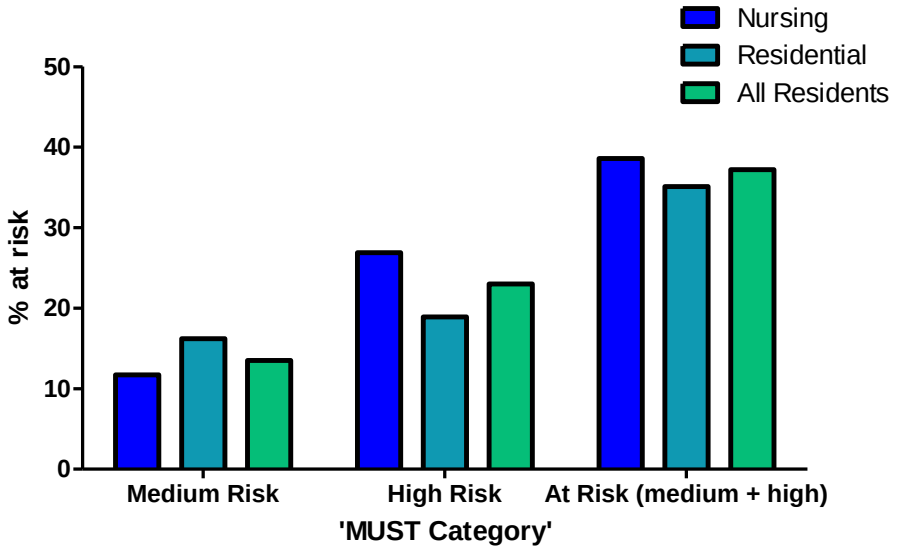


Figure 2.5 Prevalence of malnutrition according to 'MUST' category and type of care

2.5.3.5 Malnutrition according to age categories

Those at risk of malnutrition were found to be significantly older than those not at risk (87.9 ± 8.9 years versus 85.9 ± 7.9 years, p=0.001), increasing with age category (Figure 2.6).

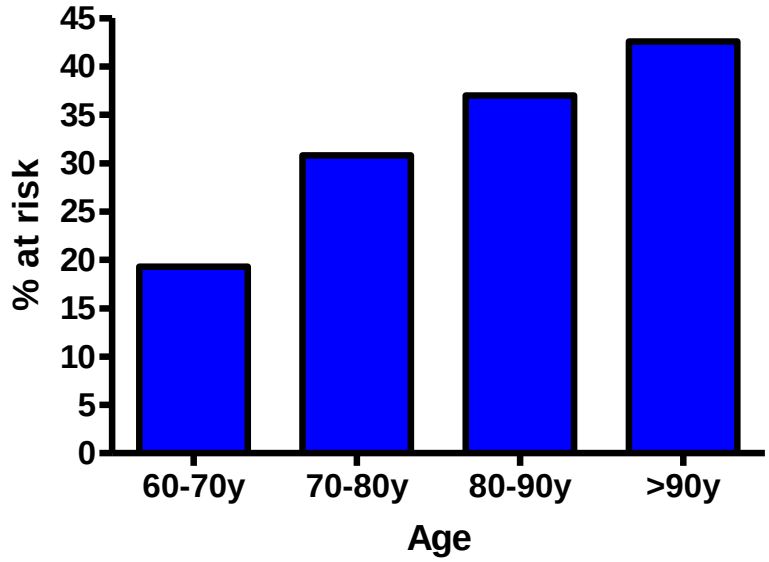


Figure 2.6 Prevalence of malnutrition according to age categories

2.5.3.6 Malnutrition according to gender

The percentage of women at risk of malnutrition was higher than men (40.6% of women at risk versus 26% of men, p<0.0001).

2.5.3.7 Malnutrition according to body systems and health conditions

The presence of health conditions affecting different body conditions was also considered. A range of health conditions were noted from residents' records, with two thirds of residents having health conditions affecting the central nervous system. The prevalence of malnutrition varied according to the body system affected, with malnutrition risk being higher amongst those residents with problems affecting the central nervous system (40.7%), and lower amongst those with endocrine disorders (28.3%) (Figure 2.7)

The prevalence of malnutrition varied according to the presence of particular conditions, with the prevalence of malnutrition being highest amongst those with cancer (48.1%) and lowest amongst those with diabetes (26.4%) (Figure 2.8).

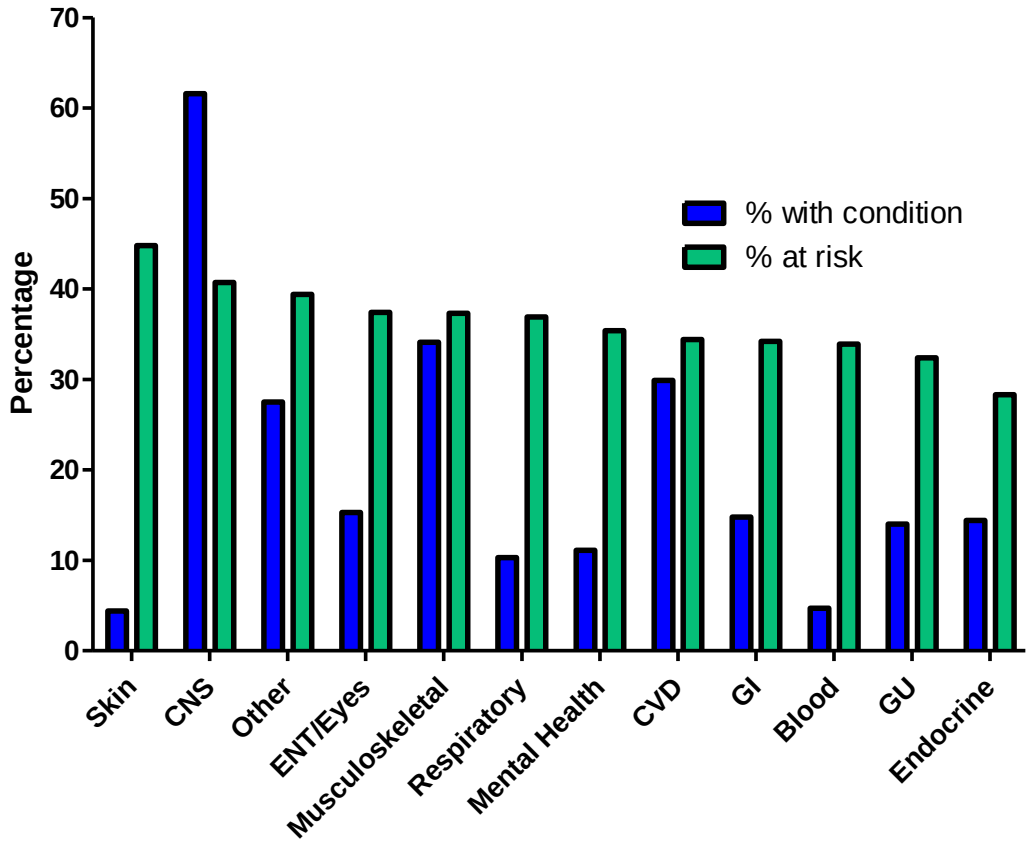


Figure 2.7 The presence of conditions affecting body systems, and the prevalence of malnutrition according to each body system

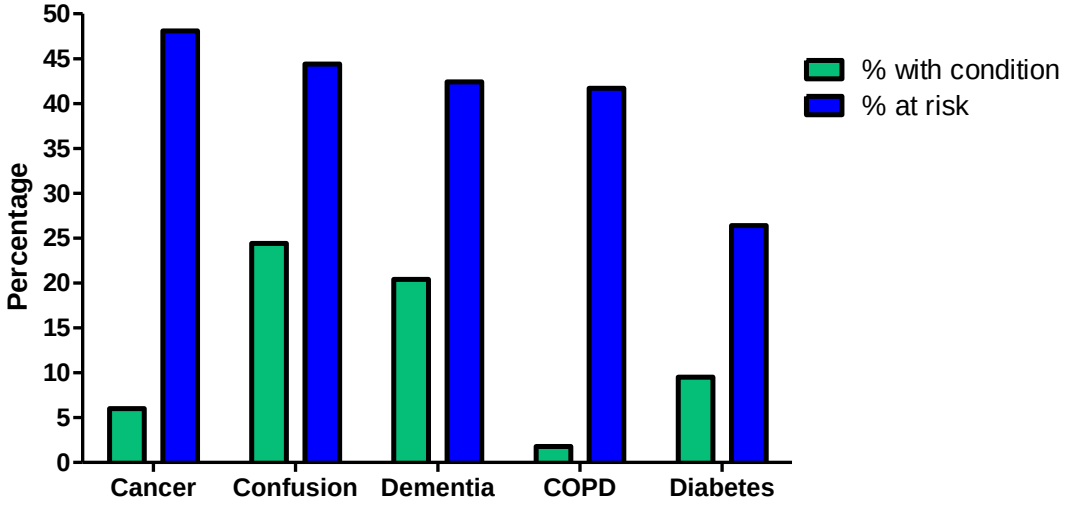


Figure 2.8 The presence of specific conditions, and the prevalence of malnutrition according to each condition

2.5.4 Malnutrition according to the length of residency

The Hampshire population was split into two groups, to investigate whether there were any differences between those residents that had been in residence for less than six months and those whose length of residency was greater than six months (Table 2.12). From this cross-sectional survey, the age and proportion of male and female residents varied significantly according to duration of residency (85.7 ± 7.7 years versus 87.19 ± 8.5 years, p=0.021; <6 months; 28% men, 72% women, >6 months; 20% men, 80% women, p=0.018). There was a trend towards a lower risk of malnutrition amongst those that had been in residence for greater than six months compared with those with a shorter length of residence (35.5% versus 42.7%, p=0.057). There was no significant difference in malnutrition risk according to age category, with the exception of those aged over 85 years, where the risk was significantly higher in those in residence for less than six months compared with those in residence for greater than six months (48.4% versus 37.2%, p=0.020). Malnutrition risk was not significantly affected by the type of care or gender, however malnutrition risk was significantly higher amongst women in residence for less than six months, compared with those in residence for greater than six months (51.6% versus 38.3%, p=0.003).

Table 2.12 Number of residents and resident characteristics according to length of residency (less than six months compared with greater than six months)

	Length of residency		
HAMPSHIRE	Less than 6 months	Greater than 6 months	P value†
Number of subjects	218	723	
Age (years)	85.7 ± 7.7	87.19 ± 8.49	0.021
Sex			0.018
Male; n, (%)	61/218 (28.0)	147/723 (20.3)	
Female; n, (%)	157/218 (72)	575/723 (79.5)	
% malnutrition			
Overall risk; n, (%)	93/218 (42.7)	257/723 (35.5)	0.057
'MUST' Category			
Medium risk; n, (%)	35/218 (16.1)	87/723 (12.0)	0.121
High risk; n, (%)	58/218 (26.6)	170/723 (23.5)	0.351
Type of care			
Residential care; n, (%)	36/87 (41.4)	113/330 (34.2)	0.217
Nursing care; n, (%)	57/131 (43.5)	144/393 (36.6)	0.161
Sex			
Male; n, (%)	12/61 (19.7)	36/147 (24.5)	0.453
Female; n, (%)	81/157 (51.6)	220/575 (38.3)	0.003
Age			
<70y; n, (%)	3/9 (33.3)	4/31 (12.9)	0.156
70-84y; n, (%)	28/80 (35.0)	68/196 (34.7)	0.961
>85y; n, (%)	62/128 (48.4)	184/495 (37.2)	0.020

†ANOVA for comparisons between length of residency

2.5.5 Comparison of the characteristics and prevalence of malnutrition between the Hampshire and BAPEN Nutrition Screening Week (NSW) 2007 & 2008 Surveys

Comparing the Hampshire survey (including all care home residents) with the BAPEN NSW 2007 & 2008 surveys [27, 28] (including only those admitted in the six months prior to the surveys) resulted in there being some difference between the two groups (Table 2.13). The proportion of males and females differed, with there being a higher proportion of women in the Hampshire group (76.4% female versus 70% female, $p<0.0001$). Malnutrition risk differed significantly between groups, with 37.2% being at risk in Hampshire compared with 33.3% nationally ($p=0.018$). Comparing medium and high malnutrition risk categories, the percentage at medium risk was higher amongst the Hampshire population (13.5% versus 10.3%, $p=0.004$), however there were no significant differences amongst the high risk groups. Malnutrition risk increased with age categories within both groups, however there was a trend towards a higher percentage at risk within those aged over 85 years in the Hampshire group (40.4% versus 36.1%, $p=0.052$). There was no significant difference between the surveys in terms of gender and malnutrition risk.

Table 2.13 Comparison of the characteristics and prevalence of malnutrition between the Hampshire and BAPEN Nutrition Screening Week (NSW) 2007 & 2008 Surveys

	Hampshire	BAPEN	P value†
Number of subjects	1322	2387	
Age (years)	86.7 ± 8.7		
Sex			
Male; n, (%)	311/1322 (23.5)	716/2387 (30.0)	0.000
Female; n, (%)	1010/1322 (76.4)	1671/2387 (70.0)	
% malnutrition			
Overall risk; n, (%)	492/1322 (37.2)	741/2224 (33.3)	0.018
'MUST' Category			
Medium risk; n, (%)	178/1322 (13.5)	229/2224 (10.3)	0.004
High risk; n, (%)	314/1322 (23.8)	506/2224 (22.8)	0.495
Type of care			
Residential care; n, (%)	184/524 (35.1)		
Nursing care; n, (%)	308/798 (38.6)		
Sex			
Male; n, (%)	81/311 (26.0)	200/716 (27.9)	0.533
Female; n, (%)	410/1010 (40.6)	728/1671 (43.0)	0.228
Age			
<70y; n, (%)	11/57 (19.3)	44/156 (28.0)	0.189
70-84y; n, (%)	132/390 (33.8)	278/897 (31.0)	0.313
>85y; n, (%)	337/834 (40.4)	421/1165 (36.1)	0.052

†ANOVA for comparisons between Hampshire and BAPEN surveys

2.5.6 Comparison of the characteristics and prevalence of malnutrition between the a subset of the Hampshire Survey and BAPEN Nutrition Screening Week (NSW) 2007 & 2008 Surveys

Analysis of a subset of the Hampshire survey (only those in residence for less than six months) and BAPEN surveys [27, 28] (Table 2.14) also resulted in some differences between the two surveys. In this comparison there was a non-significant difference in the proportion of men and women between groups, however there was a significant difference in malnutrition risk between the surveys, with there being a higher percentage at risk amongst the Hampshire cohort (42.7% versus 33.3%, p=0.006). The percentage at medium risk was also significantly higher amongst the Hampshire group (16.1% versus 10.3%, p=0.009), however the percentage at high risk was not significantly different (26.6% versus 22.8%, p=0.198). Malnutrition risk increased with age categories amongst both groups, however there was a significantly higher percentage at risk amongst the over 85 years category in the Hampshire survey (48.4% versus 36.1%, p=0.006). There was no significant difference between the surveys in terms of gender and malnutrition risk.

Table 2.14 Comparison of the characteristics and prevalence of malnutrition between a subset of the Hampshire Survey (those in residence for less than six months) and BAPEN Nutrition Screening Week (NSW) 2007 & 2008 Surveys

	Hampshire	BAPEN	P value†
Number of subjects	218	2387	
Age (years)	85.7 ± 7.7		
Sex			
Male; n, (%)	61/218 (28.0)	716/2387 (30.0)	0.534
Female; n, (%)	157/218 (72)	1671/2387 (70.0)	
% malnutrition			
Overall risk; n, (%)	93/218 (42.7)	741/2224 (33.3)	0.006
'MUST' Category			
Medium risk; n, (%)	35/218 (16.1)	229/2224 (10.3)	0.009
High risk; n, (%)	58/218 (26.6)	506/2224 (22.8)	0.198
Type of care			
Residential; n, (%)	36/87 (41.4)		
Nursing; n, (%)	57/131 (43.5)		
Sex			
Male; n, (%)	12/61 (19.7)	200/716 (27.9)	0.084
Female; n, (%)	81/157 (51.6)	728/1671 (43.0)	0.037
Age			
<70y; n, (%)	3/9 (33.3)	44/156 (28.0)	0.740
70-84y; n, (%)	28/80 (35.0)	278/897 (31.0)	0.459
>85y; n, (%)	62/128 (48.4)	421/1165 (36.1)	0.006

†ANOVA for the for comparisons between Hampshire and BAPEN surveys

2.5.7 Use of nutritional interventions in Hampshire care homes

The prevalence of malnutrition varied significantly between residents that were receiving ONS (85%), PEG feeding (23%), or no nutritional intervention (34%) ($p<0.0001$, Chi^2) (Figure 2.9). The use of ONS varied according to malnutrition risk category (Figure 2.10).

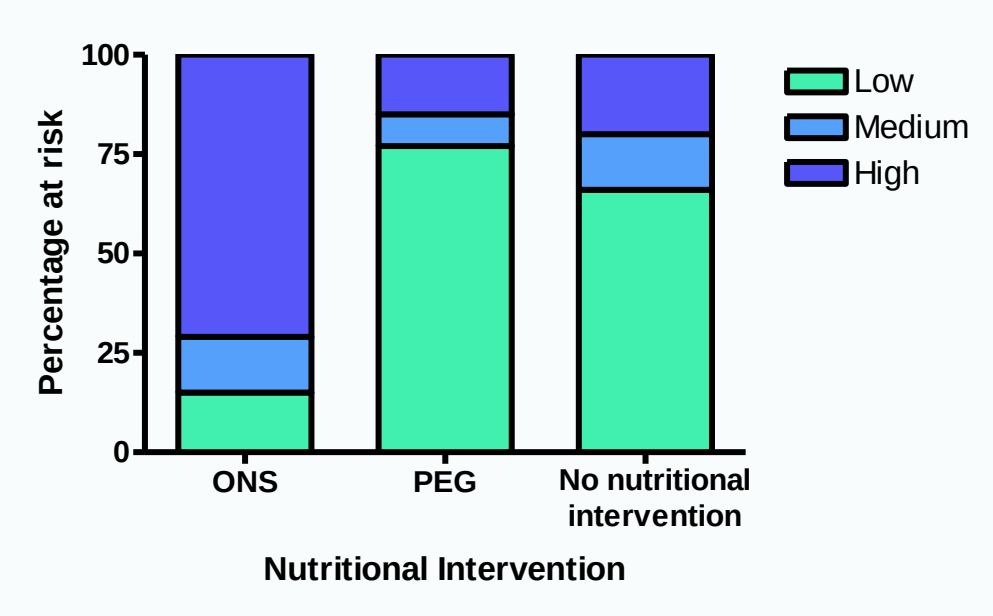


Figure 2.9 Percentage of residents at risk of malnutrition, using 'MUST', according to nutritional intervention

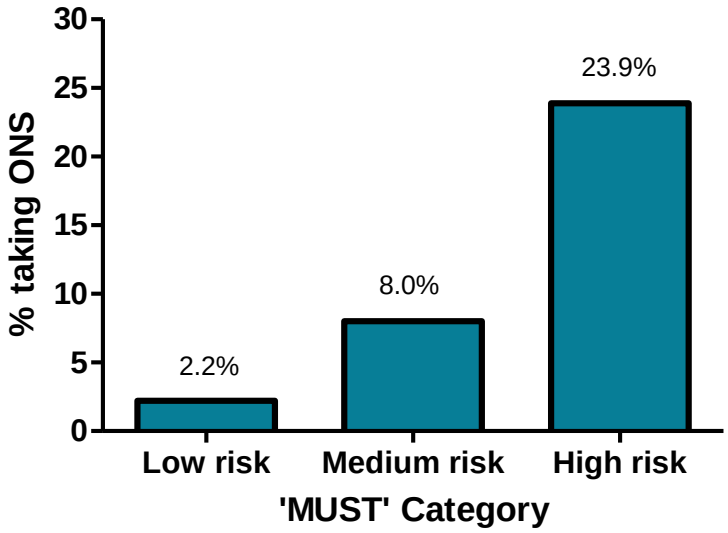


Figure 2.10 Use of ONS according to malnutrition risk category

The use of ONS was further explored according to low BMI and percentage weight loss categories. Amongst those residents with a low BMI (<18.5kg/m^2), prescription of ONS ranged from 27% for those with a BMI less than 18.5kg/m^2 to 46.7% for those with a BMI less than 14kg/m^2 (Figure 2.11). Weight loss in the previous three to six months occurred in all these low BMI categories and the percentage unintentional weight loss increased as BMI decreased. The use of ONS also varied according to percentage weight loss category, with 7.3% of those with less than 5% weight loss being prescribed ONS, to 13.2% of those with greater than 10% weight loss being prescribed ONS.

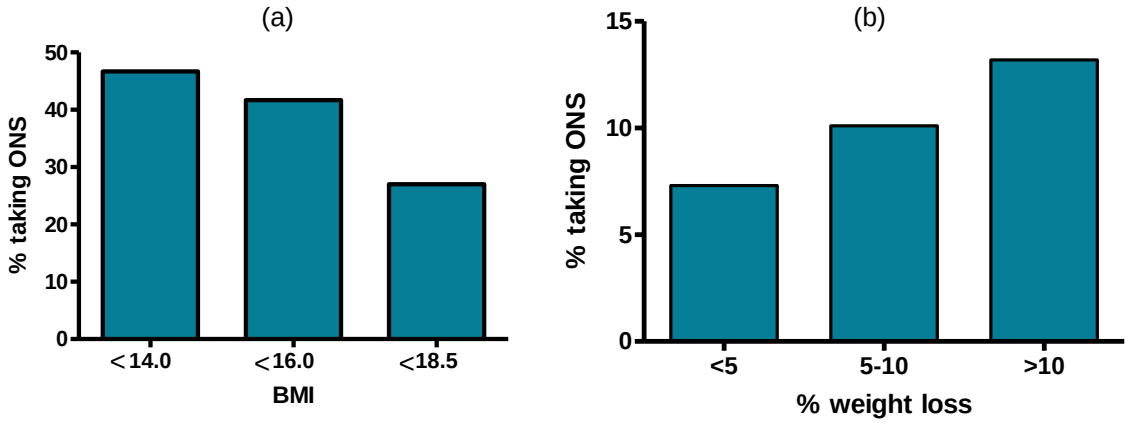


Figure 2.11 The prescription of ONS according to low BMI (kg/m^2) categories (a) and percentage weight loss categories (b)

The BMI and percentage weight loss of residents that received ONS were explored. Of the 104 residents that received ONS, 14.5% did not have a BMI less than 20kg/m^2, and had experienced less than 5% weight loss. Of the 85.5% of residents who had a BMI less than 20kg/m^2 (74%), or had experienced weight loss of greater than 5% (35.5%), 50% had a low BMI, 11.5% had weight loss of greater than 5%, and 24% had both a low BMI and greater than 5% weight loss (Figure 2.12).

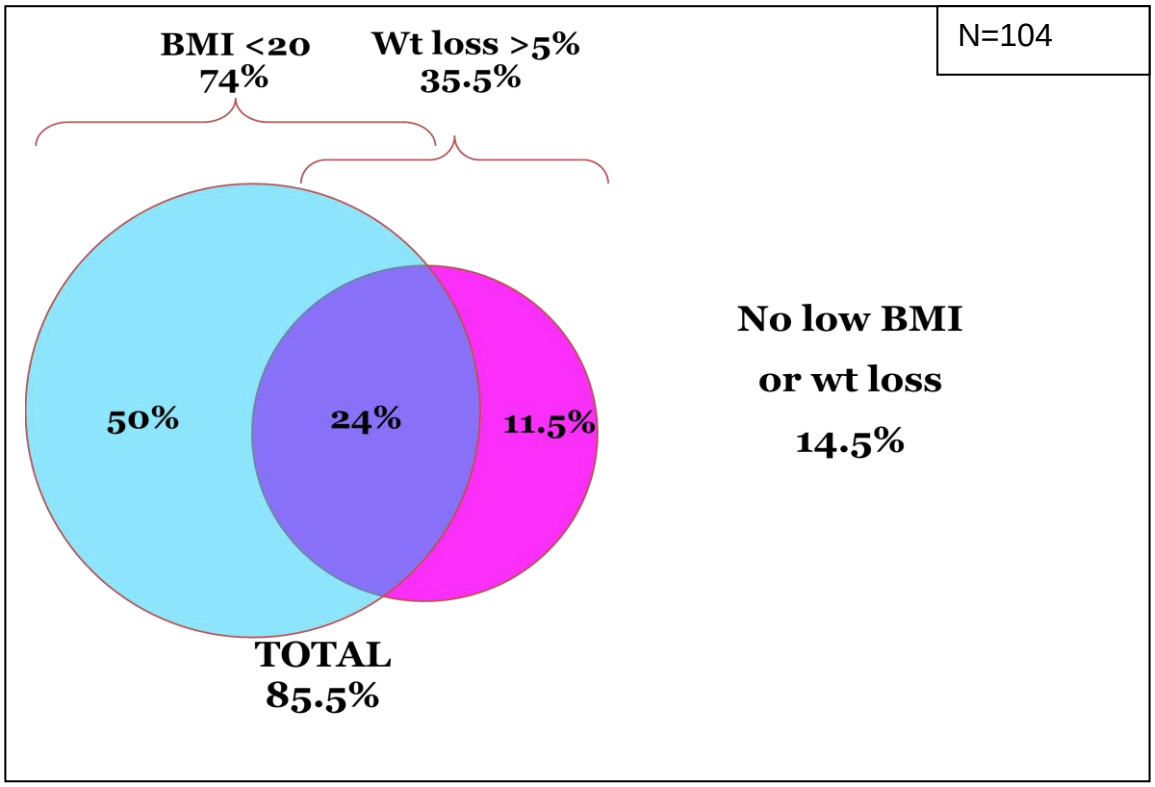


Figure 2.12 A Venn diagram showing the proportion of residents that were prescribed ONS that had a low or normal BMI and/or weight loss

2.6 Discussion

This is the largest survey of nutritional screening in Hampshire and the largest survey in the UK examining all residents within the care homes using 'MUST'. It demonstrates a prevalence of malnutrition of 37%, which is intermediate between those reported in previous studies. Unlike several previous surveys, this survey included all residents present in care homes, rather than only using a proportion of residents, such as the BAPEN Nutrition Screening Week surveys [27, 28] where only those residents admitted in the last six months were included.

2.6.1 Part A – Operational infrastructure for the detection and management of malnutrition

The survey of Hampshire care homes identified areas where the infrastructure for detecting and managing malnutrition could be improved in order to reduce the prevalence of malnutrition among older people.

The first step in the nutritional care pathway is to identify malnutrition risk. This survey of routine nutritional care provided by privately owned residential, nursing and dual registered homes has found that although the majority of care homes weighed their residents on a monthly basis, the type of weighing scales varied according to type of care home. Both nursing and dual registered homes were more likely to use weighing scales that conformed to the Department of Health's directive on weighing scales for medical use [54]. However, the majority of residential homes were using bathroom scales, which may have never been calibrated. This may result in inaccurate weight measurements, and assessment of malnutrition risk. A survey of weighing scales in Southampton hospitals found that weight measurements could vary considerably between wards, therefore, particularly in care homes where scales were not routinely recalibrated, it is likely that the precision of the weight measurements would be worse in residential homes than nursing or dual registered homes. Also, in a small number of homes residents' weights were not recorded at all, potentially resulting in an entirely missed opportunity to identify malnutrition.

Despite national guidance on nutrition screening in the community [2, 20], it would appear that the routine use of nutrition screening tools was low in Hampshire care homes, with less than 50% of the nursing and residential care homes that participated in the survey reporting use of nutrition screening tools. This figure is lower than that reported by the BAPEN Nutrition Screening Week Survey (68%) [6]. This suggests that either the care homes were not aware of the national guidance, or were unsure of how to implement the

guidance. Nursing homes were more likely to use a nutrition screening tool than a residential home, possibly due to the greater level of governance that nursing homes must adhere to.

Where nutrition screening tools were used, 'MUST' was used most frequently. Despite this difference in the use of nutrition screening tools according to care home type, the prevalence of malnutrition between homes that did and did not use a screening tool was not significantly different. This may suggest that where screening for malnutrition was taking place regularly, the results were not being acted upon to reduce malnutrition risk. Given that 87.5% of residential homes, and 54.5% of nursing homes were not using a nutrition screening tool, it suggests that many care homes in Hampshire are in need of training related to nutritional screening, in order to ensure care homes are familiar with and competent to use nutrition screening tools effectively and meet CQC regulations for nutritional care [57].

The use of nutritional interventions was also explored in the Hampshire survey. In line with variations in weighing and screening for malnutrition, use of interventions such as oral nutritional supplements varied in a similar way. Use of ONS was three fold higher where a nutrition screening tool was used, and was higher in nursing than residential homes. Although use of ONS was higher, only 8% of the care home population received ONS. This percentage is low when it is considered that 37% of the care home population were at risk of malnutrition. In addition to this, dietetic input was only provided to 0.3% of the care home population, and very few residents receiving ONS or tube feeds were being reviewed by a dietitian. These findings suggest that an unstructured, non-uniform approach to the use of ONS and dietetic input is currently being employed, which is not necessarily linked to the results of nutritional screening.

2.6.2 Part B – Prevalence of malnutrition and use of nutritional interventions

The second part of the survey focussed on the prevalence of malnutrition and the use of nutritional interventions. The survey using 'MUST' found that 37.2% of residents were at risk of malnutrition. As the majority of care homes were not routinely using a nutrition screening tool at the time of the survey, it suggests that the majority of malnutrition in Hampshire care homes was not being identified.

2.6.2.1 Factors affecting malnutrition risk in Hampshire care home residents

2.6.2.1.1 Trends according to type of care, age and health conditions

A number of factors affecting malnutrition risk were identified in the Hampshire survey, which could potentially help lead to a more targeted approach to the identification and treatment of malnutrition in care homes. The prevalence of malnutrition varied according to type of care, and in addition to this the proportions at medium and high risk also varied according to type of care, with there being a greater proportion at medium risk in residential care, and a greater number at high risk in nursing care. This is suggestive of a greater proportion of residents in nursing homes having greater care needs due to more advanced chronic diseases which are adversely affecting their nutritional status more so than those residents living in residential homes, with less severe health needs.

There was a clear association between older age and malnutrition, with the prevalence of malnutrition being greatest amongst those aged over 90 years. Such trends according to age have also been reported by the BAPEN screening surveys. Those aged greater than 90 years are likely to have experienced many physiological changes that occur with aging, including loss of lean muscle mass, bone mass and changes in appetite. All of these changes, coupled with any deterioration in health are likely to have impacted on their nutritional status, resulting in greater vulnerability to malnutrition and the health complications associated with malnutrition.

The prevalence of malnutrition was higher amongst women than men, an observation that has been reported in other surveys of malnutrition [27, 28, 58]. Women also tended to reside in care homes for longer and be older than their male counterparts. The increased length of care home residency could be explained by women entering a care home at an earlier stage than men, and experiencing a slower decline in health. The proportion of men admitted for less than six months was greater than those admitted for more than six months. It is therefore possible that they tended to be admitted to care homes at a later stage, with more advanced disease and a compromised nutritional status, resulting in a shorter length of residency.

Residents with dementia and cancer were at greatest risk of malnutrition. These findings are similar to the nutrition screening survey of nursing homes in Finland by Suominen et al. (2005), the Dutch survey of nursing homes [5] and the BAPEN screening surveys [27, 28]. As discussed in chapter one, dementia can have serious implications on a resident's nutritional status. The condition can affect an individual's ability to remember if they have eaten, or they may experience taste changes and behavioural changes. All of these factors may affect their nutritional intake and requirements.

A resident with cancer may experience a range of physiological and psychological changes that may affect their nutritional requirements and intake, resulting in greater nutritional risk. Residents with cancer are likely to experience weight loss due to the catabolic disease processes, alterations in taste preferences, reductions in appetite, and side effects of medication.

The presence of associations between type of care and health conditions with malnutrition risk may represent the potential to target interventions both according to the type of care and the level of malnutrition risk in each setting. This may potentially allow for nutritional interventions to be implemented at an earlier stage. However, currently, little is known regarding the best intervention to treat those at risk of malnutrition. The survey found that malnutrition risk increased with age category and also varied according to diagnosis. If training of care home staff increased awareness that those residents aged over 85 years, or with conditions such as dementia or cancer were at a greater risk of malnutrition, it might help to ensure people receive nutritional interventions at an earlier stage.

2.6.2.1.2 Trends according to length of residency

Interestingly, there was a trend for malnutrition risk to decrease with length of residency in the care home. This could be explained either by a period of adaptation to living in the care home, after which resident's nutritional status improves, or that those admitted for less than six months were more acutely unwell, with higher needs and a greater risk of mortality. The length of residency in a nursing home was shorter than that of residential or dual registered homes, though this is more likely to be due to the advanced levels of dependency and disease in those residents in nursing homes. The data also suggests that there is a shift in the proportion of men and women between those admitted for more, or less than six months, with the proportion of men decreasing after six months. This may be explained either by men being more acutely unwell when admitted to a care home, or being admitted at a later stage than women.

2.6.2.1.3 Trends according to deprivation status of the care home localities

The survey took place throughout Hampshire, including both inner city and rural areas. The deprivation status of the locality of the care homes was not associated with malnutrition prevalence of the care homes. This result is somewhat surprising considering that reports on malnutrition in hospital inpatients [52] and outpatients [53] have reported converse findings.

It is possible that due to residents moving from other localities, using the postcode of the care homes was not sensitive enough to detect an association between deprivation and malnutrition. In addition to this, due to the heterogeneous nature of the care home population it is possible that the sample of care home residents was not large enough to observe differences in this parameter. Conversely it may be possible that moving to a care home has a positive effect on residents' nutritional status due to the food and nutrition standards and provision of meals that care homes must adhere to. An individual may have experienced social malnutrition in addition to disease related malnutrition at home. People may have experienced difficulty in accessing food and preparing it in their own homes, however upon moving to a care home, where meals were prepared for them, their dietary intake may have increased.

2.6.2.1.4 Comparison of the prevalence of malnutrition between the Hampshire and BAPEN Nutrition Screening Week Surveys

There were many similarities between the Hampshire data and the BAPEN Nutrition Screening Week data, but also some key differences. When comparing the whole cohort from Hampshire with the BAPEN surveys, the prevalence of malnutrition, the proportion at medium risk and the proportion of women were all higher in the Hampshire cohort, and the proportion of residents at medium risk of malnutrition was also higher in the Hampshire survey than the national surveys. These differences may be explained by the inclusion of all care home residents, rather than those admitted in the last six months and women having a longer life expectancy and a longer duration of stay in care homes.

The inclusion of all care home results in the Hampshire survey may have resulted in a higher proportion of residents' at medium risk than the BAPEN surveys due to the severity of disease present in individuals according to their duration of stay. The Hampshire survey suggested that the proportion of men, and those with cancer was less in those residents admitted for greater than six months, compared with those admitted for a shorter duration. It may therefore be possible that the BAPEN survey included a greater proportion of acutely unwell residents in comparison to the Hampshire survey.

The BAPEN survey also could not include those already established on oral nutritional supplements. The omission of these residents, the majority of whom would be at greatest nutritional risk, may have implications for the prevalence of malnutrition reported by the national surveys.

Little is known regarding the locality of the care homes included in the BAPEN surveys, and the effect the locality may have had on malnutrition risk. If a greater number of inner city areas had participated in the national surveys it is possible that trends according to deprivation score may have been observed, and could help to explain some of the

differences in malnutrition risk observed between the national surveys and the Hampshire survey.

2.6.2.2 Use of nutritional interventions in the management of malnutrition in Hampshire care homes

The characteristics of those residents receiving ONS were explored, with prescription increasing according to 'MUST' category. Only 2.2% of residents at low risk of malnutrition were prescribed ONS. It is generally considered that people at low risk of malnutrition should not be prescribed ONS, however it is possible that those residents at low risk received ONS in order to maintain them within the low risk group. As discussed in chapter one, there are a range of health conditions that increase an individual's nutritional needs and it is therefore feasible, for some people, that their nutritional needs are not met by food alone, despite consuming three meals per day. The addition of ONS to their diets may help to prevent weight loss for this small subgroup of the population.

Having a BMI less than 20kg/m^2 was a common characteristic in those receiving ONS. The use of ONS increased according to low BMI categories, however less than 50% of those with a BMI of less than 14kg/m^2 received ONS. Use of ONS increased according to percentage weight loss category, however less than 15% of those with a weight loss of greater than 10% received ONS.

Although data was collected on the use of ONS, it did not include information on individuals' compliance to the intervention. Data on the type and composition of ONS, number of ONS prescribed per day and volume consumed was not recorded. Any future surveys should consider including these parameters in order to assess residents' compliance to the nutritional intervention.

Malnutrition risk was lower amongst those who received enteral tube feeding than those residents who received ONS, or no known nutritional intervention. It is likely that malnutrition risk was lower amongst enterally fed residents, due to this route of feeding having provided their total nutritional needs through the administration of enteral liquid feeds that are nutritionally complete.

In this survey, only information on the use of oral nutrition supplements and enteral feeds were collected. As seen in chapter one, a range of nutritional intervention are available for the treatment of malnutrition, including improvements to the ambience of mealtimes, feeding assistance and food fortification. It was not clear from this survey whether those residents were receiving an alternative nutritional intervention, however it does suggest

that those at highest need are not being identified as being at risk of malnutrition or receiving an appropriate intervention.

This low use of ONS within this group of malnourished residents suggests that staff were not identifying those at greatest risk of malnutrition or implementing appropriate nutritional interventions. This may be due to the limited use of nutrition screening tools. It also highlights that care home staff require further education on malnutrition and how to recognise the signs and symptoms of this condition. In addition to recognising malnutrition, it suggests that staff may require clearer guidance on the use of nutrition screening tools and care planning for those at high risk of malnutrition, however little is known regarding the evidence base for the use of ONS in care homes. If guidance on the use of nutrition interventions in care homes was established, care home staff need to be given clear directions on when to use such an intervention, and receive appropriate training to support the use of these products.

2.6.3 Limitations of the Hampshire survey

This survey of Hampshire care homes does have some limitations, including the design of the survey, sample of homes used and completion of the survey.

This survey used a cross sectional design, and therefore is only able to represent a snap shot of both the nutritional practice in the care homes and the prevalence of malnutrition amongst care home residents. It can only provide data on the prevalence of malnutrition at one time point, and does not take into account changes in prevalence that could occur over the course of a year. However as the survey took place over a two year period, it is possible that any changes in prevalence of malnutrition were accounted for through the rolling screening programme throughout this period. Ideally, a prospective study would need to be conducted in order to assess the prevalence of malnutrition in more detail.

The selection criteria for care homes in Hampshire was broad, however it did exclude homes with less than 10 beds, those on the peripheries of the county, those with residents with advanced dementia, learning disabilities, drug dependence and those solely for people aged less than 50 years. It is possible that the characteristics of residents within these homes may have differed from those included in the survey, and as a result of these differences a survey of nutritional practice, malnutrition risk and use of nutritional interventions may produce differing results in these settings. It would be important for any future surveys in care homes to address this.

This was a voluntary survey of care homes in Hampshire, and their participation was entirely dependent upon the agreement of care homes to participate. This may have

resulted in only those with a greater interest in nutrition participating in the survey. However given the range of results in this survey, particularly with regards to the infrastructure for the detection and management of malnutrition, it would suggest that both homes with infrastructure in place, and those without infrastructure in place took part in the survey.

The survey sampled 18% of the Hampshire care home population (care homes for people aged over 65years), and represents a sample of 0.4% of the care home population in England (care homes for people aged over 65years). In comparison, the national surveys conducted by BAPEN, which included homes for both under 65 year olds and over 65 year olds represented a sample of 0.5% of the care home population in England.

The questionnaire on nutritional practices gave an overview of the practices that were occurring in the care homes, however does not provide detail on why processes were performed well or not so well. Having ascertained that use of nutritional screening tools was variable in this setting, further work is required to ascertain why this is so. In this survey, only the care home managers were asked to respond to questions on nutritional practice, and it is possible that members of nursing or care staff may have answered questions differently. As with many hospitals that state nutritional screening takes place for every patient, it is well known that this does not occur for 100% of patients. It is likely that a similar scenario also occurs in care homes.

The success of use of any tool in a care setting is reliant on the skill of the staff completing the tool. In this survey no questions were asked regarding staff training in the nutritional needs of older people, or their competence in completing nutrition screening tools. This is a key area to explore in more detail in the community. As previously reported, the majority of malnutrition occurs in the community, however little is known regarding the knowledge and expertise of care staff in completing nutritional tasks. Other surveys of malnutrition screening in the Netherlands and Finland have both highlighted that nursing care staff require further education and training in the completion of nutrition screening tools, in order for all residents at risk of malnutrition to be correctly identified [59, 60]. In addition to this a small scale survey in Scotland has indicated that accurate completion of nutritional screening by nurses improves with staff training [61].

In the survey of malnutrition prevalence, much data was collected on the health conditions of residents, however resident's home postcode and their ethnicity were not recorded. As previously discussed, the recording of residents' home postcode would allow further analysis of the association between deprivation and malnutrition. In 2009, 99% of the population aged over 85 years in Hampshire described their ethnicity as White (including British, Irish and Other White), compared with the national average for England

is 98% for this age group. In the same year, 95% of people aged 65 to 74 years described their ethnicity as being White, with this differing between counties and rural and inner city areas [62]. It is possible that in coming years, associations between malnutrition and ethnicity may be observed, as the proportion of people from different ethnic origins increases amongst the older age group.

The methods for obtaining information from care homes differed between the Hampshire survey and the BAPEN Nutrition Screening Week Surveys in that data was collected by a dietitian and a research assistant in the Hampshire care homes, using standardised methodology, and by the care home staff in the BAPEN surveys. To an extent, both surveys relied upon the quality of record keeping in the participating care homes, however the Hampshire survey had the advantage that the researchers were able to verify residents' weights and heights and malnutrition risk scores. The BAPEN survey relied solely on the ability of the care home staff to complete the questionnaires correctly.

There may also have been differences in the populations included in the two surveys. Both surveys relied on the voluntary participation of care homes, however it is possible that a wider selection of care homes were included in the BAPEN survey as restrictions were not placed on the geographical location, type or size of care home. Despite these potential differences in care home characteristics, both surveys reported a similar prevalence of malnutrition within the care home population.

2.6.4 Conclusions

The screening survey has highlighted that the infrastructure for the identification and treatment of malnutrition in care homes is inadequate. Use of nutrition screening tools varies according to setting, and there is minimal access to dietetic services and nutritional interventions. There is a need to improve nutritional screening practice, linked to nutritional care plans which implement appropriate nutritional interventions according to malnutrition risk. However, in an environment where dietetic input is extremely limited, little is known about the best way to intervene in this frail, elderly population.

Given the prevalence of malnutrition amongst older people in care homes, and the low use of nutritional interventions, there is a need to undertake a systematic review of nutritional intervention studies in order to assess the effect of nutritional interventions on clinical, functional and health economic outcomes in this malnourished population. This is addressed in the next chapter.

Chapter Three: Systematic review of nutritional interventions in care homes

3.1 Introduction

Malnutrition is common in care homes in the UK [4], however, as discussed in the previous chapter, little is known regarding the best way to treat malnutrition in this setting. Although nutrition intervention trials have taken place in the community [38, 50, 63-65], including care homes, currently the literature related to the use of oral nutritional interventions has not been reviewed. Apart from treating the underlying disease, including any physiological or psychological problems, several forms of nutritional support are available [66].These include the use of snacks, food fortification, dietary advice and oral nutritional supplementation. There is some evidence for the use of oral nutritional supplements in the community [35, 44, 67], and less evidence for dietary advice [35, 67]. Surprisingly however, there is no formal review of the effectiveness of some of these modalities of treatment, for example, food fortification and oral nutritional supplementation in the care home setting (residential and nursing homes). Both NICE & Cochrane have recommended that research is needed in this area in order to improve the treatment of malnutrition in care homes [2, 35]. Therefore there is uncertainty about the extent to which these interventions improve nutritional intake, weight and muscle mass, and both functional and clinical outcome measures.

3.2 Aim of the systematic review

The aim of this systematic review and meta-analysis was to review the evidence base for the use of oral nutritional interventions (Oral Nutritional Supplements and food fortification, dietary advice) in care homes and to identify gaps in knowledge that needed attention and exploration through further research.

3.3 Methods

The review was planned, conducted and reported according to published guidelines [68, 69]. Figure 3.1 illustrates the principle stages and processes undertaken.

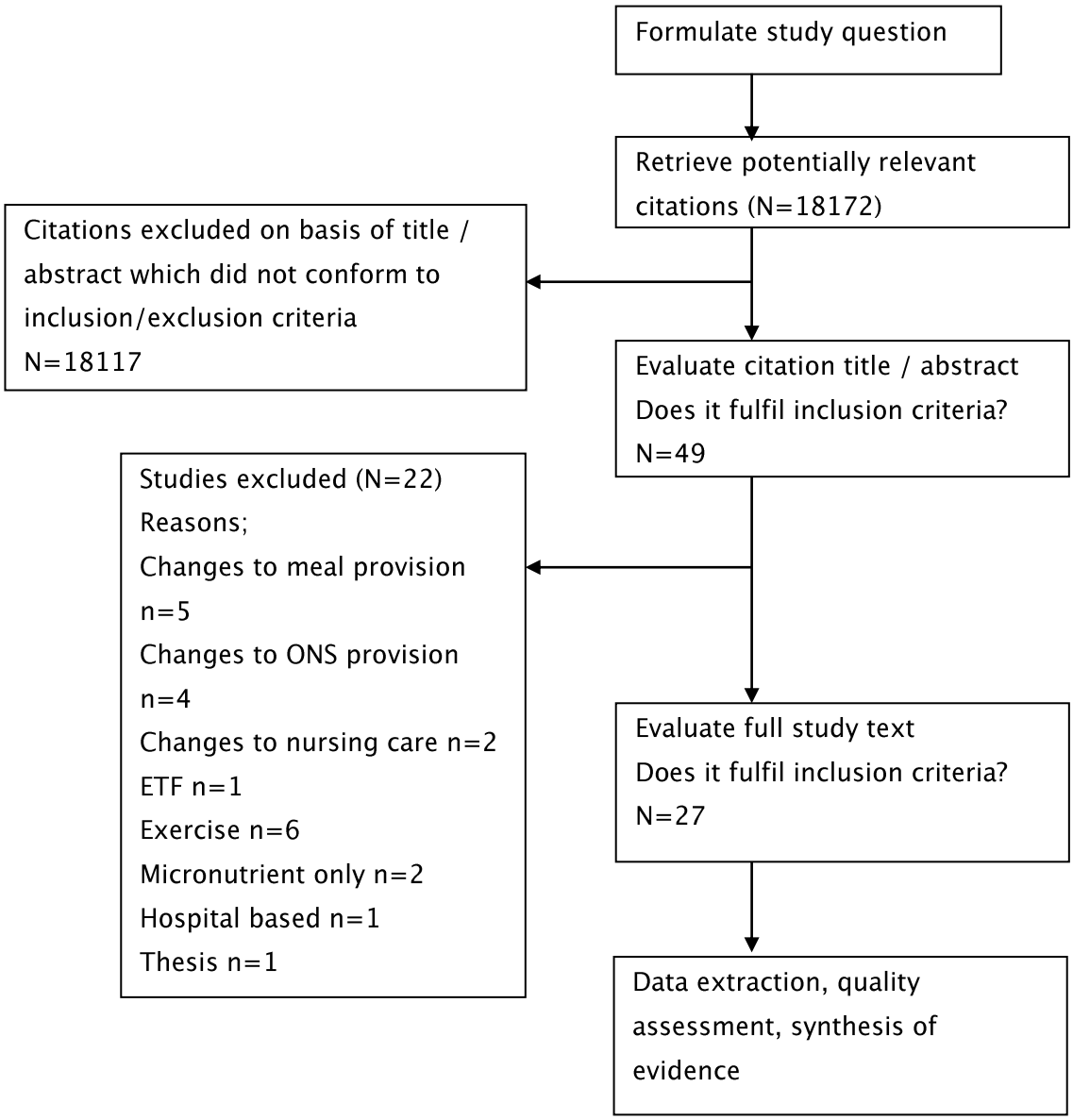


Figure 3.1 Flow diagram of the principle stages included in the systematic review

3.3.1 Identification and retrieval of studies for the systematic review

Potentially relevant studies were identified by searching electronic databases. These were PubMed (PubMed 2009) accessed 07/12/2009, CAB abstracts 1973 to 2009 week 48 accessed 8/12/2009, Embase 1980 to 2009 week 49, accessed 08/12/2009, Ovid Medline 1950 to November week 3 2009 accessed 08/12/2009, Ovid medline Daily Update November 18, 2009 accessed 08/12/2009, Ovid medline In Process and other non-indexed citations December 2007 to 2009 accessed 08/12/2009 and Embase Classic and EMBASE 1947 to 7th December 2009 accessed 08/12/2009. The search terms included: supplement*, dietary advice, food fortification, sip, nutrition support, home, residential, nursing, institution*. Bibliographies were checked and experts in the field were contacted for additional studies.

3.3.2 Study selection criteria for the systematic literature review

Studies were deemed eligible for inclusion in the systematic review if they conformed to pre-determined inclusion and exclusion criteria (Table 3.1).

Subjects eligible for inclusion were adults living in a residential or nursing home, of any nutritional status (well nourished, malnourished). Eligible interventions were ONS, food fortification (including use of snacks) and dietary advice, and combinations of these interventions. ONS included all Advisory Committee on Borderline Substances (ACBS) approved supplements, containing both macro and micronutrients in a readymade format. Food fortification included the addition of other food products to normal daily meals and drinks in order to increase the energy and protein content of meals and drinks. This also included the addition of food snacks. Dietary advice included the provision of written and or verbal dietary advice by a dietitian, or other suitably trained healthcare professional. The intervention supplemented subjects' normal diet. Studies that concurrently assessed a combination of the interventions stated above were included. Those studies utilising only enteral tube feeding or parenteral nutrition were excluded. No other restrictions were placed on studies with regard to type of comparator (e.g. routine care (no nutritional support), dietary advice), year of publication, language (providing an English abstract was available) and source. The priority was Randomised Controlled Trial (RCT) evidence, although non randomised Controlled Clinical Trials (CCT) and before-after Clinical Trials (CT) were admissible. Observational study designs (e.g. cohort, case study) were not eligible. Meta-analysis was only undertaken using RCTs.

Table 3.1 Inclusion and exclusion criteria for the systematic review

Selection criterion	Inclusion criteria	Exclusion criteria
Population	All adult human studies Nutritional status either well-nourished or malnourished Residing in residential or nursing homes	Animal studies
Intervention	Food fortification ONS Dietary advice Food snacks Intervention could include one or combinations of oral nutritional support Comparator group – routine care or oral nutritional support (Food fortification, ONS, dietary advice, food snacks)	Enteral Tube Feeding Parenteral nutrition only No other types of intervention, e.g. exercise, environmental
Study design	RCT, CT	Observational design
Main outcome measures	Quality of life Functional measures Healthcare use Mortality Dietary intake Nutritional status Compliance	

Following the identification of potentially relevant studies based on titles and abstracts, full papers were obtained and evaluated by one researcher; a second assessor verified inclusion/exclusion decisions.

3.3.3 Data extraction and outcome measures

A pre-determined data extraction table was designed to capture study characteristics and outcome data, and allow the assimilation of data from differing study designs. Outcomes sought were quality of life, functional measures, healthcare use, mortality, dietary intake and nutritional status. Outcomes were recorded based on the definitions provided by the original authors of each study.

3.3.4 Compliance to the interventions

Compliance to interventions was investigated, and where possible the volume consumed was expressed as a percentage of the volume prescribed. Suppression of food intake was also calculated. The following methods [70] were used to calculate compliance:

1. In RCTs involving matched groups of people, the percentage of supplement energy intake that was additive to food intake was calculated as:

$$100 - \left(\frac{\text{EIF during S} - \text{EIF before S} + \Delta\text{EIF in control group}}{\text{ONS energy intake}} \times 100\right.$$

Where EIF is energy intake from food, S is supplement, ΔEIF is change in energy intake from food.

2. When baseline information on energy intake in supplemented residents was not available, but results of the food energy intakes in the supplemented and unsupplemented groups during the study were, the following equation was used. The % of supplement energy intake that was additive to food intake was calculated as:

$$\frac{\text{TEI of S group} - \text{TEI of US group}}{\text{ONS energy intake}} \times 100$$

Where TEI is total energy intake, S is supplemented and US is unsupplemented.

3. This method was used when data from a control group was unavailable. It involved longitudinal assessment of energy intake from food before and during supplementation in patients with relatively stable disease, but may be subject to errors associated with spontaneous changes in food intake resulting from a change in disease activity or as a result of the interest and attention provided by the study investigators/health professionals (placebo effect).The extent of the

error with this method is again likely to be smaller when the energy intake from the supplement is large. The percentage of supplement energy intake that was additive to food intake was calculated as:

$$\frac{\text{EIF during S} - \text{EIF before S}}{\text{ONS energy intake}} \times 100$$

Where EIF is energy intake from food and S is supplementation.

3.3.5 Quality assessment

The quality of individual studies was assessed using the Jadad scoring system (Table 3.2) [71]. The system scores papers according to whether they are randomised, blinded, and if there is a description of withdrawals and drop outs. The maximum score was five and the minimum score was zero. The score for each category was described both as a five digit code (e.g. 10011) and a total score. Non randomised trials were categorised as non randomised controlled trials (systematic allocation, non-random, concurrent trials) (code B) and prospective, non randomised, non controlled trials (code C) [70].

Table 3.2 Jadad scoring of randomised controlled trials [71]

	Score	
Jadad criteria	Yes	No
Was the study described as randomised (includes the use of words such as randomly, random, randomisation)	1	0
Was the method to generate the sequence of randomisation described and was it appropriate (e.g. table of random numbers, computer generated)?		
• Described and appropriate or	1 or	0
• Described and inappropriate	-1	
Was the study described as double-blind?	1	0
Was the method of double-blinding described and appropriate (identical placebo, active placebo, dummy)		
• Described and appropriate or	1 or	0
• Described and inappropriate	1	
Was there a description of withdrawals and drop outs?	1	0

3.3.6 Synthesis of data and statistical methods

Following extraction of data, where appropriate and feasible meta-analysis was conducted for any consistent outcome measure that was represented by two or more comparable studies. Meta-analysis was conducted using fixed and random effects models. Where data were available, but not amenable to meta-analysis, a paired t-test was used. Outcomes that were not consistent or numerical were described in a narrative manner in the text.

3.4 Results

3.4.1 Overall search findings

A total of 18,172 studies were identified by the search strategy (Figure 3.1). Following evaluation of the title and abstract, 49 papers were deemed potentially relevant and obtained in full. Upon reading the full text of these 49 papers, 27 complied with the inclusion criteria and were included in the systematic review.

Meta analyses were possible for changes in energy intake [72-75], weight [73, 75-77] and BMI [73, 76, 78].

The other 22/49 studies were rejected from the systematic review and meta-analysis due to: changes in meal provision rather than food fortification [79-83], changes to ONS provision [84-87], changes to nursing care [88, 89], enteral tube feeding [90], hospital based study [91], micronutrient supplementation [92, 93], an intervention with an exercise component [94-99] and a thesis [100].

3.4.2 Description of studies included in the systematic literature review

The 27 studies included in the systematic review comprised of 19 RCTs (Table 3.3) [41, 72-78, 101-111] and eight non randomised trials [112-119]. The minimum trial duration was four days [102] and the maximum was 52 weeks [78]. The populations studied were elderly, with a range of chronic health problems. Residents with Alzheimer's dementia were included in nine studies (Two food fortification versus control [103, 112], four ONS versus control [77, 78, 107, 115] and three food fortification versus ONS studies [108-110]). The majority of studies (78%, 21/27) included residents that were malnourished, or at risk of malnutrition, with 11% (3/27) including non malnourished care home residents and the remaining 11% (3/27) not classifying the residents (Table 3.3). The studies measured a range of outcomes (Table 3.5).

3.4.3 Food fortification versus control

There were eight studies comparing food fortification with standard care, including five RCTs [72, 76, 102, 103, 120] and three non-randomised trials [112-114]. Food fortification included the use of homemade supplements, addition of energy and protein rich foods to meals (e.g. high fat dairy, sugar), use of milk powder, high energy and protein snacks, yoghurts and individualised food plans. Further details on the food fortification conducted in the trials are recorded in Table 3.4. The aims of the trials

included improvements in food intake, body weight, nutritional status and cognitive and behavioural function, with further detail on the individual trial aims being recorded in Table 3.4.

3.4.4 ONS versus control

There were 12 studies comparing ONS with standard care or a placebo, including nine RCTs [73, 75, 77, 78, 104-107] and three non randomised trials [115, 116, 119]. ONS were multi-nutrient liquid supplements, ranging from 125mls to 250mls, containing 170kcal to 500kcal and 7.5g to 20g protein. Further details on the ONS provided in the trials are recorded in Table 3.4. The aims of these studies included improvements in food intake, weight, nutritional status, function and reductions in morbidity and mortality. Further details on the aims of the trials are recorded in Table 3.4.

3.4.5 ONS versus food fortification / snacks

There were five studies comparing ONS with food fortification/snacks, including three RCT [41, 108-110] and one non randomised intervention [117]. ONS included the use of multi-nutrient liquid supplements and bars. Food fortification included the use of enriched meals and food snacks. The aim of these studies (Table 3.4) was to examine the effects of the intervention on nutritional status [41, 109, 117], including BMI, and cognitive and behavioural measures [108].

3.4.6 ONS versus ONS

There were two studies that compared one type of ONS with another ONS, including one RCT [111] and one non RCT [118]. The RCT involved the use of two supplements, one containing 1.3g oligosaccharides and the other containing no oligosaccharides [111]. The non RCT involved the use of multinutrient liquid supplements containing either 14% or 24% protein [118]. The aim of both studies was to aid pressure ulcer healing.

3.4.7 Dietary advice versus control

No studies were identified that investigated the use of dietary advice versus a control group in care homes.

Table 3.3 Characteristics of included studies, including the type of study, Jadad score, number of subjects, presence of Alzheimer's, malnutrition, and setting, according to the type of nutritional intervention.

Study	Type of Study	Quality – Jadad components	Total Jadad score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)		Setting
Food Fortification versus Control									
Beck et al., 2002	RCT	10001	2	66	Not recorded	No	M + NM	Yes MNA<23.5 + BMI<24kg/m^2	NH
Castellanos et al., 2009	Randomised cross over	10001	2	33	26	Not recorded	M + NM	Not specified Mean BMI 25.1 ± 3.6kg/m^2	NH
Kwok et al., 2001	RCT	10001	2	47	47	No	M+ NM	BMI<27 for inclusion Mean BMI 19.1 ± 3.1kg/m^2 (I) 20.1 + 3.1kg/m^2 (c)	NH
Simmons et al., 2008	RCT	11001	3	173	124	Yes	M + NM	BMI < 20kg/m^2 =undernutrition 14-20% undernourished	NH
Smoliner et al., 2008	RCT	10001	2	65	52	No	M	MNA<23.5 63 at risk 3 malnourished	NH

Study	Type of Study	Quality – Jadad components	Total Jadad score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)		Setting
Food Fortification versus Control									
Carlsson et al., 2009	Non randomised (Pilot)	C		15	13	Yes	NM	Not specified Mean BMI 26.2kg/m^2	RH
Christensson et al., 2001	non randomised	C		14	11	Not recorded	M	Yes Weight index %< 80%, TSF<6mm women, <12mm men, AMC, Serum proteins	CH
Odlund Olin et al., 2003	non randomised	B		35	35	Not recorded	NM	Not specified Mean BMI: 22.7 (20.1–24.4)kg/m^2 (l) 23.5 (20.0–26.8)kg/m^2 (c)	NH

	Type of Study	Quality – Jadad components	Total Jadad score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)		At risk of Malnutrition? (Y/N)	Setting
ONS versus Control									
Fiatarone Singh et al., 2000	RCT	10110	3	50	50	No	NM	Not specified: Mean BMI 25.4±0.7kg/m^2(I) 25.6 ± 0.5kg/m^2 (c)	NH
Gil Gregorio et al., 2003	RCT	10000	1	99	Not recorded	Yes	M + NM	Yes ± No MNA	NH
Johnson et al., 1993	RCT	10001	2			No		Yes + No	NH
Lauque et al., 2000	RCT	10001	2	88	78	No	M + NM	According to MNA score: >24 = 19 17–23.5 = 41 <17 = 19	NH
Lee et al., 2006	RCT	11111	5	89	71	Not recorded	M + NM	Not specified: Mean BMI 27 ± 8.8kg/m^2(I) 27 ± 7.9kg/m^2 (c)	LTCF
Manders et al., 2009	RCT	10111	4	176	111	No	M + NM	Not specified: Mean BMI 25.3 ± 3.6kg/m^2 (I) 25.0 ± 3.5kg/m^2 (c)	NH + RH

Study	Type of Study	Quality – Jadad components	Total Jadad score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)		Setting
ONS versus control									
Manders et al., 2009	RCT	10111	4	176	111	No	M + NM	Not specified: Mean BMI 25.3±3.6kg/m^2(I) 25.0 ± 3.5kg/m^2 (c)	NH + RH
Wouters-Wesseling et al., 2002	RCT	10111	4	42	35	Yes	M + NM	Yes: BMI < 23kg/m^2 for men and <25kg/m^2 for women: Mean BMI: 20.7±3.2kg/m^2(I) 20.7 ± 2.7kg/m^2 (c)	NH
Young et al., 2004	RCT	10001	2	34	31	Yes	M + NM	Not specified: Mean BMI 23.8 ± 3.6kg/m^2	CH

Study	Type of Study	Quality – Jadad components	Total Jadad score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)		Setting
ONS versus control									
Faxen-Irving et al., 2002	non randomised	B		36	33	Yes	M + NM	Yes – According to Nutrition Index Score (BMI, TSF, AMC, Albumin, Transferrin, IGF-1) 11/31 – no risk 20/58 – at risk 4/11 – PEM	RH
Harrill et al., 1982	Non randomised	C		18	18	No		Not recorded	NH
Heyman et al., 2008	Non randomised	C		245	245	No		Not specified Mean weight – 61.3 ± 15.5kg	NH

	Type of Study	Quality – JADAD components	Total JADAD score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)	Setting
Food Fortification versus ONS								
Parrott et al., 2006	RCT	10001	2	34	30	Yes	M + NM	Not specified Mean BMI 23.7 + 3.8kg/m^2 3 subjects BMI<20kg/m^2 19 subjects BMI 20-24kg/m^2	CH
Welch et al., 1991	Non randomised	C		15	15	No		Below average body weight established using Master et al (1960) tables	NH
Turic et al., 1998	RCT	11001	3	68	50	No	M	Yes – according to Omnibus Budget Reconciliation Act (1987) (10% wt loss in 6 months or 5% in the previous month, or current wt <90% of ideal wt) Mean BMI 20.6 ± 3.8kg/m^2 (snack) 20.0 ± 3.42kg/m^2 (ONS) All subjects had 6-7lbs wt loss in 6 months	LTCF

	Type of Study	Quality – JADAD components	Total JADAD score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)		At risk of Malnutrition? (Y/N)	Setting
Food Fortification versus ONS									
Wouters-Wesseling et al., 2006	RCT	10001	2	34		Yes	M + NM	Yes – BMI<23kg/m^2 (men) <25 (women) Mean BMI 20.7 ± 2.7kg/m^2 (c) 20.7 ± 3.2kg/m^2 (I)	NH
Young et al., 2005	RCT	10001	2	34	31	Yes	M + NM	Not specified Mean BMI 23.7 ± 3.8kg/m^2 3 subjects BMI<20kg/m^2 19 subjects BMI 20-24kg/m^2	CH

	Type of Study	Quality – JADAD components	Total JADAD score	Total N (start)	Total N (end)	Alzheimer's? (Y/N)	At risk of Malnutrition? (Y/N)		Setting
ONS versus ONS									
Breslow et al., 1993	Non randomised	B		28	28	No	M + NM	Serum albumin<35g/L, body weight>10% below the midpoint of weight range recommended by an age specific body weight table (Andres et al, 1985) Mean BMI 22 ± 4kg/m^2 (14% protein ONS) 20 ± 4kg/m^2 (24% protein ONS)	NH
Schriffin et al., 2007	RCT	10110	3	74	74	Not recorded	M	Yes MNA<23.5	FL + NH

B = Non randomized trials were categorised as non randomised controlled trials (systematic allocation, non-random, concurrent trials), C = prospective, non randomised, non controlled trials, Food fortification (FF), Oral nutritional supplements (ONS), Randomised controlled trial (RCT), Malnourished (M), Not malnourished (NM), Body mass index (BMI), Mini Nutritional Assessment (MNA), Triceps skinfold (TSF), Arm muscle circumference (AMC), Weight (Wt), Intervention (I), Control (c), Free Living (FL), Residential (RH), Nursing (NH), Care Home (CH), Long term care facility (LTCF)

Table 3.4 Aims and intervention details of the included studies, according to the type of nutritional intervention

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus control					
Beck et al., 2002	RCT	To examine the effect of a homemade oral supplement on body weight and energy intake	2 months	Homemade oral supplement: 200mls provided 240kcal, including 73% energy from fat and 5% from protein	Normal diet
Castellanos et al., 2009	Randomised cross over	To determine whether energy and protein enhancement of a small number of menu items would result in increased three meal calorie and protein intakes	4 days	Each subject tested under 3 menu conditions, on two non sequential menu days (Tuesday and Thursday) Meals were enhanced through the addition of fats (margarine, high fat dairy, eggs) and sugar to increase energy and protein content of meals Enhancement options: 1. Only lunch enhanced (additional 222kcal at lunch) 2. Breakfast and Lunch enhanced; Both meals enhanced (additional 482 kcal) For data analysis pt's assigned to small eater (<1150kcal) (n=12) or bigger eater (>1150kcal) (n=14)	No meals enhanced (Breakfast 675kcal, Lunch 875kcal, Dinner 730kcal served)

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus control					
Kwok et al., 2001	RCT	To investigate whether a low lactose milk powder would be better tolerated in Chinese nursing home residents and result in improvements in nutritional intake, without reducing habitual intake	7 weeks	25g Milk powder (87.5kcal, 9.4g protein, plus a range of micronutrients) twice daily	Normal diet
Simmons et al., 2008	RCT	To examine the effect of a feeding assistance intervention on food and fluid intake and body weight	52 weeks	Cross-over controlled study Intervention 24 weeks, 2 groups 1. Mealtime feeding assistance (individual feeding assistance, proper positioning for eating, compliance with dining location, optional meal tray substitutions) 2. Between meal snack (Snacks given at 10am, 2pm and 7pm. Offered a variety of foods, including juices, yogurts, ice cream, fresh fruit, puddings, pastries, cheese or peanut butter crackers)	Normal diet

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus control					
Smoliner et al., 2008	RCT	To examine the effect of fortified food on nutritional and functional status in nursing home residents at risk of malnutrition	12 weeks	Food Fortification (Standard diet + protein + energy enriched soups and sauces + 2 additional high energy and protein snacks) Protein powder was added to soups (5g protein powder per 100ml), rapeseed oil to sauces (5g oil per 100ml), milk based snacks were served in 150ml cups (300kcal, 20g protein (including 15g added protein powder), 20g fat and 20g carbohydrates)	Standard diet (2000kcal, 80g protein, 60g fat, 260g CHO)

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus control					
Young et al., 2005	RCT	To examine the effect of changing meal composition, by increasing the carbohydrate content, on food intake, weight and functional outcomes	6 weeks	Cross over intervention Phase 1; Normal diet Phase 2; High CHO dinner or mid morning supplement Phase 3; Normal diet Phase 4; High CHO dinner or mid morning supplement High CHO = 1 container of juice, 1 slice of bread with jam, 1 bowl of hot or cold cereal, 1 hard boiled egg, one half of a muffin, one half of a fruit Danish, one half of a slice of either cheddar or mozzarella, one half of a banana, coffee or tea, fruit dessert CHO dinner = 733kcal, 25g protein, 112g CHO, 24g fat	Usual dinner = 730kcal, 27g protein, 90g CHO, 31g fat
Carlsson et al., 2009	Pilot intervention	To examine the effect of consuming a drinkable yogurt on bowel movements and body weight	6 months	Drinkable yogurt (200mls, 140kcal, 6g protein) given daily + normal food	

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus control					
Christensson et al., 2001	non randomised	To examine the effect of providing a mid morning supplement on energy intake, body weight, cognitive and behavioural function	12 weeks	Individual food plan based on individual energy requirement	
Odlund Olin et al., 2003	non randomised	To investigate whether the addition of natural energy dense ingredients to a standard diet would improve voluntary energy intake and ability to perform ADL's	15 weeks	Meals fortified with natural energy dense ingredients e.g. butter and cream Aim for total energy intake of 2100kcal/day	Standard meals 1600kcal/day

Study	Type of Study	Aim	Duration	Intervention	Control
ONS versus control					
Fiatarone Singh et al., 2000	RCT	To investigate the effect of the addition of multi-nutrient oral supplements on the diet of frail elders, and whether ONS would improve their overall nutritional status and functional level	10 weeks	1 x 240mls multi-nutrient liquid supplement daily (360kcal with 60% carbohydrate, 23% fat and 17% protein, one third of the recommended daily allowance for vitamins and minerals)	1 x 240ml Placebo drink daily (non-nutritive liquid)
Gil Gregorio et al., 2003	RCT	To investigate the nutritional status and effect of an intervention with nutritional supplements on morbidity and mortality after a 1 year follow up	12 months	Multi-nutrient liquid supplement (Nutrison, 125kcal, 7.5g protein per 100ml) Volume was not specified	Normal diet

Study	Type of Study	Aim	Duration	Intervention	Control
ONS versus control					
Johnson et al., 1993	RCT	To determine why elderly nursing home patients received liquid oral protein supplements, what nutritional assessment was utilised and whether there was evidence of effectiveness		Retrospective case-control 1. Oral nutrition supplements	Non supplemented residents
Lee et al., 2006	RCT	To compare PUSH scores at 8 weeks in long term care residents with pressure ulcers who were given standard care plus a concentrated, fortified, collagen protein hydrolysate supplement vs. standard care with a placebo	8 weeks	1.5 fluid ounce (15g of fully hydrolysed protein) orally or via feeding tube 3 x daily	1.5 fluid ounce of placebo orally or via feeding tube 3 x daily

Study	Type of Study	Aim	Duration	Intervention	Control
ONS versus control					
Lauque et al., 2000	RCT	To investigate the effect of a nutritional intervention with ONS on dietary intake, anthropometry, hand grip and MNA	60 days	MNA 17-23.5 = oral supplement MNA <17 = oral supplement Supplement = 300-500kcal, 7.5-15g protein, 4 types of ONS offered	MNA >24 = no oral supplementation MNA 17-23.5 = no oral supplement
Manders et al., 2009	RCT	To determine whether nutritional supplementation in the institutionalised elderly has a positive effect on dietary intake and nutritional status	24 weeks	2 x 125mls nutrient dense drink daily (125mls: 250kcal, 8.75g protein, 11.25g fat, 28.5g carbohydrate, 4.5g fibre, and a range of vitamins and minerals)	placebo drink (2 x 125ml, no energy)
Manders et al., 2009	RCT	To determine whether a nutrient dense drink has a positive effect on mental and physical function	24 weeks	2 x 125mls nutrient dense drink daily (125mls; 250kcal, 8.75g protein, 11.25g fat, 28.5g carbohydrate, 4.5g fibre, and a range of vitamins and minerals)	placebo drink (2 x 125ml, no energy)

Study	Type of Study	Aim	Duration	Intervention	Control
ONS versus control					
Wouters-Wesseling et al., 2002	RCT	To evaluate the acceptance of a multinutrient liquid supplement and its effect on weight, plasma nutrients and ADL's	12 weeks	2 x 250mls Multinutrient liquid supplement daily (250mls; 272kcal, 8.5g protein)	Placebo (2x 250mls 0kcal)
Young et al., 2004	RCT	To investigate whether the provision of a mid-morning nutrient supplement increases the habitual intake of seniors with Alzheimer's Disease and whether body weight, cognitive and behavioural function responds to the intervention.	12 weeks	4 phase trial: 1. 21 day normal diet 2. 21 day supplement (3/4 of nutrient supplement bar and a glass of juice (258kcal, 11g protein) OR 1x200mls Ensure (250kcal, 9g protein)) 3. 21 day normal diet (washout) 4. 21 day alternate dinner choices (not reported)	

Study	Type of Study	Aim	Duration	Intervention	Control
ONS versus control					
Faxen-Irving et al., 2002	non randomised	To investigate the nutritional status and effect of ONS on body weight, cognition and ADL's	5 months	2 x 200ml ONS (1x Juice ONS 170kcal, 8g protein, 1 x balanced ONS 240kcal, 10g protein) Staff given training on nutrition and diet	No ONS, no education
Harrill et al., 1982	Controlled trial	To investigate the effect of ONS on dietary intake and nutritional status	30 days	236mls Ensure Plus liquid supplement daily (355kcal, 13g protein, 12.6g fat, 47.3g carbohydrate, plus a range of vitamins and minerals)	No control group
Heyman et al., 2008	Controlled trial	To investigate the effect of ONS and standard care on the healing of pressure ulcers	9 weeks	ONS + standard pressure ulcer care in addition to normal diet or enteral feed 3 x 200mls ONS daily (250kcal 20g protein, arginine, vitamin C, vitamin E and zinc)	No control group
ONS versus ONS					
Schriffin et al., 2007	RCT	To investigate the effect of oral nutritional supplements on malnutrition risk	12 weeks	Daily liquid supplements, with (1.3 g/250 ml) and without oligosaccharides (OS)	No control group
Breslow et al., 1993	Controlled trial	To evaluate the effect of dietary protein on the healing of pressure ulcers	8 weeks	3 x 240mls ONS daily containing either 14% or 24% protein.	No control group

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus ONS					
Parrott et al., 2006	RCT	To determine whether an increase in caloric intake associated with the consumption of a mid-morning nutritional supplement for 3 weeks was maintained in the week after stopping the supplement and the effect on BMI and cognitive and behavioural measures	6 weeks	ONS in the form of bars or liquid, containing 250 to 258kcal	Normal diet
Turic et al., 1998	RCT	To investigate the effect of ONS on nutritional status	6 weeks	Supplement (3x8oz daily, 300kcal, 15g protein, 40g carbohydrate, 9g fat, 4.0g fibre, 25% RDI for all vitamins and minerals)	standard diet + 3 snacks
Wouters-Wesseling et al., 2006	RCT	To investigate the effect of early use of ONS on weight loss in acute illness	5 weeks	200ml liquid nutrition supplement daily	Standard treatment (enriched food after dietitian referral)

Study	Type of Study	Aim	Duration	Intervention	Control
Food fortification versus ONS					
Young et al., 2005	RCT	To determine whether an increase in caloric intake associated with the consumption of a mid-morning nutritional supplement for 3 weeks was maintained in the week after stopping the supplement and the effect on BMI and cognitive and behavioural measures	6 weeks	cross over intervention 3 week, daily, nutrition supplement	3 week, daily, snack supplement
Welch et al., 1991	Intervention	To investigate the change in nutritional intake and status with a pureed diet and commercial ONS	6 months	non randomised Pureed diet and commercial supplements	

RCT – Randomised controlled trial, ADL – Activities of daily living

Table 3.5 Outcomes measured by the included studies, split according to the type of nutritional intervention

Study	Study Type	Duration	QoL	ADL	Healthcare use	Infections	Mortality	Handgrip	Anthro-pometry	Nutritional Status	Nutrient Intake	Primary Outcome
Food fortification versus Control												
Beck et al., 2002	RCT	2 months								*	*	Weight EI
Castellanos et al., 2009	RCT	4 days								*	*	EI, PI
Kwok et al., 2001	RCT	7 weeks		*				*	*	*		NI
Simmons et al., 2008	RCT	52 weeks								*	*	Weight NI
Smoliner et al., 2008	RCT	12 weeks	*	*				*	*	*	*	NI Function
Carlsson et al., 2009	non-RCT	6 months								*	*	Weight
Christensson et al., 2001	non-RCT	12 weeks		*					*	*		Weight EI Function
Odlund Olin et al., 2003	non-RCT	15 weeks		*						*	*	EI ADL

QoL – Quality of Life, RCT – Randomised Controlled Trial, NI – Nutritional Intake, EI – Energy intake, PI – Protein Intake, ADL – Activities of Daily Living, PU – Pressure Ulcers

Study	Study Type	Duration	QoL	ADL's	Health-Care use	Infections	Mortality	Hand grip	Anthro-pometry	Nutritional Status	Nutrient Intake	Primary Outcome
ONS versus Control												
Fiatarone Singh et al., 2000	RCT	10 weeks								*	*	ADL's, Weight, BMI, EI
Gil Gregorio et al., 2003	RCT	12 months				*	*		*			Morbidity Mortality
Lee et al., 2006	RCT	8 weeks								*	*	PU
Lauque et al., 2000	RCT	60 days						*	*	*	*	NI Anthro-pometry Handgrip Nutritional status
Manders et al., 2009	RCT	24 weeks		*					*	*	*	NI Nutritional status
Manders et al., 2009	RCT	24 weeks		*						*	*	Function
Wouters-Wesseling et al., 2002	RCT	12 weeks		*						*	*	Weight ADL's
Young et al., 2004	RCT	12 weeks								*	*	Weight Function

Study	Study Type	Duration	QoL	ADL's	Health-Care use	Infections	Mortality	Hand grip	Anthro-pometry	Nutritional Status	Nutrient Intake	Primary Outcome
ONS versus Control												
Faxen-Irving et al., 2002	non-RCT	5 months		*						*	*	Weight ADL's Cognition
Harrill et al., 1982	non-RCT	30 days								*	*	NI Nutritional status
Heyman et al., 2008	non-RCT	9 weeks								*	*	PU
Johnson et al., 1993	non-RCT					*	*			*		Nutritional status

QoL - Quality of Life, RCT - Randomised controlled trial, NI - Nutritional intake, EI - Energy intake, PI - Protein Intake, ADL - Activities of daily living

Study	Study Type	Duration	QoL	ADL's	Health – Care use	Infections	Mortality	Hand grip	Anthro-pometry	Nutritional Status	Nutrient Intake	Primary Outcome
ONS versus ONS												
Schriffin et al., 2007	RCT	12 weeks								*	*	Nutritional status
Breslow et al., 1993	non-RCT	8 weeks								*	*	PU

QoL – Quality of Life, RCT – Randomised Controlled Trial, NI – Nutritional Intake, EI – Energy Intake, PI – Protein Intake, ADL – Activities of Daily Living, PU – Pressure Ulcers

Study	Study Type	Duration	QoL	ADL's	Health-Care use	Infections	Mortality	Hand grip	Anthro-pometry	Nutritional Status	Nutrient Intake	Primary Outcome
Food fortification versus ONS												
Turic et al., 1998	RCT	6 weeks								*	*	Nutritional status
Wouters-Wesseling et al., 2006	RCT	5 weeks							*	*	*	Weight
Parrott et al., 2006	RCT	6 weeks								*		Nutritional status Function
Young et al., 2005	RCT	12 weeks								*		Weight NI Function
Welch et al., 1991	non-RCT	6 months									*	NI Nutritional status

QoL – Quality of Life, RCT – Randomised Controlled Trial, NI – Nutritional Intake, EI – Energy Intake, PI – Protein Intake, ADL – Activities of Daily Living

3.5 Results

3.5.1 Quality of Life

Only one study included in the review reported changes in quality of life [76].

3.5.1.1 Food fortification versus control

One study comparing food fortification with standard care recorded quality of life in malnourished residents without dementia [76]. Using the SF-36 physical disability dimension they found the score decreased significantly in both the intervention group (17.1 ± 22.7 to 10.7 ± 15.6, p=0.047) and the control group (24.0 ± 24.3 to 13.6 ± 13.9, p=0.001), however the difference between groups was not significant.

3.5.1.2 ONS versus control

No studies comparing ONS with standard care measured quality of life.

3.5.1.3 ONS versus ONS

No studies comparing one type of ONS with another ONS measured quality of life.

3.5.1.4 Food fortification versus ONS

No studies comparing food fortification with ONS measured quality of life.

3.5.2 Activities of Daily Living

Seven studies reported activities of daily living (ADL's), using a variety of tools, with there being insufficient data for statistical analysis. This included four RCTs [73, 76, 77, 106] and three non RCTs [113-115].

3.5.2.1 Food fortification versus ONS

Three studies measured activities of daily living in malnourished residents, using a variety of tools, with results differing according to the tool used [76, 113, 114]. This included one RCT [76] and two non RCTs [113, 114]. Using the Barthel's Index (0-100 scale) [76], activity levels remained the same in the intervention group (57.0 ± 27.0) but decreased significantly in the control group (58.0 ± 29.0 to 51.0 ± 31.0, p=0.001) over 12 weeks. Using the RAI-ADL [114], activity levels decreased in the intervention group (16.0 (14.0 to 18.0) to 15.0 (14.0 to 18.0)) but not to a level of significance, and increased significantly in the control group (15.5 (10.0 to 17.0) to 16.0 (15.0 to 18.0), p<0.001). Using the Activity Index Score [113], activity levels increased significantly (67 (33 to 90) to 72 (34 to 92), p<0.01) over 12 weeks.

3.5.2.2 ONS versus Control

Four studies (Three RCT's [73, 77, 106] and one non RCT [115]) comparing ONS with standard care measured activities of daily living in both malnourished and non malnourished residents, using either the Katz ADL score [73, 115] or the Barthel's Index [77, 106]. Using the Katz ADL score with nursing home residents, the randomized controlled trial by Fiatarone Singh et al., 2000 found increasing levels of dependency in both groups over a 10 week period, with a slightly greater increase in the ONS group compared with control (1.96 ± 0.33 to 2.27 ± 0.36 versus 1.72 ± 0.2 to 1.92 ± 0.22, p<0.05). A further non randomised study by Faxen Irving et al., 2002 conducted in residents with dementia found that ADL's decreased significantly over five months within both the intervention (E (A-G) to F (B-G), p=0.078) and control groups (D (A-G) to E (B-G), p=0.093). Using the Barthel's Index with residents without dementia, neither of the two studies reported any changes in ADL's either within or between groups over 12 weeks [77] and 24 weeks [106].

3.5.2.3 ONS versus ONS

No studies reported activities of daily living

3.5.2.4 Food fortification versus ONS

No studies reported activities of daily living

3.5.3 Handgrip

Three RCTs reported changes in handgrip, with two studies comparing food fortification with a control [72, 76] and one comparing ONS with a control [106].

3.5.3.1 All interventions

The RCTs were not amenable to meta-analysis, however analysis using a paired t-test found a non-significant change in handgrip strength of 0.6 ± 0.4kg, p=0.122 over a seven to twelve week period among a combination of malnourished and non malnourished residents [72, 76, 106].

3.5.3.2 Food fortification versus control

Neither of the two food fortification versus control RCTs reported significant changes in handgrip strength [72, 76]. Smoliner et al., 2008 compared food fortification with standard care in malnourished residents without dementia. Over 12 weeks, handgrip in the intervention group showed a small, non-significant change of 0.2kg (14.1 ± 6.3kg to 13.9 ± 6.1kg), but in the control group there was a significant decrease of 0.8kg (13.0 ± 6.4kg to 12.2 ± 6.3kg, p=0.030), however the difference between groups was not significant. Kwok et al., 2001 compared the use of milk powder with standard care in frail older Chinese nursing home residents. There were reductions in handgrip in both groups. Although the reduction was greater in the control group than the intervention (-0.5kg versus 0.3kg), the difference was not significant.

None of the non randomised control trials either measured or reported handgrip strength.

3.5.3.3. ONS versus control

Only one ONS versus control trial reported changes in handgrip. The study by Manders et al., 2009 compared the use of ONS with a placebo drink in a population of both malnourished and non-malnourished care home residents over 24 weeks. There was a non-significant reduction in handgrip in both groups , with the intervention groups handgrip decreasing by 0.5 ± 3.5kg compared with a reduction of 1.5 ± 3.8kg in the control group [106].

None of the non-randomised control trials reported handgrip strength.

3.5.3.4 ONS versus ONS

No studies comparing one type of ONS with another type of ONS measured handgrip.

3.5.3.5 Food fortification versus ONS

No studies comparing food fortification with ONS measured handgrip.

3.5.4 Infections

Only one RCT within this review reported infection rates [78].

3.5.4.1 Food fortification versus control

No studies comparing food fortification with a control group reported infections.

3.5.4.2 ONS versus control

A significant reduction in infection rate amongst malnourished and non malnourished residents with dementia taking ONS was reported by Gil Gregorio et al., 2003. Over one year, the infection rate was significantly lower in the intervention group compared with the control group (47% versus 66%, p=0.05) [78]. In the ONS group 53% had no infections and 47% had one infection, whereas in the control group 44% had no infections, 21% had one infection, 30% had two infections and 15% had greater than three infections, (p=0.001 Chi squared test (calculated using published data)) [78].

3.5.4.3 ONS versus ONS

No studies comparing one type of ONS with another type of ONS reported infections.

3.5.4.4 Food fortification versus ONS

No studies comparing food fortification with ONS reported infections.

3.5.5 Pressure Ulcers

Three studies reported pressure ulcers, including one RCT [105] and two non RCTs [116, 118].

3.5.5.1 Food fortification versus control

No studies comparing food fortification with a control group reported pressure ulcer incidence.

3.5.5.2 ONS versus control

One RCT by Lee et al., 2006 reported a significantly higher rate of healing in care home residents with pressure ulcers over eight weeks in favour of the ONS group at two, six and eight weeks (change in pressure ulcer score at eight weeks; 5.56 versus 2.85, $p<0.05$), however baseline scores were significantly higher in the intervention group [105].

A non randomised trial of care home residents with pressure ulcers also reported a significant reduction in pressure ulcer area (53%) over a nine week period of supplementation [116]. In nine weeks, the mean pressure ulcer area decreased from 1580 ± 3743mm^2 to 743 ± 1809mm^2 ($p<0.0001$).

3.5.5.3 ONS versus ONS

The study by Breslow et al., 1993 found that the higher percentage protein formula resulted in significant reductions in pressure ulcer size both for all ulcers (28.6 ± 38.1cm^3 to 24.4 ± 36.7cm^3, $p<0.02$) and stage four pressure ulcers (42.6 ± 47.3cm^3 to 35.0 ± 45.0cm^3, $p<0.02$), with there also being a significant difference between the lower and higher percentage protein supplement groups for stage four pressure ulcer healing (14% protein; 26.6 ± 34.4cm^3 to 23.5 ± 20.9cm^3 vs 24% protein; 42.6 ± 47.3cm^3 to 35.0 ± 45.0cm^3, $p<0.05$) [118].

3.5.5.4 Food fortification versus ONS

No studies comparing food fortification with ONS reported pressure ulcer incidence.

3.5.6 Days in bed

Only one RCT within this review reported days in bed [78].

3.5.6.1 Food fortification versus control

No studies comparing food fortification with a control group reported days in bed.

3.5.6.2 ONS versus control

One RCT comparing ONS with a control group reported days in bed, with there being a significant reduction in days in bed over one year, in favour of the ONS group (7.5 ± 2.1 days versus 17.3 ± 5.6 days, $p<0.001$ (calculated using published data)), [78].

3.5.6.3 ONS versus ONS

No studies comparing one type of ONS with another type of ONS reported days in bed.

3.5.6.4 Food fortification versus ONS

No studies comparing food fortification with ONS reported days in bed.

3.5.7 Mortality

Only one RCT included in this review reported mortality [78].

3.5.7.1 Food fortification versus control

No studies comparing food fortification with standard care recorded mortality rates.

3.5.7.2 ONS versus control

Only one RCT comparing ONS with a control group reported a non significant reduction in mortality over one year, in favour of the ONS group (16% versus 22%). However, the study was underpowered with respect to this outcome variable [78].

3.5.7.3 ONS versus ONS

No studies comparing one type of ONS with another type of ONS recorded mortality rates.

3.5.7.4 Food fortification versus ONS

No studies comparing food fortification with ONS reported mortality rates.

3.5.8 Energy intake

Ten trials reported changes in energy intake, including five RCTs and five non RCTs. The five RCTs that reported changes in energy intake, included three ONS versus control studies [73-75], one food fortification versus control study [72] and one ONS versus snacks [41]. A further study [120] involving food fortification had a complex study design and was difficult to interpret (see below). The five non randomised interventions included two food fortification trials [112, 114], one ONS trial [119], one ONS versus ONS trial [118] and one food fortification versus ONS trial [117].

3.5.8.1 All interventions

In studies in which an intervention was compared to a control group [72-75], the change in energy intake favoured the intervention group in all studies (significant in three of the four trials [73-75]). The difference between groups ranged from 48kcal [73] to 257kcal [74] over seven weeks [72] to 24 weeks [75].

Four studies were amenable to meta-analysis, including one food fortification versus control trial [72] and three ONS versus control trials [73-75]. The trials ranged from 60 days to 24 weeks in duration and included a mixture of malnourished and non malnourished residents. The mean difference between the groups was 123.2kcal (SE 15.9, 95%CI 92 – 154kcal; $I^2 = 0.000$, $p < 0.0001$), in favour of the intervention (Figure 3.2).

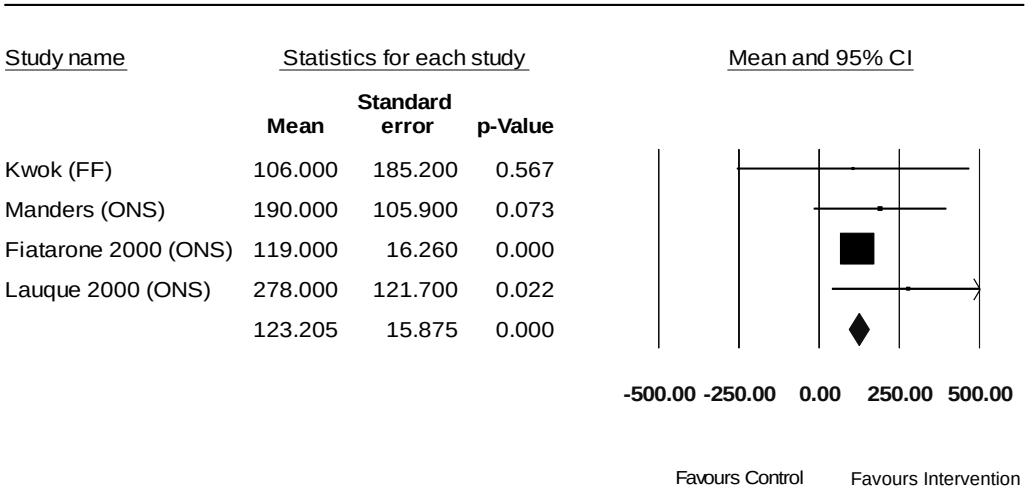


Figure 3.2 Meta-analysis of mean daily energy intake (kcal) in four nutrition intervention trials

FF = Food Fortification, ONS = Oral Nutritional Supplement

3.5.8.2 Food fortification versus control

Two randomised [72, 120] and two non randomised control trials [112, 114] reported changes in energy intake, and are considered in turn. A significant increase in energy intake in favour of food fortification was reported in one RCT [120] and one non RCT [114].

Kwok et al., 2002 fortified both malnourished and non-malnourished residents' drinks with milk powder over a seven week period. The study found small, non significant changes in energy intake, with the intervention groups' mean intake increasing slightly and the control groups' intake decreasing slightly with no significant difference between them (Intervention: 1099 ± 368kcal to 1182 ± 367kcal, Control: 1198 ± 403kcal to 1175 ± 476kcal, non significant difference between groups) [72].

A further RCT by Beck et al., 2002, which was not suitable for inclusion into meta-analysis reported a significant median change in energy intake of 1.6MJ/d (0 to 2.1MJ/d, $p<0.001$) among residents with a MNA score less than 17 that received a homemade supplement drink for two months. The control groups intake increased by a median of 0.1MJ/d (-0.7 to 2.0MJ/d) over the two month period. The increase in overall energy intake in those residents with a MNA score less than 17 occurred without suppression of habitual food intake. The homemade drink provided a median intake of 1.5MJ/d (1.3 to 1.6MJ/d). However, homemade supplement drinks were also given to a second group of residents with MNA scores between 17 and 23.5. In this group of residents at risk of malnutrition, their overall energy intake decreased by 0.1MJ/day (-1.9 to 3.6MJ/d) during the intervention period, suggesting that drinks suppressed their food intake with the addition of ONS to their diet. Their median intake from the homemade supplement was 1.57MJ/d (0.15 to 1.6MJ/d) during the intervention [120].

Two non randomised trials [112, 114] in non malnourished residents recorded changes in energy intake with food fortification, however only one trial included a control group. The study without a control group [112] reported a small, non-significant decrease in energy intake over six months (1454 ± 304kcal to 1413 ± 264kcal) and the other [114] reported a significant increase in comparison with a control group over 15 weeks (Intervention; 1336kcal (1261 to 1578kcal) to 1840kcal (1497 to 2012kcal) $p<0.001$, Control; 1431kcal (1142 to 1564kcal) to 1437kcal (1252 to 1617kcal), $p<0.01$ between groups).

3.5.8.3 ONS versus control

Three RCTs reporting changes in energy intake when comparing ONS with a control or placebo group [73-75] were amenable to meta-analysis. These studies included both malnourished and non malnourished residents, with interventions ranging from 60 days to 24 weeks. The ONS ranged from 1.5kcal/ml to 2kcal/ml multinutrient liquid supplements (See Table 3.4 for further details on the types of ONS provided). The mean change in energy intake was 123.3kcal (SE 15.9, 95%CI 92 – 155kcal, p<0.0001, I^2 0.000), favouring ONS (Figure 3.3).

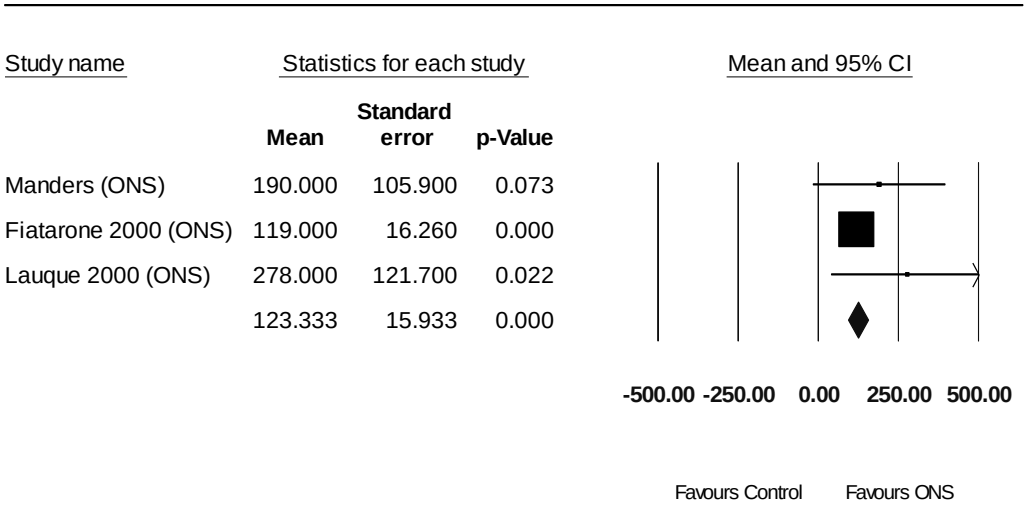


Figure 3.3 Meta-analysis of mean daily energy intake (kcal) in the ONS versus control trials.
ONS = Oral Nutritional Supplement

A non randomised trial of ONS [119] found a small, non-significant increase in energy intake over 30 days in care home residents with a food intake that was deemed to be less than normal at baseline (1665 ± 63kcal to 1673 ± 50kcal).

3.5.8.4 ONS versus ONS

Only one of the two studies investigating the use of different types of ONS reported energy intake. The non randomised study by Breslow et al., 1993 found that energy intake increased non-significantly between the groups over an eight week period in a population of malnourished and non malnourished care home residents with pressure ulcers. The 14% protein formula groups energy intake increased from 1822 ± 828kcal to 2080 ± 664kcal and

the group that received the 24% protein formula groups from 1886 ± 2073kcal to 2073 ± 900kcal [118].

3.5.8.5 Food fortification versus ONS

Two studies comparing food fortification with ONS reported changes in energy intake, including one RCT [41] and one non RCT [117]. Increases in energy intake were observed in malnourished residents receiving either ONS or snacks in the RCT by Turic et al., 1998. The increase in intake was significantly greater in the ONS group than the snack group over the course of the six week trial (ONS: 1296 ± 292kcal to 1888 ± 285kcal, Snack: 1228 ± 316kcal to 1545 ± 340kcal, $p<0.01$ between groups) [41].

In the non randomised study by Welch et al., 1991, residents energy intakes increased significantly over the six month intervention period (Intake as a percentage of the RDA for energy: Baseline: 85.7 ± 6.4%, Six months: 129.5 ± 4.9%, $p<0.0001$).

3.5.9 Protein intake

Eight studies reported changes in protein intake, including four RCTs and four non RCTs. The four RCTs included one food fortification versus control trial [72], two ONS versus control trials [74, 75] and one food fortification versus ONS trial [41]. The four non RCTs included one food fortification trial [114]), one ONS trial [119], one ONS versus ONS trial [118] and one food fortification versus ONS trial [117].

3.5.9.1 All interventions

The RCTs were not amenable to meta-analysis, however analysis of four studies using a paired t-test found mean changes in protein intake which were significantly greater in the intervention compared with the control (15.6 ± 6.9g, $p=0.020$) [72, 74, 75, 114].

3.5.9.2 Food fortification versus control

Two studies investigating the use of food fortification versus a control reported changes in protein intake. This included one RCT [72] and one non RCT [114], which are considered in turn.

One RCT reported non-significant changes in protein intake for malnourished and non malnourished residents over 17 weeks (Intervention: 55.6 ± 21.6g to 67.6 ± 23.9g, Control: 61.6 ± 22.0g to 63.5 ± 30.2g) [72].

A further 15 week non randomised trial [114] in non malnourished residents found increases in protein intakes amongst both the intervention and control groups, with the change being significant for the intervention group, but not the control group. Overall, the difference in protein intake between groups was not significant. (Intervention: 48.3g (41.8 to 54.3g) to 57.9 (46.2 to 61.2g) $p<0.001$, Control: 53.7g (42.7 to 58.7g) to 54.7g (47.0 to 59.9g), NS) [114].

3.5.9.3 ONS versus control

Three studies investigating the use of ONS versus a control reported changes in protein intake. This included two RCT [74, 75] and one non RCT [119].

The combined analysis of two ONS RCTs [74, 75] using a t-test found a non-significant increase in protein intake (mean change 16.7 ± 9.9g (9.7 to 23.7g, $p=0.253$)). The trials ranged from 60 days [74] to 24 weeks [75], involving both malnourished and non malnourished residents.

A non randomised trial by Harril et al., 1982 found that protein intake increased over 30 days, from 61.4 ± 2.8g to 67.6 ± 3.4g, however this increase was not significant.

3.5.9.4 ONS versus ONS

Only one trial reported change in protein intake [118]. Over 30 days the trial found a significant difference in protein intake between groups receiving a 14% protein formula and the 24% protein group, favouring the higher protein group (14% protein groups change in protein intake: -1 ± 32g, 24% protein groups change in protein intake: 28 ± 41g, $p<0.01$ between groups).

3.5.9.5 Food fortification versus ONS

Two studies reported changes in protein intake, including one RCT [41] and one non RCT [117]. The RCT by Turic et al., 1998 reported a significant mean change in protein intake of 19g between groups, favouring the supplement group ($p<0.001$) over a six week period in malnourished residents. In the non RCT by Welch et al., 1991 the protein intake increased significantly from 197.5 ± 14.0% to 291.7 ± 10.8% as a percentage of the RDA, $p<0.0001$.

3.5.10 Body weight

Twelve studies reported weight change including seven RCTs and five non RCTs. The seven RCTs included two food fortification versus control trials [72, 76], four ONS versus control trials [73-75, 77], and one food fortification versus ONS trial [110]. The five non RCTs included two food fortification trials [112, 113], one ONS trial [115], one ONS versus ONS trial [118] and one food fortification versus ONS trial [117].

All RCTs reported mean results for each group. Two of these trials did not report standard deviation of the change [72, 74], which meant that four RCTs (one food fortification [76], three ONS trials[73, 75, 77]) were suitable for meta-analysis. The control groups involved either routine care [76] or a placebo drink [73, 75, 77].

3.5.10.1 All interventions

All studies showed a mean weight change that was greater in the intervention than the control by 1.7 ± 0.7kg, $p=0.003$, paired t-test. There was a universal increase in weight in the intervention group and a weight loss in five out of the six control groups. Meta-analysis of four RCTs [73, 75-77] also resulted in a significant difference in weight change in favour of the intervention (1.32kg, SE 0.381, 95% CI 0.575 – 2.069, $p=0.001$, I^2 0.000) (Figure 3.4).

Figure 3.4 Meta-analysis of the mean weight change (kg) in four nutrition intervention trials

FF = Food Fortification, ONS = Oral Nutritional Supplement

3.5.10.2 Food fortification versus control

Four studies reported changes in weight, including two RCTs [72, 76] and two non RCTs [112, 113]. In the two RCTs comparing food fortification with a control group in malnourished residents, the mean weight change was in favour of the food fortification group [72, 76]. Meta-analysis was not possible since the standard deviation of the changes could not be established in one study. Neither of the studies showed significant differences between groups. Over a 12 week period, the study by Smoliner et al., 2008 reported that the weight change was 0.4kg greater in the food fortification group than the control group, ($p=0.557$). In the study by Kwok et al., 2001 weight increased in the fortification group from 42.94 ± 7.55kg to 44.39 ± 8.36kg and decreased in the control group from 46.73 ± 8.49kg to 46.39 ± 8.11kg over a seven week period.

There were two non randomised studies that recorded weight change, with varying results. Christensson et al., 2001 reported a significant increase in weight of 2.2kg (49.8kg (31.0-62.8kg) to 52.0kg (32.6 to 67.2kg), $p<0.05$) over 12 weeks in a group of 11 malnourished care home residents. In contrast, Carlsson et al., 2009 reported a significant decrease in weight of 3.9kg, $p<0.05$ over six months in a group of 13 non malnourished care home residents.

3.5.10.3 ONS versus control

Four ONS versus control studies reported changes in weight, including three RCTs [73, 75, 77] and one non RCT [115]. The three RCTs were amenable to meta-analysis, resulting in a significant change in weight, favouring the ONS group (1.74kg, SE 0.460, 95% CI 0.81 – 2.64, $p<0.0001$, I^2 0.000) (Figure 3.5). The trials included a combination of malnourished and non-malnourished residents, with trial duration ranging from 10 to 24 weeks.

Figure 3.5 Meta-analysis of the mean weight change (kg) in three ONS versus control trials
ONS = Oral Nutritional Supplement

One non randomised trial [115] reported significant weight changes over a five month period, in a mixture of malnourished and non-malnourished residents, with the weight change favouring the ONS group ($p=0.003$). The weight of residents within the intervention group increased significantly from baseline (3.4kg; from 55.4 ± 10.4kg to 58.8 ± 11.2kg, $p<0.001$) and decreased non significantly in the control group (0.3kg; 62.2 ± 8.2kg to 61.9 ± 10.4kg).

3.5.10.4 ONS versus ONS

One non randomised control trial [118] involving both malnourished and non-malnourished residents with pressure ulcers reported non-significant increases of 1kg in weight within both groups over an eight week period when using ONS with differing protein contents (14% protein group; 58 ± 12kg to 59 ± 14kg, 24% protein group; 56 ± 11kg to 57 ± 10kg).

3.5.10.5 Food fortification versus ONS

Two studies reported weight change, including one RCT [110] and one non RCT [117]. The RCT by Young et al., 2005 did not result in a significant change between groups in terms of body weight during the intervention, with weight increasing by 0.36 ± 1.12kg, p=0.076.

In the non RCT by Welch et al., 1991 weight increased significantly over the six month intervention period, with the mean weight change being 2.09 ± 0.91kg (p<0.04).

3.5.11 BMI

Seven studies reported mean BMI changes [72-74, 76-78, 115].

3.5.11.1 All interventions

All seven studies which reported BMI found greater BMI's in the intervention group than the control group. The overall change was 1.7 ± 1.1kg/m^2, p=0.015 (t-test). Two ONS versus control studies [73, 78], and one food fortification versus control study [76] were eligible for meta-analysis (Figure 3.6), resulting in a significant difference in BMI between the intervention and control groups (0.49kg/m^2, SE 0.148, 95% CI 0.19 – 0.78, p=0.001, I^2 0.000).

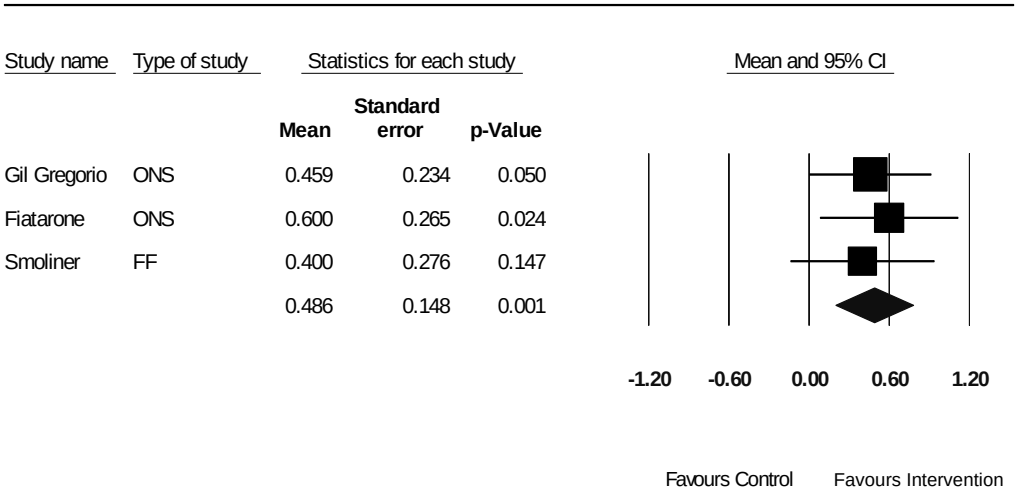


Figure 3.6 Meta-analysis of the mean change in BMI (kg/m^2) in three nutrition intervention trials. FF = Food Fortification, ONS = Oral Nutritional Supplement

3.5.11.2 Food fortification versus control

Two studies comparing food fortification with standard care measured BMI [72, 76] in residents without dementia who were at risk of malnutrition. These studies are considered in turn. In the 12 week RCT by Smoliner et al., 2008 BMI increased significantly in both the intervention (21.6 ± 3.6kg/m^2 to 22.4 ± 3.8kg/m^2, p=0.007) and control group (22.5 ± 3.4kg/m^2 to 22.9 ± 3.1kg/m^2, p=0.005), however the difference between groups was not significant.

Over seven weeks of supplementation with milk powder, the RCT by Kwok et al., 2001 reported non-significant changes in BMI between groups, however there was a trend for BMI to increase in the intervention group (19.12 ± 3.06kg/m^2 to 19.79 ±3.66 kg/m^2) and decrease in the control group (19.70 ± 2.91kg/m^2 to 19.57 ± 2.82kg/m^2).

3.5.11.3 ONS versus control

In all four RCT's comparing the effects of ONS with a control group, there was a significant difference between groups, favouring the interventions. Two of the trials were amenable to meta-analysis [73, 78], with there being a significant difference in BMI between the intervention and control groups (0.52kg/m^2, SE 0.175, 95% CI 0.17 – 0.87, p=0.003, I^2 0.000) (Figure 3.7). The shortest trial, covering 10 weeks [74] resulted in the most significant difference between groups (Intervention: 22.3 ±0.7kg/m^2 to 22.8 ±0.7kg/m^2, Control: 21.8 ± 0.9kg/m^2 to 21.3 ± 0.9kg/m^2, p<0.001 between groups). The 10 week RCT by Fiatarone et al., 2000 (Intervention: 25.9 ± 0.7kg/m^2 to 26.3 ± 0.8kg/m^2, Control 25.5 ± 0.6kg/m^2 to 25.3 ± 0.6kg/m^2, p=0.024 between groups) and the 12 week RCT by Wouters-Wesseling et al., 2002 (Intervention: 20.7 ± 3.2kg/m^2 to 21.2 ± 2.9kg/m^2 Control: 20.6 ± 2.7kg/m^2 to 20.4 ± 3.0kg/m^2, p<0.05 between groups) produced similar changes in BMI. The one year RCT by Gil Gregorio et al., 2003 also resulted in significant differences in BMI between groups (Intervention: +1.6kg/m^2, Control: -0.3kg/m^2, p=0.05 between groups).

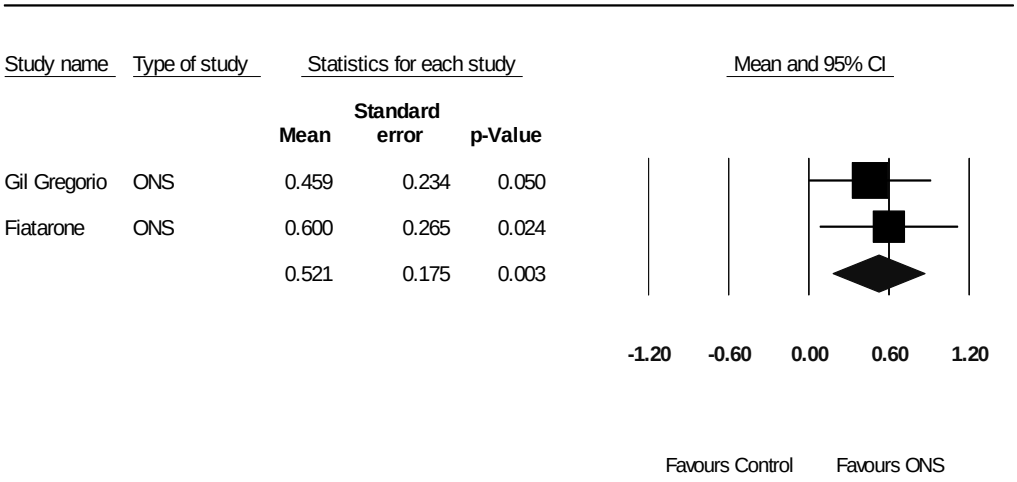


Figure 3.7 Meta-analysis of the mean change in BMI (kg/m^2) in two ONS versus control trials

ONS = Oral Nutritional Supplement

3.5.11.4 ONS versus ONS

No studies comparing ONS with another type of ONS recorded BMI.

3.5.11.5 Food fortification versus ONS

No studies comparing food fortification with ONS recorded BMI.

3.5.12 Anthropometry

Three studies reported changes in anthropometry, including two food fortification versus control studies [72, 113] and one ONS versus control study [78].

3.5.12.1 Food fortification versus control

Two studies reported changes in anthropometry, including one RCT [72] and one non RCT [113]. The study by Kwok et al., 2001 found no significant differences in triceps and biceps skinfolds and mid arm circumferences over seven weeks. In the non RCT by Christensson et al., 2001, both triceps skinfolds and arm muscle circumference were reported. Over a period

of 12 weeks, triceps skinfolds thickness increased from 7.5 (4.3 to 10.2)mm to 7.9 (5.0 to 13.8)mm, however this was not significant. Over the same period, arm muscle circumference increased significantly (19.5 (15.6 to 23.7)cm to 20.7 (16.6 to 24.5)cm, $p<0.05$).

3.5.12.2 ONS versus control

One study comparing ONS with control reported changes in biceps and triceps skinfolds over a period of one year of supplementation compared with a control group, in malnourished care home residents with dementia [78]. The biceps skinfold increased in the ONS group and decreased in the control group, however the difference between the groups was not significant (1.2cm versus -0.2cm). There was a significant difference between the groups with the triceps skinfolds measurements, with the ONS group increasing by 2.4cm and the control groups measurements decreasing by 1.5cm ($p=0.01$).

3.5.12.3 ONS versus ONS

No studies reported changes in anthropometry.

3.5.12.4 Food fortification versus ONS

No studies reported changes in anthropometry.

3.5.13 Compliance to the interventions

Compliance to interventions was high (85%), with interventions resulting in 29% to 34% suppression of habitual food intake (Table 3.6). However, only a very limited number of trials reported information on compliance (n=3), or suppression of food intake (n=3). Food fortification versus control studies did not provide any data that allowed compliance according to the quantity of fortified food provided, however one food fortification study provided data that allowed suppression of habitual intake to be calculated [114]. Two ONS versus control studies provided information on compliance to be calculated according to volume consumed [74, 77], and two studies provided information on suppression of food intake [74, 75]. One snacks versus ONS study provided information on both percentage consumed and suppression of food intake [41].

Table 3.6 Compliance to nutritional interventions

	Intervention	Compliance	Suppression of habitual food intake	
			A	B
Odlund Olin et al., 2003	Food vs. Control	No data	-1%	-2%
Lauque et al., 2000	ONS vs. Control	98%	35%	29%
Manders et al., 2009a	ONS vs. Control	No data	<50%	7.2%
Wouters Wesseling et al.,2002	ONS vs. Control	91%	No data	No data
Turic et al.,1998	ONS vs. Snacks	68%	No data	No data
Mean compliance		85%	29%	34%

3.6 Discussion

This review represents the first review of the evidence for investigating the use of nutritional interventions in both residential and nursing homes. It identified large variations in study designs, types of interventions and outcomes. Given that malnutrition is a common problem in care homes, the number of randomised controlled studies that have examined the impact of dietary advice (n=0), food fortification and ONS on any type of outcome, such as nutritional intake or functional and clinical outcomes, is surprisingly few (n=19). The lack of trials investigating the use of dietary advice in care homes was surprising given that dietary advice is a common first line therapeutic treatment for nutrition support which is provided by health professionals such as dietitians [66]. More RCTs examined the effect of ONS versus control than food fortification versus control, with the result that the evidence base, although generally weak, is stronger for ONS than food fortification.

3.6.1 Study characteristics

A detailed examination of the studies suggested that studies were set up for very different purposes. Some studies aimed to examine the effects of the intervention on treating malnourished residents [41, 76, 111, 113], whereas other trials aimed to prevent complications and/or deteriorating function associated with the potential development of disease related malnutrition [73-75, 77, 78, 105-108, 110, 112, 114-116, 118, 119], and in some cases this involved cluster randomisation according to care home [103] or ward [76, 107]. The duration of such studies ranged from 0.5 to one year, and appeared to involve non malnourished subjects, with or without malnourished subjects.

Using the Jadad system for scoring quality of papers [71], the majority scored two out of a possible five points, with only one paper scoring five out of five points for quality. The variable and generally poor quality of the studies coupled with differences in study design probably contributed to the different outcomes observed between studies.

The classification of malnutrition also varied between trials, making comparisons between trials more difficult. The inclusion of residents with dementia also varied between studies, potentially introducing the possibility for residents with dementia to have responded very differently to nutritional interventions, given their advancing disease.

The sample sizes of the included trials were also small, ranging from 11 to 111 care home residents. None of the trials included information as to whether sample size calculations had

been used in order to inform decisions on sample sizes required to achieve significant differences in outcomes measured. The duration of the trials also varied, from four days to one year. The wide variation in the duration of trials may explain why some functional and healthcare outcomes had not been measured in those trials of very short duration.
With such different groups of subjects and different aims, some of the results are probably better considered separately rather than together. For example, a range of tools were used to assess nutritional status and activities of daily living, making results for outcomes such as activities of daily living more difficult to combine. It is also difficult to combine results because of the different ways in which they are expressed, sometimes as medians, and at other times mean and standard deviations or 95% confidence intervals.

3.6.2 Outcomes

The trials included in the review measured a range of outcomes, as illustrated in Table 3.5. Interestingly it appeared that there was a difference in the scope of studies of ONS versus a control group compared to studies of food fortification versus a control group. Studies that examined the effects of food fortification versus a control group tended to measure nutritional intake and nutritional status, whilst those that examined the effects of ONS versus control trials tended to have a broader scope, measuring nutrition intake, nutritional status and a wider range of functional measures. None of the other categories of studies evaluated functional outcomes: ONS versus ONS measured only nutritional intake and nutritional status; and food fortification versus ONS trials measured nutritional intake, nutritional status and anthropometry. Variations in the outcomes measured in nutrition intervention trials may be explained by changes to the focus of clinical nutrition research over the years, with health practitioners now becoming more focused on the effectiveness of interventions through the measurement of improvements in quality of life and functional outcomes, rather than investigating whether nutritional interventions improve nutritional intake, weight and BMI.

Only one out of 19 randomised controlled trials included quality of life as an outcome variable, however in this trial of food fortification versus a control group no significant differences in quality of life were observed [76]. Given that there is a move to ensure patient focussed outcomes are achieved through nutritional interventions, it is imperative that future nutrition intervention trials include this outcome measure.

Both food fortification and ONS based interventions measured activities of daily living, but a variety of tools were used to measure this outcome. As a result it was not possible to

combine the results from different studies, although all the primary studies reported non-significant results. Future studies need to decide which tool to use to assess activities of daily living. The Barthel's Index could be adopted, as it produces scores for each component of the ADL tool and also an overall score.

Handgrip strength was not found to significantly improve in any of the trials that reported this outcome, and due to the variation in these trials, it was not possible to combine these results for analysis using a t-test or meta-analysis. Given the relatively small sample sizes used in these trials and the variation in the duration of the interventions, future studies investigating changes in handgrip may achieve significant changes if a larger population, or standardised reporting methods were used. Interventions including an exercise component may also aid improvements in functional outcomes for malnourished care home residents. Trials in care homes using both resistance training and oral nutritional supplements have suggested that improvements in functional outcomes are possible using a combination of oral nutritional supplements and resistance training to aid muscle synthesis and improvements in function [97, 99].

Some encouraging results have been reported with ONS trials. For example, one study reported that ONS (compared to control) significantly reduced the number of infections and the number of days in bed in nursing home residents with Alzheimer's dementia [78]. A further two studies reported that ONS improved healing of pressure ulcers [105, 118]. However, a large body of evidence for such effects is lacking, which makes it difficult to extrapolate the results of these studies to other situations, such as the effects of ONS on infections and bed-days in residents without dementia.

Although there were some encouraging results for ONS versus control trials, some studies failed to find a significant effect of ONS on outcomes. However the sample sizes used (11 – 111 participants) suggests that the studies were grossly underpowered to examine certain outcomes such as mortality. A study examining the effect of ONS on mortality (using figures reported in Gil Gregorio et al., 2003) would require a sample size of 1340 care home residents (670 per group) to detect a significant effect ($p < 0.05$) with 80% power. This sample size is greater than the combined sample size (Total N=754) of all nine RCTs comparing ONS with control group [73-75, 77, 78, 104-107].

Meta-analysis can increase power by combining studies, but differences in study design and methods of reporting results in primary studies limits the application of meta-analysis to

address key issues related to clinically relevant outcomes. The same issues apply to food fortification.

There is evidence from the mean results of individual studies and from meta-analysis that ONS increases total energy intake (Figure 3.3) and body weight (Figure 3.5). The results for these outcomes were more mixed when food fortification was used, with only approximately half of the trials measuring these outcomes reporting significant improvements.

As illustrated by these findings, there are a variety of outcomes that have not been measured by food fortification trials. This does not necessarily mean that food fortification is ineffective. It may reflect that the available studies did not adequately examine the issues. Indeed, four out of the five RCTs of food fortification versus control, which were not of high quality (Table 3.3) failed to examine any functional or clinical outcomes; they were mainly undertaken to examine food intake. In contrast several RCTs (n=9) comparing ONS with a control group set out to examine functional and clinical outcomes and were generally of higher quality than the food fortification studies.

3.6.3 Compliance to interventions

Another potential explanation for the lack of reported effects of primary trials is that the residents were not adequately exposed to the intervention. Information on this is sparse but there is some evidence that compliance was good and total intake was increased by ONS. Out of 27 trials (19 RCTs and 8 non RCTs) only three trials reported compliance to the intervention [41, 74, 77], and three trials reported the percentage suppression of food intake [74, 75, 114]. The compliance ranged from 68% in the food fortification versus ONS trial [41]to 98% in an ONS versus control trial [74].

No comparable data exists for food fortification. This raises the possibility that a failure to achieve benefits with food fortification may have been due either to the lack of compliance or to food fortification replacing (rather than adding to) intake from normal food.

3.7 Conclusions

This systematic review and meta-analysis has highlighted that there is a very limited body of evidence to support the use of nutritional interventions in care homes. The evidence base does not currently exist for dietary advice, and is very limited for food fortification but somewhat less so for ONS.

Given the range of interventions, sample sizes, randomisation details, populations studied and outcomes measured by the trials included in this review, there is a need to rationalise the aims and methodology of future nutrition intervention trials in care homes.

As many care home residents are at risk of malnutrition, it would be important for any future trials to consider the effectiveness of nutritional interventions in this group, as also advised by key research guidelines in the UK [2]. Dietary advice and ONS are two common nutritional interventions used in clinical practice in the community, however no such trials comparing these interventions were identified by this review. Therefore, any future trials in care homes should consider including these two interventions. Given the current variability in the methodology of nutrition intervention trials in care homes, future studies must ensure that they are good quality randomised controlled trials, measuring a range of outcomes (including quality of life, clinical, functional and healthcare use). The time period over which the trial is conducted, together with the case mix of residents included in the trial and compliance to the interventions must also be considered. These key research questions are addressed by the next chapter.

Chapter Four: Nutrition Intervention Trial

4.1 Introduction

As illustrated in previous chapters, it is vital for malnutrition to be treated in order to prevent, or reduce the health and economic costs of malnutrition. The systematic review of nutritional interventions in care homes (Chapter Three) highlighted the lack of evidence to support the use of nutritional interventions in this setting. There was more evidence to support the use of oral nutritional supplements (ONS) to improve a range of outcomes than food fortification or dietary advice, however many of the studies were small, and often included both malnourished and non-malnourished participants. Given the prevalence of malnutrition in care homes and the limited use of nutritional interventions reported in the care homes in Hampshire (Chapter Two), it suggests that further research into the effectiveness of nutritional interventions is required.

None of the studies included in the systematic review considered the use of dietary advice, a common first line dietetic treatment of malnutrition. In addition to this, although many of the ONS versus control trials had considered a range of functional and some healthcare use outcomes, none measured quality of life. With any intervention it is important to take into account participants' wellbeing in addition to interventions aiming to reduce healthcare use and associated costs.

Quality of life is an important measure of an individual's wellbeing, and nutritional status is known to affect this [15]. Older people are at risk of nutritional deficiencies due to the range of physiological, psychological and social changes that occur with aging. People with a nutritional intake that does not meet their nutritional needs may experience lower energy levels, weight loss and have a reduced resistance to infections and illnesses [121]. Reductions in body weight, including the loss of lean tissue can lead to difficulties in performing daily activities such as washing and dressing, walking and accessing meals. This can result in feelings of anxiety and frustration due to the loss of independence. Nutritional interventions for malnourished individuals may therefore help to improve their quality of life through improving the nutritional quality of their diet. Increasing nutritional stores as a result of an increase in dietary intake may lead to improved energy levels and feelings of independence with daily activities.

In the area of nutrition support in care homes, measurement of this important outcome appears to be very limited, despite guidance from NICE and Cochrane recommending this as a key area for future research [2, 35]. The measurement of quality of life not only allows participants wellbeing to be considered over the course of interventions, but if the tool used to measure quality of life produces a final score, the results may also be used in cost-utility analyses, when healthcare cost data is collected.

4.2 Aims

The aim of this RCT was to investigate the effects of ONS and dietary advice on malnutrition risk and improvement in outcomes such as quality of life, clinical, functional and healthcare outcomes in malnourished care home residents.

4.3 Study design

It was a prospective, randomised, parallel, open-label trial.

4.3.1 Subject population and cohorts

The nutritional intervention trial aimed to recruit 150 consenting older residents in privately run care homes in Hampshire who were at risk of malnutrition. Suitable residents were identified from the nutrition screening completed as part of the audit of nutritional care, as described in Chapter Two. The number of subjects recruited was based on power calculations; see section 4.3.11 for further details.

As described in Chapter two, care homes were selected using a convenience sample, using details from a database of care homes in Hampshire (n=633). Care homes with less than ten beds, those on the peripheries of the county, those with residents with advanced dementia, learning disabilities, drug dependence and those solely for people aged less than 50 years were not included. The study took place from August 2007 to December 2009.

4.3.2 Protocol

Eligible subjects were randomised to receive ONS or dietary advice. Measurements were undertaken at baseline, week 6 (± 48hrs) and week 12 (± 48hrs) (Figure 4.1). These included quality of life, anthropometrics, functional measurements, dietary intake and healthcare use.

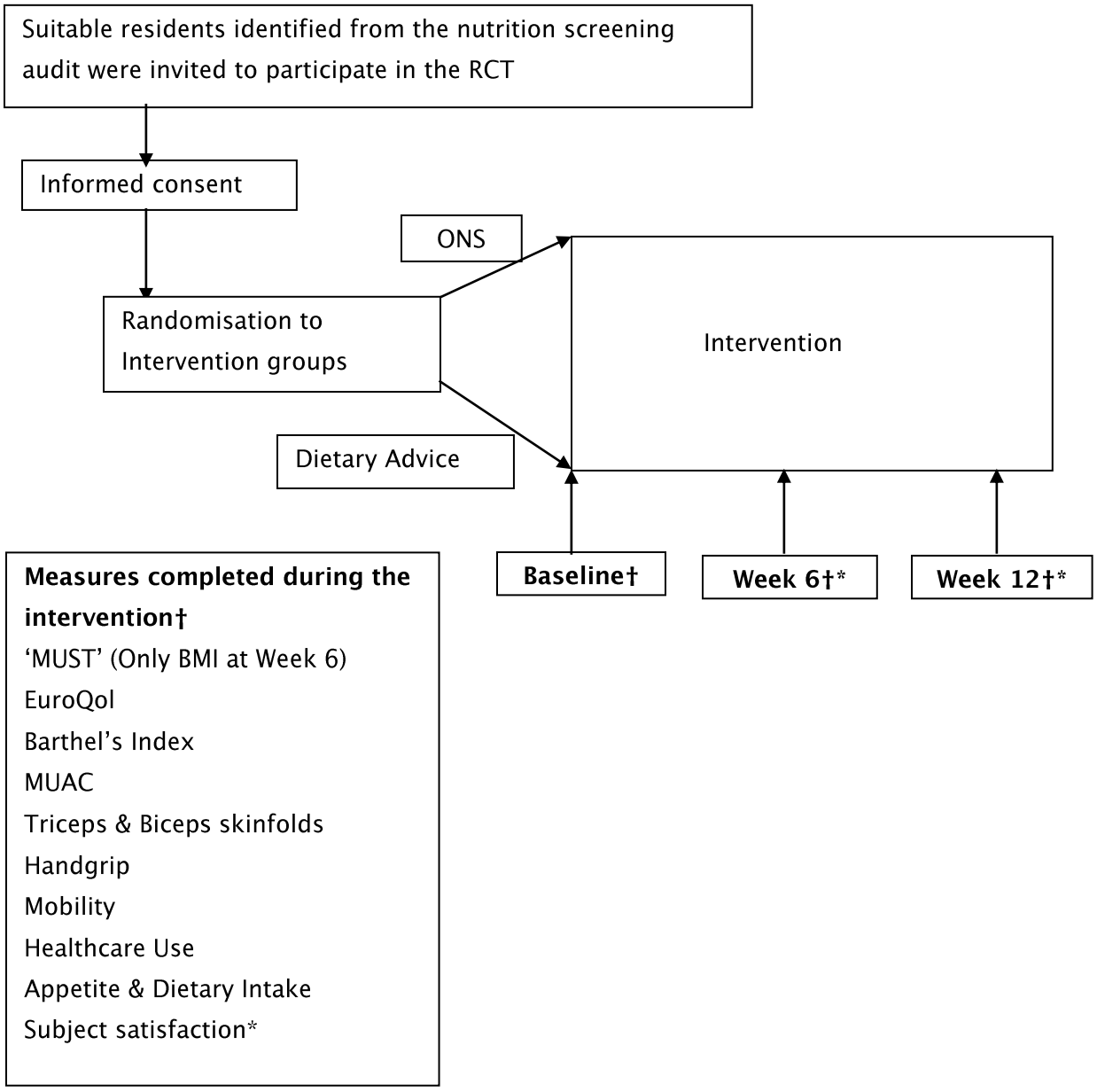


Figure 4.1 Trial schematic indicating the intervention, duration, and outcomes measured

4.3.3 Recruitment of residents

Care home staff approached eligible residents with an invitation letter from the care home manager (Appendix Four). If a resident expressed an interest in participating in the trial the care home staff introduced researchers to the residents. Eligible residents were then consented and randomised.

4.3.4 Inclusion and exclusion criteria

To facilitate recruitment, discussions took place between the researcher and care home managers or heads of care regarding the prevalence of malnutrition in each care home, using the results of the screening survey from individual care homes (Chapter Two), and the inclusion/exclusion criteria (Section 4.3.4.1 and 4.3.4.2). The inclusion and exclusion criteria were based on clinical judgement, ethical considerations, and previous studies conducted in this area.

4.3.4.1 Inclusion criteria

- Male or female
- Age greater than 50 years
- At risk of malnutrition (medium or high risk of malnutrition using 'Malnutrition Universal Screening Tool' ('MUST') score of one or more)
- Competent to provide written informed consent and able to answer questions
- Able to eat and drink
- Willing to take part in the trial and to follow the trial protocol

4.3.4.2 Exclusion criteria

- Requirement for tube or parenteral nutrition
- Galactosemia
- Receiving current (and within the last four weeks) oral nutritional supplementation
- Palliative care
- Chronic kidney disease requiring dialysis
- Liver failure
- Malignancy
- Participation in other studies

4.3.5 Informed consent

Written informed consent was obtained from each resident after adequate explanation of the trial. The Good Clinical Practice standard procedure for gaining informed consent was followed (Appendix Five).

4.3.6 Randomisation and cohorts

Randomisation into one of two intervention groups (ONS or dietary advice) was undertaken independently of the researchers using random number tables produced using Microsoft Excel for Windows 2003 (Appendix Six). Stratified randomisation was undertaken with participants according to malnutrition risk (medium or high risk of malnutrition with 'MUST') and type of care (residential or nursing care). Opaque, numbered randomisation envelopes containing the designated interventions were produced at the start of the study according to the sequences produced by the random number tables. The envelopes contained a label with the intervention group the participant is assigned to, and space to record their name, date of birth and date of consent. The envelopes were only opened once consent had been obtained from the participant. At the point of randomisation the residents and those involved in the study were blinded to the designated intervention.

4.3.7 Data collection and documentation

On recruitment to the study, residents were allocated a unique study number, which was the only resident identifier on all data sheets. The master list of residents' details and study numbers were also kept in a secure place.

All data was recorded directly onto printed case report forms in black ink. Upon completion of the study, the accuracy of the data collected in each case report form was confirmed by the principle investigator. Throughout the period of the study, monitoring and auditing of the study was conducted by the University of Southampton.

4.3.8 Intervention

Eligible subjects received either ONS or dietary advice. Allocation of intervention was based on the randomisation envelopes (Section 4.3.6). Participants were asked to follow the intervention for a 12 week period.

4.3.8.1 Oral nutritional supplements (ONS)

A range of ONS: Fortisip Extra, Fortisip Protein, Fortisip Bottle, Fortisip Yogurt Style, Fortifresh, Fortisip Multifibre, Fortijuce, Fortimel, Renilon 7.5, Fortisip Savoury Multifibre, Fortisip Fruit Dessert, Forticreme Complete, Scandishake, Calogen (Nutricia Ltd, Trowbridge, Wiltshire, UK) were provided *ad libitum* daily. The ONS used in this RCT contained energy and a range of nutrients (Appendix Seven) and were classified by the MHRA as non-medicinal (Appendix Eight). Participants were provided with written and verbal instructions on taking their ONS (Appendix Nine). This included information on storage, temperature and timing. The minimum daily target provision of ONS was 600kcal and 16g protein. The intake of the ONS was voluntary and there was no minimum intake. Subjects remained in the trial irrespective of the quantity of the ONS consumed.

4.3.8.2 Dietary advice

A specially designed diet sheet ('Build yourself up', Southampton Dietitians, Southampton, UK) (Appendix Ten), encouraging intake of high energy foods, drinks and snacks, was provided and discussed with the subject at the initial baseline visit and at week six of the intervention.

4.3.9 Outcome measures

A range of outcomes were measured at the intervals described in section 4.3.2. Further details of these measures are shown below.

4.3.9.1 Malnutrition risk

Malnutrition risk was measured using the Malnutrition Universal Screening Tool ('MUST') (Appendix Three). As discussed in the previous chapters, 'MUST' is a validated nutrition screening tool that is recommended for use in the UK by the National Institute for Health and Clinical Excellence, BAPEN, and the Care Quality Commission, as the tool measures BMI, percentage weight loss and the time frame over which the weight change occurred. Further details on the rationale for using 'MUST' can be found in Section 1.6.

Subjects' weight and BMI were recorded at each visit using the procedures described in Sections 2.3.5 and 2.3.4.1. At baseline and week 12, their 'MUST' scores were recalculated

according to the protocol described in section 2.3.4. At baseline, subjects' weight and height were checked, according to the standard procedures described in Sections 2.3.5 and 2.3.6.

4.3.9.2 Quality of life

A range of quality of life tools exist, including EuroQol (EQ-5D), the Health Utility Index (HUI) and the SF-36. As with the choice of nutrition screening tool, there are a number of factors to consider when selecting a tool to measure quality of life. Firstly, regarding the population specificity and whether it allows for easy comparison with quality of life scores reported in other trials. However, this may present challenges when tools are used with the elderly or people with cognitive impairment. In these instances, tools specifically designed for such populations may be better suited. For tools where weightings are applied according to the relative importance of the components of quality of life tools, it is important to consider whether the weightings applied to components are appropriate for the population expected to complete the tool. In the case of EuroQol, weightings applied to the components of the tool are population specific, with a set of weightings for each country the tool has been developed in [122]. Selection of a quality of life tool should also consider whether the tool produces a final score that could be used in an economic analysis. Tools such as EQ-5D have this capability as overall scores are produced. SF-36 until more recently could not be used for this.

In this RCT, the EuroQol (EQ-5D) Health Questionnaire and Visual Analogue Scale (VAS) were used to assess quality of life. The tool was chosen as EQ-5D is a standardized tool for use as a measure of healthcare outcome. The tool can be used in a variety of settings, covering a range of health conditions and treatments [123]. The tool consists of a descriptive system covering five dimensions of health (EQ-5D TTO and EQ-5D VAS rescaled) and the Visual Analogue Scale (VAS) which assessed participants' self-reported health on a 0-100 scale [122] (Appendix Eleven).

4.3.9.2.1 EQ-5D TTO score

Subjects responded to five dimensions covering their mobility, self care, usual activities, pain and anxiety. Each dimension has three levels (no problems (1), moderate problems (2), extreme problems (3)), which were assigned a rank and an associated co-efficient for each level of dependency (Table 4.1). These co-efficients were then used to calculate the Time Trade Off (TTO) score using the following formula [122]:

TTO Score = 1 – Constant – N3 – Mobility – Self care – Usual activities – Pain or discomfort – Anxiety or depression

Where a resident scored a one for any of the five components of EQ-5D, a zero was inserted into the above formula for the corresponding component.

Table 4.1 UK EQ-5D TTO value set [122]

	UK Co-efficient
Full Health (11111)	1
At least one 2 or 3 (Constant)	0.081
At least one 3 (N3)	-0.269
Mobility = 2	-0.069
Mobility = 3	-0.314
Self care = 2	-0.104
Self care = 3	-0.214
Usual activities = 2	-0.036
Usual activities = 3	-0.094
Pain / discomfort = 2	-0.123
Pain / discomfort = 3	-0.386
Anxiety / depression = 2	-0.071
Anxiety / depression = 3	-0.236

As this assessment of quality of life produced an overall score, this allowed the EQ-5D TTO score to be used in a cost-utility analysis (Chapter 5).

4.3.9.2.2 EQ-5D Visual Analogue Score (VAS) rescaled score

An alternative set of co-efficients were applied to the five dimensions of EuroQol in order to produce the EQ-5D VAS rescaled score. These were based upon a set of co-efficients that were assigned by a cohort of people in the UK [122]. The co-efficients were allocated according to where people thought combinations of the EQ-5D dimensions should be placed on a 0 to 100 VAS scale. Respondents were also asked where they would place death and unconsciousness on the scale (Table 4.2). From their responses new co-efficients were produced. This rescaling of responses allowed an alternative score to be produced, which could also be used for cost-utility analysis (Chapter 5). The co-efficients were used in this RCT to calculate the VAS rescaled score using the following formula [122]:

VAS rescaled score = 1 – Constant – N3 – Mobility – Self care – Usual activities – Pain or discomfort – Anxiety or depression

Where a resident scored one for any of the five components of EQ-5D, a zero was inserted into the above formula for the corresponding component.

Table 4.2 UK EQ-5D VAS rescaled value set [122]

	UK Co-efficient
Full Health (11111)	1
At least one 2 or 3 (Constant)	-0.155
At least one 3 (N3)	-0.215
Mobility = 2	-0.071
Mobility = 3	-0.182
Self care = 2	-0.093
Self care = 3	-0.145
Usual activities = 2	-0.031
Usual activities = 3	-0.081
Pain / discomfort = 2	-0.084
Pain / discomfort = 3	-0.171
Anxiety / depression = 2	-0.063
Anxiety / depression = 3	-0.124

4.3.9.2.3 EQ-5D Visual Analogue Scale

The subjects were asked to indicate their health state, for the day they were seen, on a VAS scale of 0-100, where 0 is the worst imaginable health state and 100 is the best imaginable health state [122].

For this study, some older people required assistance in completion of the Visual Analogue Scale. A tool to aid completion of the scale was produced with the assistance of a Speech and Language Therapist at Southampton University Hospitals Trust (Appendix Twelve). The tool was only used when a subject was not able to produce a score using the standard instructions for use provided with the EuroQol tool.

4.3.9.3 Activities of Daily Living

The Barthel's Index was used to assess subjects' daily functioning, specific to activities of daily living and mobility (Appendix Thirteen). It consisted of ten items covering continence (bowels, bladder), grooming, toilet use, feeding, transfer, mobility, dressing, use of stairs and bathing. Subjects received a score reflecting whether they required assistance to carry out a task. The Barthel's Index had a maximum score of 20, which indicated an individual was fully independent. A score of zero indicated a bedridden state.

4.3.9.4 Anthropometry

Anthropometric measures were taken at each visit throughout the trial. This included the measurement of weight, height, triceps and biceps skinfolds. Protocols for measuring weight and height can be found in Sections 2.3.5 and 2.3.6. All anthropometric measurements were undertaken according to standard, published methodology [124].

4.3.9.4.1 Protocol for measuring Mid Upper Arm Circumference (MUAC)

The subject was standing or sitting. The measure was taken using their right arm, if possible. It was bent at the elbow at a 90 degree angle. The measurement was taken in two stages. Firstly, the midpoint of the upper arm was identified and marked. This is the distance between the bony protrusion at the top of the shoulder (acromion) and the point of the elbow (olecranon process) (Figure 4.2). Secondly, the subject let their arm hang loose. With the tape measure, the circumference of the arm was measured at the midpoint (Figure 4.2). The measurement was recorded in centimetres, to the nearest 0.1cm.

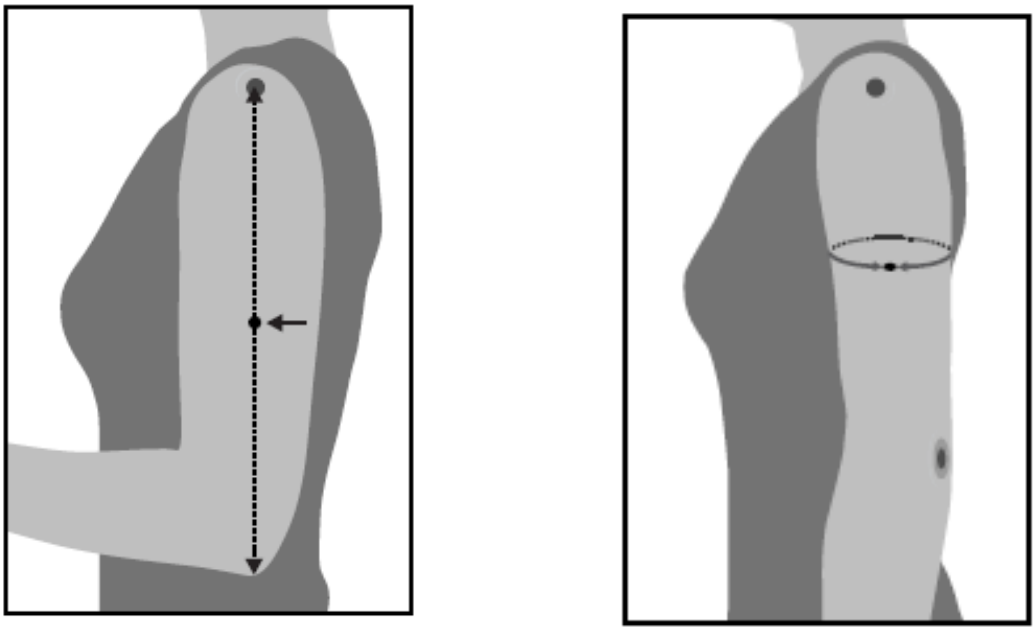


Figure 4.2 Measurement of mid upper arm circumference [23]

4.3.9.4.2 Protocol for measuring Biceps and Triceps Skinfold

Both biceps and triceps skinfolds were measured at baseline, week six and week 12, according to standard, published methodology [124].

4.3.9.4.2.1 Biceps Skinfold

Using the midpoint mark made when measuring the distance between the acromion and the olecranon process (MUAC procedure), the subject relaxed their arm by their side, with their palm facing forward, if possible. Slightly above the marked midpoint, a skinfold was obtained at the front of the arm, using thumb and forefinger. This was parallel with the length of arm. Holding the calipers horizontally, the jaws were applied at the marked midpoint. Full pressure of the calipers was applied to the skinfold for two seconds. The skinfold measure was recorded to the nearest millimetre. Three measurements were taken, from which an average was calculated.

4.3.9.4.2.2 Triceps Skinfold

Using the midpoint mark made when measuring the distance between the acromion and the olecranon process (MUAC procedure, Section 4.3.9.4.1), the subject relaxed their arm by their side, with their palm facing forward, if possible. Slightly above the marked midpoint, a skinfold was obtained at the back of the arm, using thumb and forefinger. This was parallel with the length of arm. Holding the calipers horizontally, the jaws were applied at the marked midpoint. Full pressure of the calipers was applied to the skinfold for two seconds. The skinfold measure was recorded to the nearest millimetre. Three measurements were taken, from which an average was calculated.

4.3.9.5 Handgrip Strength

Handgrip strength was measured at each visit to assess subjects' strength.

4.3.9.5.1 Protocol for measuring handgrip strength

Handgrip strength was measured using a handgrip dynamometer (Medical Physics Department, Nottingham University Hospitals NHS Trust). The handgrip dynamometer had been calibrated prior to use in this RCT (Appendix Fourteen).

At each visit, before any measurements were taken, the researcher explained to the resident how the dynamometer worked and the procedure was demonstrated to them. The subject was sat in an upright position, in a chair with arms. They were asked which hand was their dominant hand, and this was recorded. The subject then held the grip with their right hand. They squeezed as hard as they could for approximately two seconds, then released. The maximal value shown on the LCD display was recorded.

The process was then repeated until three measurements were recorded for each hand. Ideally, the subject alternated between left and right hands. It was noted whether a subject had arthritis, or had experienced a stroke or had any other neurological conditions.

Measurements were recorded to the nearest 100 grams. Mean values of handgrip strength were calculated for each hand.

Handgrip strength was not taken if the subject had swelling or inflammation, severe pain or recent injury. Subjects that had undergone surgery to the hand in the last six months did not use the handgrip dynamometer. Subjects known to have blood pressure over 160mmHg systolic or 102mmHg diastolic were also excluded from this measure.

4.3.9.6 Activity levels and mobility

Mobility levels were recorded at each visit. In order to assess mobility levels subjects were asked whether there were any changes to their general activity levels. They were asked to describe their mobility level and any assistance they required for walking and transfer from lying down to sitting or standing. The daily time a subject spent in bed, sitting and walking was also recorded in hours.

4.3.9.7 Healthcare use

Healthcare use was recorded at baseline, week six and week 12 in order to assess the effect of taking ONS and dietary advice on health care use. In this study various markers of health care use were recorded, including the number of;

- GP visits
- Other Healthcare Professional visits, including district nurses, dietitians, physiotherapists etc.,
- Out-patients visits,
- Hospital admissions and duration of hospital admissions.

This information was collected from their care plans, including the dates, times, reasons for the visits and hospital admissions and the details of any treatments received.

Data on clinical outcome, including quality of life and complications, and healthcare use were used to undertake cost-utility analyses using reference costs, which will be discussed in Chapter Five.

4.3.9.8 Appetite

Subjects' appetite was measured using 100mm visual analogue scales (Appendix Sixteen) to assess their level of hunger, fullness and desire to eat [125].

Subjects were asked to mark the strength of their appetite sensations over the last 24 hours. If subjects were unable to indicate the strength of their appetite sensations on the scale, they were asked to imagine the scale, and where they would rate their appetite sensations from zero to 10, with zero being very weak and 10 being very strong.

4.3.9.9 Nutritional intake

A 24-hour recall of dietary intake was used to assess subjects' nutritional intake over the course of the study. This form of dietary recall is commonly used both in dietetic practice and clinical trials [29]. It provides a useful snap shot of an individual's total food and fluid intake over the previous 24 hours. At each research visit, participants' dietary intake, including the intake of all foods, drinks and any ONS, was recorded on food charts (Appendix Fifteen). A checklist was used whilst taking the diet history in order to ensure all food and fluid intake was recorded. Subjects' food intake was confirmed with care home staff, in order to ensure all information was obtained.

A dietary analysis programme was used to estimate daily nutritional intake from food and from ONS, in terms of energy, protein and micronutrient intake (WISP). Where possible, menus were obtained from care homes in order to aid entry of diet histories.

4.3.9.10 Subject satisfaction

At baseline, week six and week 12, subjects were asked to rate their overall satisfaction with the intervention (ONS or dietary advice) they were receiving. Those subjects receiving ONS were asked to rate the palatability of ONS and their ONS preferences (including type, flavour, consistency, and timing) on a short questionnaire. Those receiving dietary advice were asked whether they were still following the advice and whether they had made any changes to their dietary intake.

4.3.10 Monitoring

Subjects' nutritional status was monitored closely throughout the trial. If at any time it was highlighted that a subject was continuing to lose weight or deteriorate, the subjects' treating physician was notified.

All adverse events were reported during the trial. Definitions of adverse events and serious adverse events can be found in Appendix Seventeen.

4.3.11 Statistics and data analysis

4.3.11.1 Sample size calculations

Power calculations (SamplePower 2, SPSS, 80% power, $P<0.05$) suggest that a sample size of 75 patients in each group (150 total) will detect the following differences:

Primary outcome measure

- EuroQol score (1-100); difference of 6.9, SD15 between groups.

Secondary outcome measures

- 21% difference in complication rates (40% to 19%)
- 15% difference in the number of hospital admissions (20% to 5%)
- 2.3Kg (SD 5kg) difference in handgrip strength between groups

Using data from the systematic review of nutritional interventions, it was possible to ascertain *a priori* effect sizes for outcome measures. They were ascertained from the data in the RCT by Manders et al., 2009 (Table 4.3).

Table 4.3 *A priori* effect sizes for outcome measures, based on Manders et al., 2009

Outcome	N per group	Effect Size
Weight (kg)	37	2.52 ± 3.8
	75	1.74 ± 3.8
Handgrip	37	2.3 ± 3.5
	75	1.6 ± 3.5
Energy Intake (kcal)	37	290 ± 437
	75	200 ± 437
Protein Intake (g)	37	9.7 ± 14.7
	75	6.8 ± 14.7

4.3.11.2 Statistical tests

Data was analysed on all residents who completed the study and on an intention to treat basis which included the evaluation of all residents who received at least two weeks of the assigned treatment and who had at least one follow up visit.

Unpaired t-tests were used for comparisons between the two groups of single endpoints (e.g. length of stay). Repeated measures analysis of covariance (ANCOVA) was used to assess longitudinal data (e.g. skeletal muscle strength, nutritional intake) in the two intervention groups depending on the extent of baseline imbalance in the main outcome variables. The per protocol results were adjusted for the baseline measure, designated intervention, type of care and 'MUST' category. The chi-squared test was used for comparisons of proportional data between the two intervention groups (e.g. complications). Statistical analysis was undertaken using SPSS version 18.0.

In order to account for missing quality of life data, an intention to treat analysis was performed using a multiple imputation model. Each missing value was replaced by five simulated values produced using the multiple imputation method, SPSS version 18.0. Using this method allowed missing data points for residents who dropped out to be inserted. These inserted values were randomly drawn from the data of those who completed the intervention, but had similar baseline characteristics. For example, where residents had a worse health status dropped out of the trial, random draws from data of residents with a similar health

status but had not dropped out of the trial were imputed. The imputation model included a range of independent variables measured at baseline, week six and week 12 (Table 4.4).

Table 4.4 Independent variables used in the Multiple Imputation Model

	Variables		
	Baseline	Week 6	Week 12
Designated Intervention	Total number of healthcare professional visits	Total number of healthcare professional visits	Total number of healthcare professional visits
Gender	Weight	Weight	Weight
'MUST' Category	BMI	BMI	BMI
Type of care for resident	EQ-5D mobility score	EQ-5D mobility score	EQ-5D mobility score
	EQ-5D self-care score	EQ-5D self-care score	EQ-5D self-care score
	EQ-5D usual activities score	EQ-5D usual activities score	EQ-5D usual activities score
	EQ-5D pain and discomfort score	EQ-5D pain and discomfort score	EQ-5D pain and discomfort score
	ED-5D VAS score	ED-5D VAS score	ED-5D VAS score
	Total ADL score	Total ADL score	Total ADL score
	Energy intake	Energy intake	Energy intake
	Protein intake	Protein intake	Protein intake
		Energy intake including ONS	Energy intake including ONS
		Protein intake including ONS	Protein intake including ONS

Constraints were placed on the components of the EuroQol (EQ-5D tool) with minimum values being constrained to a value to one, and maximum values constrained to a value to three. The components were also rounded to whole numbers in order to produce imputed results in line with the scale used in the tool. For the same reason, the VAS was also limited to a minimum value of zero and a maximum value of 100.

4.4 Results

4.4.1 Identification of subjects

The inclusion and exclusion criteria for the RCT were applied to the 1455 care home residents that were screened for malnutrition using 'MUST'. This resulted in 104 residents being recruited to the RCT and the remaining 1351 residents being excluded (Figure 4.3).

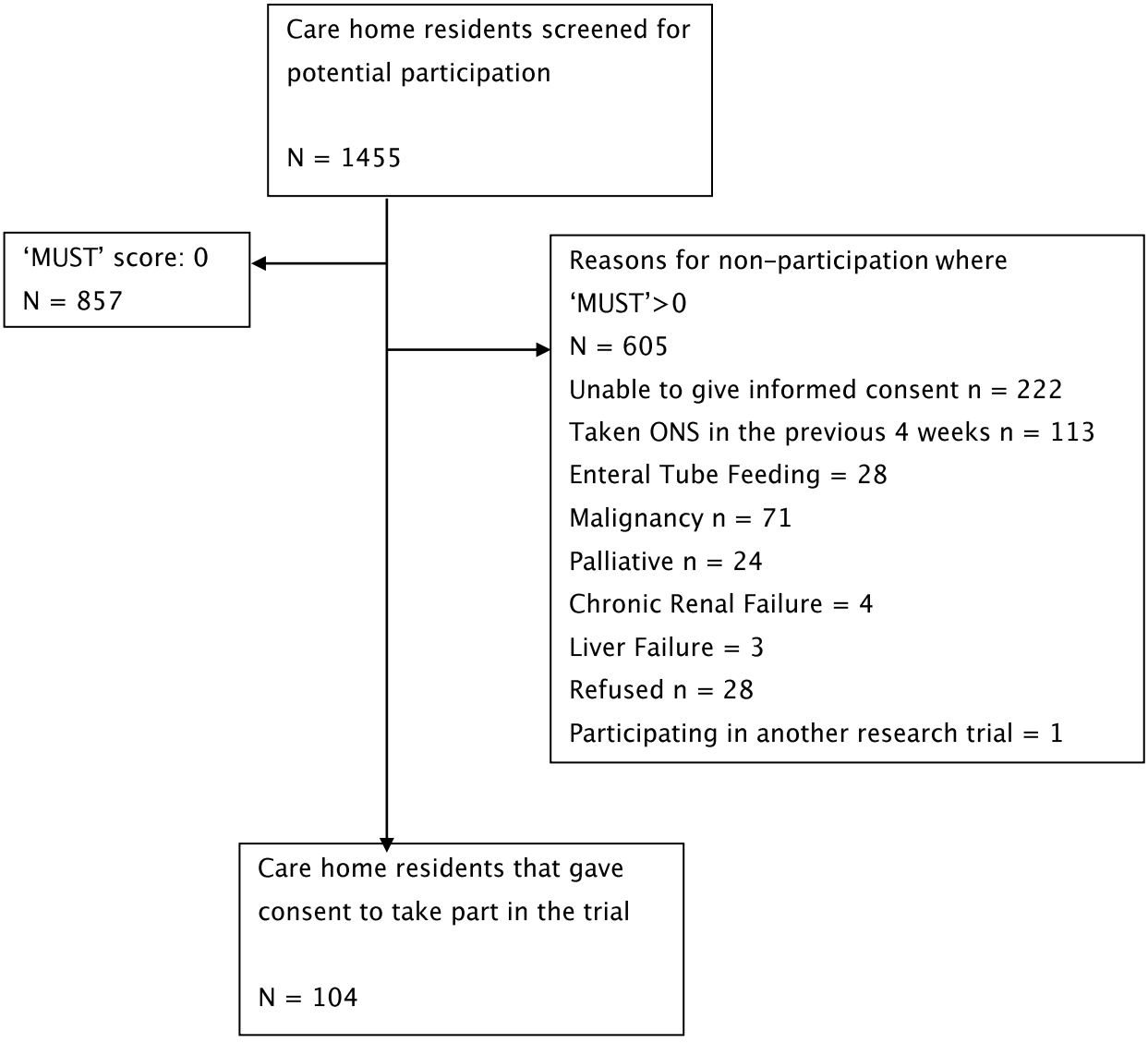


Figure 4.3 Identification of residents to participate in the Nutrition Intervention Trial, and reasons for non-participation

4.4.2 Subject characteristics

A total of 104 residents gave their consent to take part in the RCT. Of those that gave consent to participate, 53 residents received ONS and 51 residents received dietary advice. There were no significant differences between the groups in terms of age, gender, type of care, or health problems (Table 4.5 and 4.6).

There were also no significant differences between the intervention groups at baseline in terms of their weight, height, BMI categories or weight loss categories (Table 4.7). However the mean BMI of the ONS group was significantly lower than the dietary advice group (ONS: 18.44 ± 2.35kg/m^2, Dietary Advice: 19.90 ± 2.90kg/m^2, p=0.007). There was not a significant difference in mean percentage weight loss between the intervention groups (ONS; 3.04 ± 4.33%, Dietary Advice: 3.82 ± 4.70%, p=0.392).

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Subjects: n	53	51	104	
Type of care				0.230*
Nursing care: n	27	20	47	
Residential care: n	26	31	57	
'MUST' Categories				0.286*
'MUST' – Medium risk: n	22	26	48	
'MUST' – High risk: n	31	24	55	
Sex				0.843*
Male: n	8	7	15.00	
Female: n	45	44	89.00	
Age (y): mean ± SD	89.64 ± 6.95	87.25 ± 8.61	88.47 ± 7.86	0.121**

Table 4.5 Subject characteristics, according to intervention group

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.6 Classification of subjects' health problems according to the affected body system, split by intervention group

Body systems	Intervention		Totals	p value†
	ONS	Dietary Advice		
CNS: n (%)	17 (32.1)	12 (25)	29 (28.7)	0.433
Musculoskeletal: n (%)	23 (43.4)	21 (43.8)	44 (43.6)	0.971
Ear, Nose, Throat, Eyes: n (%)	16 (30.2)	10 (20.8)	26 (25.7)	0.283
CVS: n (%)	19 (35.8)	21 (41.2)	40 (38.5)	0.145
Respiratory: n (%)	12 (22.6)	3 (5.9)	15 (14.4)	0.014
GU: n (%)	6 (11.3)	9 (17.6)	15 (14.4)	0.116
GI: n (%)	11 (20.8)	12 (23.5)	23 (22.1)	0.177
Skin: n (%)	3 (5.7)	0 (0)	3 (2.9)	0.050
Blood: n (%)	3 (5.7)	2 (3.9)	5 (4.8)	0.189
Mental Health: n (%)	3 (5.7)	5 (9.8)	8 (7.7)	0.136
Endocrine: n (%)	3 (5.7)	9 (17.6)	12 (11.5)	0.026
Other: n (%)	25 (47.2)	22 (43.1)	47 (45.2)	0.199

† Relates to comparisons between ONS and Dietary advice, Chi Squared

CNS: Central Nervous System, CVS: Cardiovascular System, GU: Genito-Urinary, GI: Gastro-intestinal

Table 4.7 Subjects mean weight, height, BMI, percentage weight loss and 'MUST' risk categories, according to intervention group

	Intervention		p value†
	ONS	Dietary Advice	
Weight (kg)	48.49 ± 9.85	51.08 ± 8.92	0.167**
Height (m)	1.61 ± 0.09	1.60 ± 0.09	0.435**
BMI Categories^;			0.142*
>20kg/m^2: n (%)	6 (11.3)	13 (26.0)	
18.5 to 20.0kg/m^2: n (%)	23 (43.4)	20 (40.0)	
<18.5kg/m^2; n (%)	24 (45.3)	17 (34.0)	
Percentage weight loss categories‡			0.126*
<5%: n (%)	39 (73.6)	29 (58.0)	
5.0% to 10.0%: n (%)	8 (15.1)	16 (32.0)	
>10%: n (%)	6 (11.3)	5 (10.0)	
'MUST' Categories			0.286*
'MUST' – Medium risk: n (%)	22 (41.5)	26 (52.0)	
'MUST' – High risk: n (%)	31 (58.5)	24 (48.0)	

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test, ^BMI (kg/m^2): mean ± SD, ONS: 18.44 ± 2.35, DA 19.90 ± 2.90, p=0.007**, ‡Percentage weight loss (%): mean, SD ONS; 3.04 ± 4.33, DA 3.82 ± 4.70, p= 0.392**

4.4.2.1 Differences in characteristics between residents that completed the 12 week intervention and those that did not

During the course of the 12 week intervention, 32.7% of participating residents failed to complete the intervention. Due to the relatively large proportion of residents that did not complete the intervention, the characteristics of the completers versus the non completers were compared, to explore whether there were any differences between them.

There were no significant differences in the number of residents that did not complete the intervention due to death, or other reasons (including decline in memory due to temporary states of confusion or residents being unable to remember the purpose of the study, ill health), however there were double the number of deaths in the dietary advice group than the ONS group (Table 4.8).

Table 4.8 Reasons for non completion of the 12 week intervention, according to intervention group

	Intervention		
Reason for non completion	ONS	Dietary Advice	p value†
Death	2	4	0.321*
Other^	12	16	0.217*
Total number of non completers	14	20	0.119*

†Relates to comparisons between ONS and dietary Advice groups *Fishers exact test
^Other reasons mainly included declining short term memory

Differences in age, gender, 'MUST' category and type of care were also explored. There were no significant differences between completers and non completers in all of these categories (Tables 4.9 to 4.12).

Table 4.9 Mean age of completers and non completers, according to intervention

	Non Completer	Completer	p value†
ONS (n=53)	89.48 ± 6.75	89.32 ± 6.80	0.942*
Dietary Advice (n=51)	88.15 ± 9.42	86.66 ± 8.15	0.552*
Whole group (n=104)	88.67 ± 8.34	88.14 ± 7.49	0.748*

†Relates to comparisons between completers and non completers *ANOVA

Table 4.10 Gender of completers and non completers, according to intervention

	Non Completer		Completer		
	Male	Female	Male	Female	p value†
ONS (n=53)	2	12	6	33	0.647
Dietary Advice (n=51)	2	18	5	26	
Whole group (n=104)	4	30	11	59	0.414*

†Relates to comparisons between completers and non completers *Fishers exact test

Table 4.11 'MUST' category of completers and non completers, according to intervention

	Non Completer		Completer		
	Medium	High	Medium	High	p value†
ONS (n=53)	6	8	18	21	0.542*
Dietary Advice (n=51)	9	11	19	12	0.197*
Whole group (n=104)	15	19	37	33	0.265*

†Relates to comparisons between completers and non completers *Fishers exact test

Table 4.12 Type of care for completers and non completers, according to intervention

	Non Completer		Completer	
	Residential	Nursing	Residential	Nursing
ONS (n=53)	8	6	18	21
Dietary Advice (n=51)	12	8	19	12
Whole group (n=104)	20	14	37	33

4.4.3 Baseline characteristics

As there were no significant differences between completers and non completers, the baseline characteristics were considered for all 104 participants that started the intervention.

There were no significant differences between intervention groups in terms of the quality of life TTO score or VAS rescaled (measured using EuroQol EQ-5D), however there was a significant difference in the self reported Visual Analogue Scale, with the mean score in the ONS group being 8.25 points higher than the dietary advice group (Table 4.13). Despite the difference in the Visual Analogue Scale, there were no significant differences in any of the five dimensions of quality of life measured with EuroQol at baseline.

No significant differences in the total baseline score for activities of daily living were noted using the Barthel's Index, however there were significant differences between intervention groups for the feeding and dressing components of the tool (Table 4.14). For both of these components, a greater number of participants in the ONS group reported a higher level of dependency with feeding and dressing than participants in the dietary advice group.

There were no significant differences in mid upper arm circumference, skinfolds, handgrip, mobility, appetite scores or nutrient intake at baseline (Tables 4.15, 4.16, 4.18, 4.19). The number of Healthcare Professional visits, and pressure ulcers in the three months prior to the intervention did not differ significantly between intervention groups, however there was a tendency for a greater rate of hospital admissions in the dietary advice group than the ONS group (6% versus 0%, p=0.073) (Table 4.17).

Table 4.13 Baseline EuroQol scores, according to intervention group

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Mobility				0.109*
No problems: n (%)	23 (43.4)	25 (49)	48 (46.2)	
Some problems: n (%)	14 (26.4)	15 (29.4)	29 (27.9)	
Confined to bed: n (%)	16 (30.2)	11 (21.6)	27 (26.0)	
Self care				0.605*
No problems: n (%)	23 (43.4)	25 (49.0)	48 (46.2)	
Some problems: n (%)	14 (26.4)	15 (29.4)	29 (27.9)	
Unable to wash and dress: n (%)	16 (30.2)	11 (21.6)	27 (26.0)	
Usual Activities				0.626*
No problems: n (%)	23 (43.4)	23 (45.1)	46 (44.2)	
Some problems: n (%)	28 (52.8)	24 (47.1)	52 (50.0)	
Unable to perform usual activities: n (%)	2 (3.8)	4 (7.8)	6 (5.8)	
Pain				0.391*
None: n (%)	36 (67.9)	28 (54.9)	64 (61.5)	
Moderate: n (%)	13 (24.5)	18 (35.3)	31 (29.8)	
Extreme: n (%)	4 (7.5)	5 (9.8)	9 (8.7)	
Anxiety				0.228*
None: n (%)	42 (79.2)	35 (68.6)	77 (74.0)	
Moderate: n (%)	11 (20.8)	14 (27.5)	25 (24.0)	
Extreme: n (%)	0 (0)	2 (3.9)	2 (1.9)	
EQ-5D TTO; mean ± SD	0.51 ± 0.38	0.54 ± 0.38	0.52 ± 0.38	0.709**
EQ-5D VAS rescaled; mean ± SD	0.55 ± 0.27	0.56 ± 0.26	0.56 ± 0.26	0.846**
Visual Analogue Scale (VAS) (0-100): mean± SD	66.98 ± 17.76	58.65 ± 22.43	62.9 ± 20.51	0.042**

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.14 Baseline results for Activities of Daily Living (Barthel's Index), according to intervention group

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Bowels				0.448*
Incontinent: n (%)	3 (5.7)	3 (5.9)	6 (5.8)	
Occasional Accident: n (%)	7 (13.2)	3 (5.9)	10 (9.6)	
Fully Continent: n (%)	43 (81.1)	45 (88.2)	88 (84.6)	
Bladder				0.738*
Incontinent: n (%)	8 (15.1)	6 (11.8)	14 (13.5)	
Occasional Accident: n (%)	14 (26.4)	15 (29.4)	29 (27.9)	
Fully continent: n (%)	31 (58.5)	30 (58.8)	61 (58.7)	
Grooming				0.733*
Needs help: n (%)	11 (20.8)	12 (23.5)	23 (22.1)	
Independent: n (%)	42 (79.1)	39 (76.5)	81 (77.9)	
Toilet use				0.549*
Dependent: n (%)	11 (20.8)	8 (15.7)	19 (18.3)	
Needs some help: n (%)	10 (18.9)	7 (13.7)	17 (16.3)	
Independent: n (%)	32 (60.4)	36 (70.6)	68 (65.4)	
Feeding				0.003*
Unable: n (%)	0 (0)	3 (5.9)	3 (2.9)	
Needs help: n (%)	27 (50.9)	11 (21.6)	38 (36.5)	
Independent: n (%)	26 (49.1)	37 (72.5)	63 (60.6)	
Transfer				0.769*
Unable: n (%)	4 (7.5)	3 (5.9)	7 (6.7)	
Major help: n (%)	10 (18.9)	7 (13.7)	17 (16.3)	
Minor help: n (%)	9 (17)	7 (13.7)	16 (15.4)	
Independent: n (%)	30 (56.6)	34 (66.7)	64 (61.5)	
Mobility				0.658*
Immobile: n (%)	12 (22.6)	7 (13.7)	19 (18.3)	
Wheelchair: n (%)	5 (9.4)	4 (7.8)	9 (8.7)	
Walks with the help of 1: n (%)	12 (22.6)	13 (25.5)	25 (24.0)	
Independent: n (%)	24 (45.3)	27 (52.9)	51 (49.0)	

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Dressing				0.043*
Dependent: n (%)	16 (30.2)	7 (13.7)	23 (22.1)	
Needs some help: n (%)	10 (18.9)	21 (41.2)	30 (29.8)	
Independent: n (%)	27 (50.9)	23 (45.1)	50 (48.1)	
Stairs				0.377*
Dependent: n (%)	35 (66.0)	31 (60.8)	66 (63.5)	
Needs some help: n (%)	7 (13.2)	4 (7.8)	11 (10.6)	
Independent: n (%)	11 (20.8)	16 (31.4)	27 (26.0)	
Bathing				0.470*
Dependent: n (%)	47 (88.7)	44 (86.3)	91 (87.5)	
Independent: n (%)	6 (11.3)	7 (13.7)	13 (12.5)	
Total Score (0-20): mean, SD	12.87 ± 5.55	14.10 ±5.42	13.47 ± 5.50	0.408**

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.15 Baseline Anthropometry and Handgrip Strength, according to intervention group

	Intervention		p value†
	ONS	Dietary Advice	
Mid Upper Arm Circumference (cm)	22.85 ± 2.85	23.31 ± 3.53	0.467
Skinfolds (mm)			
Biceps	6.10 ± 2.45	6.63 ± 3.10	0.297
Triceps	10.42 ± 3.52	11.45 ± 4.91	0.221
Handgrip (kg)			
Left hand	7.78 ± 4.27	8.27 ± 3.75	0.356
Right hand	8.19 ± 4.15	8.71 ± 4.73	0.566

† Relates to comparisons between ONS and Dietary advice, Unpaired t-test

Table 4.16 Baseline activity levels and mobility, according to intervention group

	Intervention		p value†
	ONS	Dietary Advice	
Have their activity levels changed in the last three months?			0.734*
More: n (%)	2 (4.3)	2 (4.8)	
The same: n (%)	30 (65.2)	24 (57.1)	
Less: n (%)	14 (30.4)	16 (38.1)	
Mobility Level			0.600*
Bedbound: n (%)	3 (6.5)	3 (7.3)	
Limited movement: n (%)	17 (37.0)	11 (26.8)	
Walks independently: n (%)	26 (56.5)	27 (65.9)	
Assistance required for walking and transfer			0.977*
None: n (%)	47 (88.7)	44 (86.3)	
Uses a stick or frame: n (%)	6 (11.3)	7 (13.7)	
Needs help from 1-2 people: n (%)	10 (22.2)	8 (20.0)	
Needs to be hoisted: n (%)	3 (6.7)	2 (5.0)	
Daily activities: mean ± SD			
Time spent in bed (hours)	11:46:24 ± 2:45:16	10:54:17 ± 2:48:08	0.146**
Time spent sitting in a chair (hours)	11:40:07 ± 2:34:57	12:33:56 ± 2:40:42	0.114**
Time spent walking (hours)	0:33:29 ± 0:32:15	0:34:39 ± 0:29:32	0.861**

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.17 Healthcare use (Healthcare Professional (HCP) visits, pressure ulcers and hospital admissions) in the three months prior to the start of the intervention, according to intervention group.

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Number of HCP visits	2.13 ± 3.88	1.24 ± 1.79	1.70 ± 3.07	0.141**
Pressure ulcers				0.449*
Yes (n, %)	9 (17.0)	6 (11.8)	15 (14.4)	
No (n, %)	44 (83.0)	45 (88.2)	89 (85.6)	
Hospital Admissions				0.073*
Yes (n, %)	0 (0)	3 (5.9)	3 (2.9)	
No (n, %)	53 (100)	48 (94.1)	101 (97.1)	

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.18 Baseline appetite scores (hunger, fullness and desire to eat), according to intervention group

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Hunger				0.910*
Yes: n (%)	13 (24.5)	13 (25.5)	26 (25)	
No: n (%)	40 (75.5)	38 (74.5)	78 (75%)	
Hunger VAS (cm)	3.84 ± 2.52	3.21 ±2.48	3.53 ±2.51	0.217**
Fullness				0.639*
Yes: n (%)	30 (56.6)	26 (52)	56 (54.4)	
No: n (%)	23 (43.4)	24 (48)	47 (45.6)	
Fullness VAS (cm)	5.67 ± 2.60	5.25 ± 2.74	5.45 ± 2.67	0.468**
Desire				0.960*
Yes n (%)	20 (37.7)	19 (37.3)	39 (37.5)	
No n (%)	33 (62.3)	32 (62.7)	65 (62.5)	
Desire VAS (cm)	4.49 ± 2.44	3.74 ± 2.58	4.12 ± 2.53	0.164**

† Relates to comparisons between ONS and Dietary advice * Chi Squared, ** Unpaired t-test

Table 4.19 Baseline analysis of energy, protein and micronutrient intake from a 24 hour food recall, according to intervention group

	Intervention		Totals	p value†
	ONS	Dietary Advice		
Energy (kcal)	1366 ± 402	1371 ± 457	1369 ± 428	0.961
Protein (g)	51.2 ± 14.5	50.8 ± 19.0	51.0 ± 16.8	0.905
Potassium (mg/d)	2017 ± 536	1997 ± 709	2008 ± 624	0.872
Magnesium (mg/d)	165 ± 41	160 ± 57	163 ± 49	0.633
Iron (µg/d)	7.0 ± 2.6	7.0 ± 2.6	7.0 ± 2.6	0.966
Copper (µg/d)	1.1 ± 1.4	0.9 ± 1.0	1.0 ± 1.2	0.449
Zinc (µg/d)	6.37 ± 2.39	6.05 ± 2.32	6.21 ± 2.35	0.489
Selenium (µg/d)	25.60 ± 13.61	23.63 ± 10.68	24.63 ± 12.24	0.413
Iodine (µg/d)	100.30 ± 81.51	100.16 ± 49.10	100.23 ± 67.27	0.991
Vitamin A (µg/d)	749.94 ± 2308	811 ± 2000	780±2152	0.885
Vitamin D (µg/d)	2.07 ±1.69	2.30 ± 1.68	2.19±1.68	0.489

† Relates to comparisons between ONS and Dietary advice, Unpaired t-test

4.4.4 Results – Baseline to Week 12

4.4.4.1 Quality of Life

There were significant differences in quality of life scores between intervention groups for the TTO score and rescaled VAS both at the end of the 12 week intervention (Table 4.20 and Figures 4.4 & 4.5) and when the results were averaged over the course of the intervention (Table 4.21). In both instances, quality of life was greater in the ONS group than the dietary advice group, with the difference between groups being significant when both a per protocol and intention to treat analysis was conducted. The results for the Visual Analogue Scale were significantly different using the per protocol analysis at week 12 (Figures 4.4 and 4.5), favouring the ONS group. However this effect did not remain when the results for VAS were averaged over the course of the intervention or when an intention to treat analysis was conducted.

The ONS group had consistently lower average scores for all five components of the EuroQol questionnaire, with the difference between the scores being significant for the self care component (Table 4.22). There were no differences between groups, at week six or 12, for the proportion of residents within the subgroups of each component of the EQ-5D questionnaire (Table 4.23).

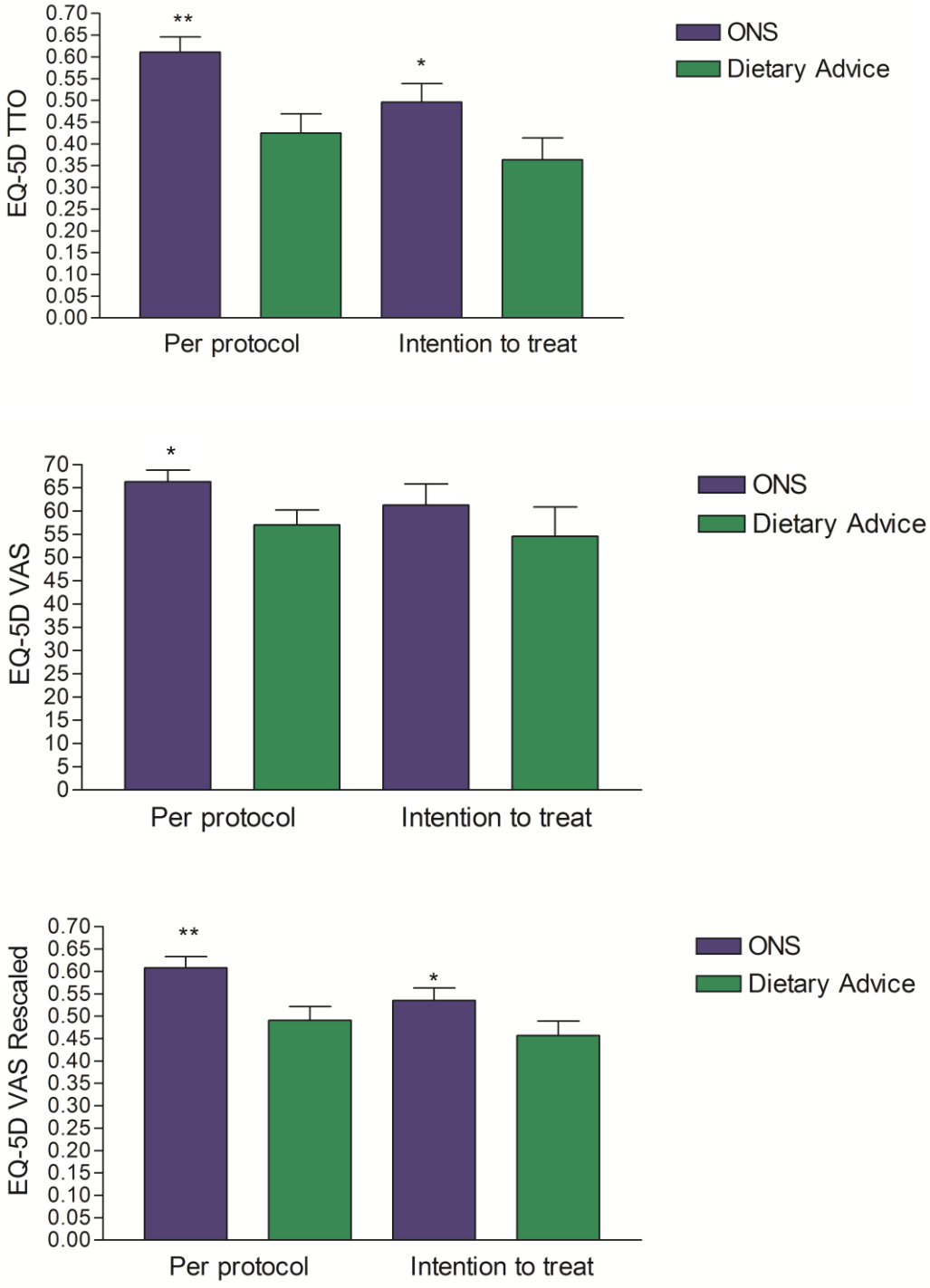


Figure 4.4 Quality of life (EQ-5D) assessed using Time Trade Off (TTO), VAS rescaled and Visual Analogue scores (VAS) for the ONS and dietary advice groups at week 12, using per protocol and intention to treat analysis ** $p<0.005$, *$p<0.03$

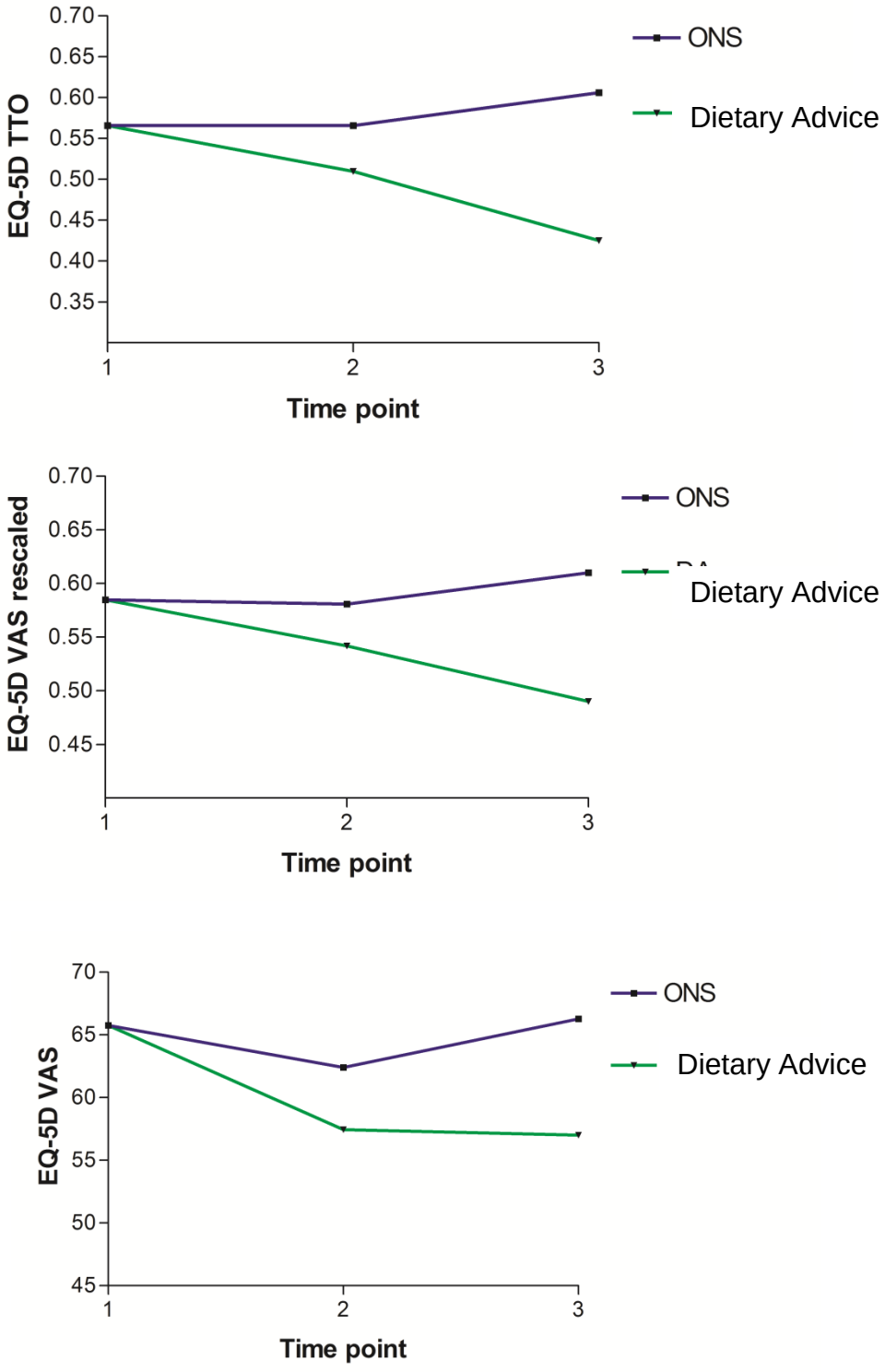


Figure 4.5 EQ-5D TTO, VAS rescaled and VAS at Baseline (1), Week 6 (2) and Week 12 (3), adjusted for the baseline value, designated intervention, type of care and 'MUST' category

Table 4.20 Quality of Life EQ-5D TTO, VAS rescaled and Visual Analogue Scale, according to intervention at week six and week 12, using per protocol and intention to treat analyses

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Per protocol						
EQ-5D TTO	0.563 ± 0.030	0.510 ± 0.035	0.257	0.611 ± 0.035	0.425 ± 0.044	0.002
EQ-5D VAS rescaled	0.581± 0.022	0.542 ± 0.026	0.254	0.608 ± 0.025	0.491 ± 0.031	0.004
Visual Analogue Scale (0-100)	62.40 ± 3.38	57.45 ± 3.89	0.350	66.3 ± 2.50	57.0 ± 3.2	0.027
Intention to treat						
EQ-5D TTO	0.468 ± 0.040	0.454 ± 0.041	0.093	0.496 ± 0.043	0.364 ± 0.050	0.005
ED-5D VAS rescaled	0.518 ± 0.026	0.509 ± 0.029	0.088	0.535 ± 0.028	0.457 ± 0.032	0.006
Visual Analogue Scale (0-100)	56.3 ± 4.1	55.8 ± 5.7	0.970	61.3± 4.5	54.6 ± 6.3	0.533

† Relates to comparisons between ONS and Dietary advice at week 6, ANCOVA, mean ± SE ‡ Relates to comparisons between ONS and Dietary advice at week 12, ANCOVA, mean ± SE. All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

Table 4.21 Average quality of life for the duration of the 12 week intervention, using per protocol and intention to treat analyses

	Intervention		P value†
	ONS	Dietary advice	
Per protocol			
EQ-5D TTO	0.580 ± 0.020	0.479 ± 0.024	0.002
EQ-5D VAS rescaled	0.591 ± 0.014	0.524 ± 0.018	0.005
Visual Analogue Scale (0-100):	63.51 ± 2.047	58.759 ± 2.509	0.154
Intention to treat			
EQ-5D TTO	0.489 ± 0.027	0.449 ± 0.028	0.013
ED-5D VAS rescaled	0.531 ± 0.018	0.507 ± 0.019	0.015
Visual Analogue Scale (0-100):	59.2 ± 2.5	57.3 ± 4.1	0.738

† Relates to comparisons between ONS and Dietary advice over the course of the intervention, ANCOVA, mean ± SE. All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

Table 4.22 Average Per protocol results for the components of EuroQol (EQ-5D), according to intervention at week 6 and week 12

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Mobility	2.086 ± 0.065	2.158 ± 0.076	0.475	2.036 ± 0.064	2.166 ± 0.080	0.211
Self care	1.734 ± 0.075	1.875 ± 0.088	0.226	1.595 ± 0.081	2.046 ± 0.102	0.001
Usual Activities	1.543 ± 0.074	1.599 ± 0.086	0.626	1.470 ± 0.070	1.512 ± 0.088	0.708
Pain	1.375 ± 0.067	1.308 ± 0.078	0.520	1.369 ± 0.078	1.562 ± 0.097	0.127
Anxiety	1.264 ± 0.065	1.354 ± 0.075	0.370	1.278 ± 0.069	1.373 ± 0.086	0.394

† Relates to comparisons between ONS & dietary advice at week 6, ANCOVA, mean ± SE ‡ Relates to comparisons between ONS & dietary advice at week 12, ANCOVA, mean±SE. All results were adjusted for baseline result, designated intervention, 'MUST' category, type of care

Table 4.23 The proportion of residents within each subgroup of the components of EuroQol (EQ-5D), using per protocol analysis, according to intervention, at week 6 and week 12

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Mobility			0.261			0.696
No problems: n (%)	6 (15.0)	3 (9.1)		6 (15.4)	4 (12.9)	
Some problems: n (%)	23 (57.5)	23 (75.8)		24 (61.5)	22 (71.0)	
Confined to bed: n (%)	11 (27.5)	5 (15.2)		9 (23.1)	5 (16.1)	
Self care			0.681			0.357
No problems: n (%)	17 (42.5)	14 (42.4)		19 (48.7)	14 (45.2)	
Some problems: n (%)	14 (35.0)	14 (42.4)		15 (38.5)	9 (29.0)	
Unable to wash and dress: n (%)	9 (22.5)	5 (15.2)		5 (12.8)	8 (25.8)	
Usual Activities			0.959			0.934
No problems: n (%)	21 (52.5)	17 (51.5)		21 (53.8)	17 (54.8)	
Some problems: n (%)	16 (40.0)	14 (42.4)		18 (46.2)	14 (45.2)	
Unable to perform usual activities: n (%)	3 (7.5)	2 (6.1)		0 (0)	0 (0)	
Pain			0.857			0.102
None: n (%)	27 (67.5)	24 (72.7)		26 (66.7)	16 (51.6)	
Moderate: n (%)	12 (30.0)	8 (24.2)		13 (33.3)	12 (38.7)	
Extreme: n (%)	1 (2.5)	1 (3.0)		0 (0)	3 (9.7)	
Anxiety			0.434			0.543
None: n (%)	30 (75.0)	22 (66.7)		29 (74.4)	21 (67.7)	
Moderate: n (%)	10 (25.0)	11 (33.3)		10 (25.6)	10 (32.3)	
Extreme: n (%)	0 (0)	0 (0)		0 (0)	0 (0)	

† Relates to comparisons between ONS and Dietary advice at week 6, Chi squared ‡ Relates to comparisons between ONS and Dietary advice at week 12, Chi Squared

4.4.4.2 Activities of daily living

There was no significant difference in the total score for activities of daily living between the ONS and dietary advice groups at week six or week 12, however the total score did increase slightly in the ONS group and decrease slightly in the dietary advice group at week 12 (13.65 ± 0.41 versus 12.86 ± 0.51) (Table 4.24). For the majority of the components of the ADL tool, there were no significant differences between groups. Continence and feeding were the only components where significant differences were observed, with their being a greater number of residents in the ONS group that were incontinent or required assistance with feeding than those in the dietary advice group (Table 4.24).

Table 4.24 Activities of daily living at week 6 and 12, according to intervention group

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary Advice		ONS	Dietary Advice	
Bowels			0.673*			0.037*
Incontinent: n (%)	7 (17.5)	4 (12.1)		5 (12.8)	0 (0)	
Occasional Accident: n (%)	2 (5.0)	3 (9.1)		1 (2.6)	4 (12.9)	
Fully Continent: n (%)	31 (77.5)	26 (78.8)		33 (84.6)	27 (87.1)	
Bladder			0.328*			0.357*
Incontinent: n (%)	6 (15.0)	6 (18.2)		7 (17.9)	2 (6.5)	
Occasional Accident: n (%)	12 (30.0)	5 (15.2)		6 (15.4)	5 (16.1)	
Fully continent: n (%)	22 (55.0)	22 (66.7)		26 (66.7)	24 (77.4)	
Grooming			0.590*			0.904*
Needs help: n (%)	8 (20.0)	5 (15.2)		8 (20.5)	6 (19.4)	
Independent: n (%)	32 (80.0)	28 (84.8)		31 (79.5)	25 (80.6)	
Toilet use			0.398*			0.804*
Dependent: n (%)	9 (22.5)	5 (15.2)		7 (17.9)	5 (16.1)	
Needs some help: n (%)	8 (20.0)	4 (12.1)		7 (17.9)	6 (19.4)	
Independent: n (%)	23 (57.5)	24 (72.7)		25 (64.1)	20 (64.5)	
Feeding			0.236*			0.044*
Unable: n (%)	2 (5.1)	1 (3.0)		0 (0)	0 (0)	
Needs help: n (%)	20 (51.3)	11 (33.3)		22 (56.4)	10 (32.3)	
Independent: n (%)	17 (43.6)	21 (63.6)		17 (43.6)	21 (67.7)	

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary Advice		ONS	Dietary Advice	
Transfer			0.037*			0.325*
Unable: n (%)	5 (12.5)	1 (3.0)		2 (5.1)	0 (0)	
Major help: n (%)	12 (30.0)	3 (9.1)		11 (28.2)	6 (19.4)	
Minor help: n (%)	2 (5.0)	4 (12.1)		2 (5.1)	4 (12.9)	
Independent: n (%)	21 (52.5)	25 (75.8)		24 (61.5)	21 (67.7)	
Mobility			0.515*			0.282*
Immobile: n (%)	7 (17.5)	4 (12.1)		6 (15.4)	4 (12.9)	
Wheelchair: n (%)	9 (22.5)	4 (12.1)		8 (20.5)	3 (9.7)	
Walks with the help of 1: n (%)	6 (15.0)	5 (15.2)		4 (10.3)	8 (25.8)	
Independent: n (%)	18 (45.0)	20 (60.6)		21 (53.8)	16 (51.6)	
Dressing			0.391*			0.720*
Dependent: n (%)	9 (22.5)	4 (12.1)		7 (17.9)	6 (19.4)	
Needs some help: n (%)	11 (27.5)	13 (39.4)		12 (30.8)	12 (38.7)	
Independent: n (%)	20 (50.0)	16 (48.5)		20 (51.3)	13 (41.9)	
Stairs			0.580*			0.441*
Dependent: n (%)	28 (70.0)	21 (63.6)		28 (71.8)	22 (71.0)	
Needs some help: n (%)	5 (12.5)	3 (9.1)		2 (5.1)	4 (12.9)	
Independent: n (%)	7 (17.5)	9 (27.3)		9 (23.1)	5 (16.1)	
Bathing			0.139*			0.378*
Dependent: n (%)	33 (82.5)	31 (93.9)		35 (87.2)	29 (93.5)	
Independent: n (%)	7 (17.5)	2 (6.1)		5 (12.8)	2 (6.5)	
Total Score (0–20):	12.78 ± 0.43	13.20 ± 0.50	0.530**	13.65 ± 0.41	12.86 ± 0.51	0.230**

† Relates to comparisons between ONS and dietary advice at week 6 * Chi Squared, ** Unpaired t-test; ‡ Relates to comparisons between ONS and Dietary advice * Chi Squared, ** ANCOVA, mean ± SE, All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

4.4.4.3 Weight, BMI, Mid Upper Arm Circumference (MUAC), skinfolds and handgrip

No significant differences in weight, BMI, MUAC, skinfolds or handgrip were observed between the intervention groups over the course of the 12 week intervention. There was a trend towards a difference in biceps skinfold between the groups, with the ONS group's mean biceps skinfold increasing by 0.58mm in 12 weeks, and the dietary advice group's mean biceps skinfold decreasing by 0.84mm (Table 4.25).

4.4.4.4 Activity levels and mobility

There was a trend towards a difference in reported activity levels at week 12, with the ONS group reporting feeling more active in the previous three months than the dietary advice group. Also, a larger proportion of the dietary advice group reported feeling less active in the previous three months than the ONS group (Table 4.26).

Residents' mobility levels and assistance required for walking and transfer did not differ between the intervention groups at week six or week 12 (Table 4.26).

There was a trend towards the dietary advice group having spent less time in bed per day and more hours sitting, however the results for these variables were not adjusted for imbalances in the baseline measures (Table 4.26).

Table 4.25 Weight, BMI, Mid Upper Arm Circumference (MUAC), skinfolds and handgrip at week 6 and 12, according to intervention group

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary Advice		ONS	Dietary Advice	
Weight (kg)	50.89 ± 0.44	49.76 ± 0.54	0.110	51.14 ± 0.44	50.26 ± 0.56	0.224
BMI (kg/m^2)	19.60 ± 0.15	19.13 ± 0.19	0.058	19.75 ± 0.17	19.40 ± 0.21	0.195
Percentage weight loss (%)				0.91 ± 0.36	1.40 ± 0.50	0.419
MUAC (cm)	23.30 ± 0.18	23.20 ± 0.21	0.716	23.85 ± 0.24	23.56 ± 0.30	0.447
Skinfolds (mm)						
Biceps	6.74 ± 0.31	6.14 ± 0.35	0.202	6.68 ± 0.30	5.79 ± 0.38	0.074
Triceps	11.55 ± 0.37	10.90 ± 0.41	0.246	11.28 ± 0.42	10.85 ± 0.52	0.525
MAMC	23.00 ± 0.19	22.88 ± 0.21	0.663	23.54 ± 0.24	23.23 ± 0.30	0.429
Handgrip (kg)						
Left hand	8.09 ± 0.52	7.49 ± 0.59	0.449	7.94 ± 0.51	8.49 ± 0.61	0.485
Right hand	8.18 ± 0.45	7.59 ± 0.52	0.398	8.15 ± 0.60	7.90 ± 0.74	0.796

† Relates to comparisons between ONS and dietary advice at week 6, ANCOVA, mean ± SE; ‡ Relates to comparisons between ONS and Dietary advice at week 12, mean ± SE, ANCOVA. All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care, MUAC: Mid Upper Arm Circumference, MAMC, Mid Arm Muscle Circumference

Table 4.26 Changes in activity levels and mobility at week 6 and week 12, according to intervention group

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary Advice		ONS	Dietary Advice	
Have their activity levels changed in the last three months?			0.324			0.068
More: n (%)	6 (17.1)	3 (11.1)		8 (22.0)	2 (7.4)	
The same: n (%)	22 (62.9)	16 (59.3)		25 (69.4)	20 (74.1)	
Less: n (%)	7 (20.0)	8 (29.6)		3 (8.3)	5 (18.5)	
Mobility Level			0.624			0.535
Bedbound: n (%)	4 (12.1)	1 (3.8)		4 (11.1)	1 (3.6)	
Wheelchair bound: n (%)	4 (12.1)	0 (0)		6 (16.7)	0 (0)	
Limited movement: n (%)	4 (12.1)	2 (7.7)		3 (8.3)	5 (17.9)	
Walks independently: n (%)	21 (63.6)	23 (88.5)		23 (63.9)	22 (78.6)	
Assistance with walking & transfer			0.289			0.478
None: n (%)	3 (9.4)	3 (11.5)		4 (12.1)	4 (14.3)	
Uses a stick or frame: n (%)	19 (59.4)	17 (65.4)		20 (60.6)	18 (64.3)	
Needs help from 1-2 people: n (%)	5 (15.6)	5 (19.2)		6 (18.2)	5 (17.9)	
Needs to be hoisted: n (%)	5 (15.6)	1 (3.8)		3 (9.1)	1 (3.6)	
Daily activities: mean ± SD						
Time spent in bed (hours)	12:02:09 ± 2:58:34	10:33:39 ± 1:49:04	0.029	11:45:47 ± 3:03:53	10:31:18 ± 1:56:08	0.068
Time spent sitting in a chair (hours)	11:29:09 ± 2:45:29	13:02:07 ± 1:41:11	0.014	11:46:03 ± 2:53:32	13:06:07 ± 1:50:10	0.039
Time spent walking (hours)	0:29:34 ± 0:36:05	0:26:15 ± 0:25:07	0.700	0:28:09 ± 0:34:41	0:23:27 ± 0:20:05	0.536

† Relates to comparisons between ONS and dietary advice at week 6, ANCOVA, mean ± SE; ‡ Relates to comparisons between ONS and dietary advice at week 12, mean ± SE, ANCOVA. All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

4.4.4.5 Number of Healthcare Professional (HCP) visits, pressure ulcers and hospital admissions

Only very small changes in the number of HCP visits, pressure ulcers and hospital admissions were observed in 12 weeks, with none of the differences between intervention groups reaching a level of significance (Table 4.27).

Table 4.27 Mean number of Healthcare professional (HCP) visits, pressure ulcers and hospital admissions, according to intervention, at week 6 and week 12

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Number of HCP visits	0.65 ± 0.21	0.65 ± 0.24	0.986	1.51 ± 0.42	1.35 ± 0.52	0.894
Number of Pressure ulcers	0.06 ± 0.04	0.08 ± 0.04	0.702	0.14 ± 0.07	0.14 ± 0.09	0.962
Number of Hospital Admissions	0.02 ± 0.03	0.02 ± 0.03	0.935	0.02 ± 0.04	0.11 ± 0.04	0.121

† Relates to comparisons between ONS and dietary advice at week 6;

‡ Relates to comparisons between ONS and dietary advice; ANCOVA, mean ± SE, All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

4.4.4.6 Appetite

Sensations of fullness differed significantly between the intervention groups at the end of the 12 week intervention, with the ONS group's mean fullness score being 1.43cm lower than the dietary advice group (p=0.021). However, neither the hunger nor desire to eat scores differed significantly between intervention groups (Table 4.28).

Table 4.28 Mean appetite scores at week 6 and week 12, according to intervention group

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Hunger			0.792*			0.834*
Yes: n (%)	11 (27.5)	10 (30.3)		8 (20.5)	7 (22.6)	
No: n (%)	29 (72.5)	23 (69.7)		31 (79.5)	24 (77.4)	
Hunger VAS (cm)	3.88 ± 0.40	4.05 ± 0.46	0.784**	3.76 ± 0.36	3.92 ± 0.49	0.792**
Fullness			0.221*			0.017*
Yes: n (%)	18 (46.2)	20 (60.6)		16 (41.0)	21 (70.0)	
No: n (%)	21 (53.8)	13 (39.4)		23 (59.0)	9 (30.0)	
Fullness VAS (cm)	4.70 ± 0.41	5.27 ± 0.45	0.355**	4.59 ± 0.36	6.02 ± 0.48	0.021**
Desire			0.609*			0.554*
Yes n (%)	17 (42.5)	16 (48.5)		18 (46.2)	16 (53.3)	
No n (%)	23 (57.5)	17 (51.5)		21 (53.8)	14 (46.7)	
Desire VAS (cm)	4.69 ± 0.41	4.59 ± 0.47	0.877**	4.63 ± 0.32	5.42 ± 0.42	0.143**

† Relates to comparisons between ONS and dietary advice at week 6; ‡ Relates to comparisons between ONS and dietary advice at week 12, * Chi Squared, ** ANCOVA – All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

4.4.4.7 Dietary intake

The total energy, protein and a range of micronutrient intakes were significantly greater in the ONS group than the dietary advice group at both week six and week 12 (Table 4.29 and Figures 4.6 and 4.7). The ONS groups mean energy and protein intake from food decreased slightly at week 6, but increased by week 12 to the levels observed at baseline, suggesting that their nutrient intake from ONS was additive, rather than suppressing their intake from meals and snacks (Figures 4.6 and 4.7). The dietary advice groups mean nutrient intake steadily decreased over the course of the 12 week intervention (Figure 4.7)

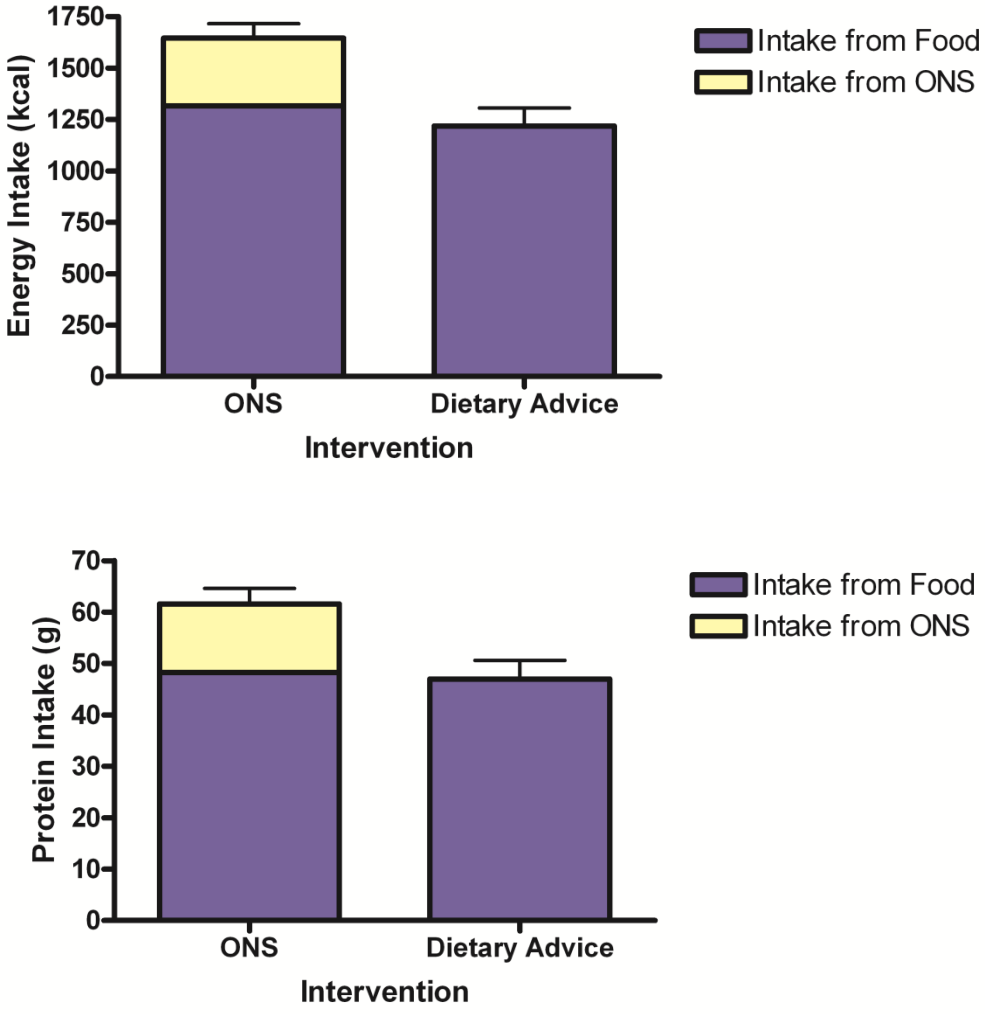


Figure 4.6 Mean daily energy (kcal) and protein (g) intake at week 12, according to intervention group

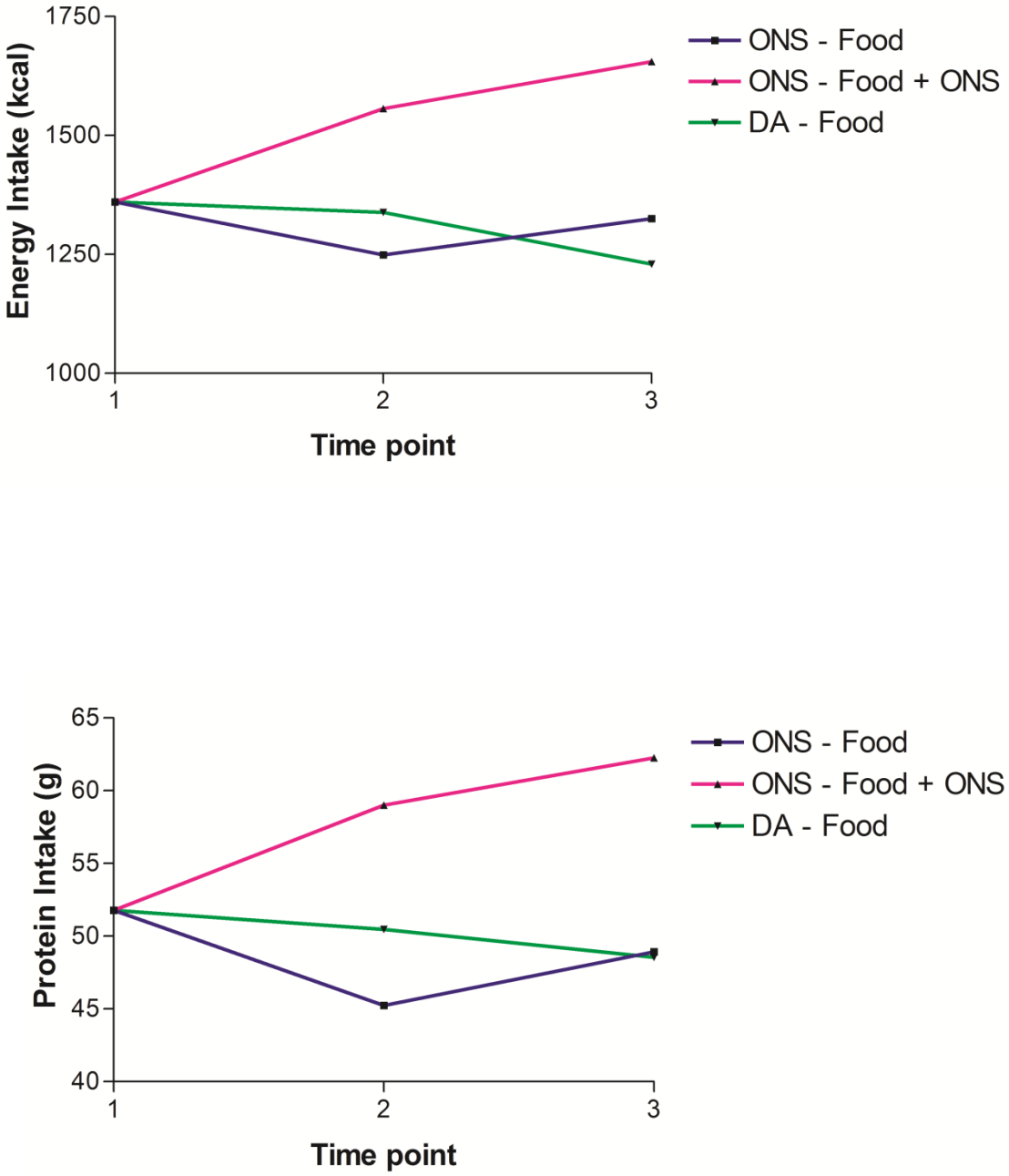


Figure 4.7 Mean daily energy (kcal/day) and protein (g/day) intake at baseline (1), week 6 (2) and week 12 (3) for the ONS group (Food only and Food plus ONS) and dietary advice (DA) group

Table 4.29 Energy, protein and micronutrient intake, according to intervention group at Week 6 and Week 12

	Week 6		p value†	Week 12		p value‡
	ONS	Dietary advice		ONS	Dietary Advice	
Energy (kcal/d)	1240 ± 68.4	1268 ± 79.9	0.792	1316 ± 70.5	1218 ± 88.4	0.393
	1554 ± 69.9*		0.010	1645 ± 74.8*		0.001
Protein (g/d)	45.9 ± 2.9	49.5 ± 3.4	0.429	48.3 ± 2.8	47.0 ± 3.6	0.770
	59.7 ±3.2*		0.038	61.6 ± 3.0*		0.004
Potassium (mg/d)	1831 ± 140.2	2083 ± 163.6	0.248	1952 ± 92.4	1795 ± 115.9	0.292
	2106 ± 142.6*		0.917	2241 ± 98.0*		0.007
Magnesium (mg/d)	148 ± 9.8	168 ± 11.5	0.206	162 ± 8.1	152 ± 10.2	0.438
	196 ± 11.0*		0.111	212 ± 10.0*		0.001
Iron (µg/d)	6.77 ± 0.40	6.46 ± 0.47	0.616	6.52 ± 0.37	6.78 ± 0.47	0.662
	10.57 ± 0.53*		0.0001	10.08 ± 0.57*		0.001
Copper (µg/d)	1.25 ± 0.62	1.50 ± 0.73	0.796	0.85 ± 0.18	0.84 ± 0.22	0.977
	1.76 ± 0.63*		0.793	1.34 ± 0.18*		0.097
Zinc (µg/d)	6.00 ± 0.50	6.23 ± 0.58	0.746	5.58 ± 0.31	5.40 ± 0.39	0.722
	9.59 ± 0.60*		0.001	9.08 ± 0.50*		<0.0001
Selenium (µg/d)	21.28 ± 2.01	21.25 ± 2.35	0.992	25.07 ± 2.10	21.29 ± 2.63	0.266
	46.05 ± 3.25*		<0.0001	49.53 ± 3.11*		<0.0001
Iodine (µg/d)	84.07 ± 94.85	108.16 ±	0.316	101.54 ± 15.50	108.16 ± 19.44	0.791
	132.38 ± 8.72*	19.44	0.007	148.98 ± 17.38*		0.149
Vitamin A (µg/d)	1202.8 ± 422.4	351.0 ± 493.1	0.194	600.93 ± 333.98	691.02 ±	0.867
	1477.6 ± 423.7		0.089	869.20 ± 332.45*	418.90	0.739
Vitamin D (µg/d)	1.73 ± 0.20	1.47 ± 0.24	0.396	2.45 ± 0.36	1.95 ± 0.44	0.381
	4.87 ± 0.43*		<0.0001	5.57 ± 0.62*		<0.0001

*including intake from ONS † Relates to comparisons between ONS and Dietary advice at week 6; ‡ Relates to comparisons between ONS and Dietary advice at week 12, ANCOVA, All results were adjusted for the baseline result, designated intervention, 'MUST' category and type of care

4.4.4.8 Subject satisfaction

Subject satisfaction with the ONS or dietary advice was monitored at week six and week 12, with differing results according to the type of intervention.

4.4.4.8.1 ONS group

Satisfaction with the ONS provided during the 12 week intervention appeared to be good. All participants in the ONS group were given an information sheet at baseline, which 91.9% of participants still had a copy of at their week six visit and 65.8% had a copy at the end of the intervention period. Again, although the majority of participants had a copy of the information sheet, only 35.9% of participants had recently looked at the sheet at the week six visit, and only 18.4% had recently looked at the sheet at week 12 (Table 4.30).

At the time of the week six and week 12 visits, approximately 50% of residents had already consumed a bottle of ONS on the day of the visit, with the timing of their ONS varying between subjects. The majority of residents (92%) reported consuming 100% of their daily ONS. A similar proportion reported finding the ONS pleasant (92.5% at week six and 87.2% at week 12), and liked the taste of the ONS (92.1% at week six and 86.8% at week 12). At week six, the majority of residents did not report any changes in their liking of the ONS (87.2%), however by week 12, 29.7% had reported liking them more (Table 4.31).

Table 4.30 Residents' satisfaction with the ONS provided at week 6 & week 12

	Week 6	Week 12
Does the subject still have the ONS sheet?		
Yes: n (%)	34 (91.9)	25 (65.8)
No: n (%)	3 (8.1)	13 (34.2)
Has the subject looked at the ONS sheet?		
Yes: n (%)	14 (35.9)	7 (18.4)
No: n (%)	25 (64.1)	31 (81.6)
Have they taken their ONS today?		
Yes: n (%)	19 (50.0)	20 (51.3)
No: n (%)	19 (50.0)	19 (48.7)
What time do they take their ONS?		
Anytime: n (%)	7 (18.4)	6 (15.4)
Between meals: n (%)	15 (39.5)	17 (43.6)
Morning only: n (%)	4 (10.5)	1 (2.6)
Afternoon only: n (%)	12 (31.6)	14 (35.9)
Did not take any ONS: n (%)	0 (0)	1 (2.6)

Table 4.31 Residents' satisfaction with the ONS provided at week 6 & week 12

	Week 6	Week 12
Quantity of ONS consumed:		
How many ONS do they take per day?	1.10 ± 0.48	1.16 ± 0.51
How many ONS do they take per week?	7.24 ± 3.82	6.62 ± 4.57
How much of the ONS do they usually take?		
None: n (%)	1 (2.6)	1 (2.6)
25%: n (%)	0 (0)	1 (2.6)
50%: n (%)	0 (0)	1 (2.6)
75%: n (%)	2 (5.2)	0 (0)
100%: n (%)	36 (92.3)	36 (92.3)
Satisfaction with the ONS:		
Do they find the ONS pleasant?		
Yes: n (%)	*37 (92.5)*	*34 (87.2)*
No: n (%)	*3 (7.5)*	*5 (12.8)*
How pleasant do they find the ONS (0-10)	7.72 ± 2.24	7.86 ± 1.58
Do they like the taste of the ONS?		
Yes: n (%)	35 (92.1)	33 (86.8)
No: n (%)	3 (7.9)	5 (13.2)
How much do they like the taste of the ONS?	7.71 ± 2.40	8.03 ± 1.44
Has their liking of the ONS changed over time?		
Like them more: n (%)	5 (13.9)	11 (29.7)
No change: n (%)	30 (83.3)	25 (67.6)
Like them less: n (%)	1 (2.8)	1 (2.7)

4.4.4.8.2 Dietary advice group

A range of questions were asked at week six and week 12 to ascertain whether the dietary advice was adhered to (Table 4.32). From these questions it would appear that the participants' use of the diet sheet varied, with 87.5% still having the diet sheet at week 6, and 58.1% having a copy of the diet sheet at week 12. Just over 50% of the group still had a copy of the diet sheet at week six and week 12, but very few participants had recently consulted the diet sheet (3.1% at week six and 9.7% at week 12). The majority of participants in this group (70.4% at week six and 60.7% at week 12) felt they were following the dietary advice, and 45% of the residents reported making some changes to their diet in order to follow the dietary advice provided. Changes to their diets included the addition of snacks between meals, the addition of dairy foods to meals and nourishing fluids between meals.

Table 4.32 Residents' satisfaction with the dietary advice provided at week 6 & week 12

	Week 6	Week 12
Does the subject still have their diet sheet?		
Yes: n (%)	28 (87.5)	18 (58.1)
No: n (%)	4 (12.5)	13 (41.9)
Has the subject looked at their diet sheet?		
Yes: n(%)	1 (3.1)	3 (9.7)
No: n (%)	31 (96.9)	28 (90.3)
Are they following the advice in the diet sheet?		
Yes: n (%)	19 (70.4)	17 (60.7)
No: n (%)	8 (29.6)	11 (39.3)
Have they made any changes to their diet?		
Some changes: n (%)	15 (45.5)	14 (45.2)
No changes: n (%)	18 (54.5)	17 (54.8)
What dietary changes have they made?		
Having three meals per day plus snacks (e.g. biscuits/cake): n (%)	10 (30.3)	13 (41.9)
Dairy foods added to meals: n (%)	4 (12.1)	1 (3.2)
Nourishing fluids (e.g. milky drinks) between meals: n (%)	8 (24.2)	7 (22.6)
No changes made: n (%)	11 (33.3)	10 (32.3)

4.5 Discussion

This 12 week RCT of ONS versus dietary advice is the first RCT in malnourished care home residents to explore the impact of ONS and dietary advice on a range of clinical, functional and healthcare outcomes. This is the first RCT in malnourished care home residents to show that ONS are effective at improving quality of life, with the provision of ONS being more effective in improving quality of life than the provision of dietary advice. In addition to improvements in quality of life, nutritional intake also improved in the ONS group, suggesting that the ONS were taken by the participants and it was more effective than dietary advice at improving quality of life.

Given that a variety of outcomes were measured it is important to consider the results and also the reasons why significant differences were not achieved, and the potential limitations of the RCT.

4.5.1 Quality of Life

The most important finding of this study was a significant improvement in quality of life in the ONS group compared with the dietary advice group. Quality of life was measured in this RCT using EuroQoL [122], which is a validated tool. EuroQol is recommended for use by NICE [126], as their guidance states that a quality of life tool should be a generic and validated classification system which uses reliable UK population based preference values, that were elicited using a choice based method such as time trade off or standard gamble. Using EQ-5D as a measure of quality of life in this trial had advantages over the use of other quality of life tools. As the tool was designed for use with adult populations, using a specific reference range for the UK population, it allows the results to be easily compared with other trials that have used the EQ-5D tool. The EQ-5D group tested the tool in a range of populations, including countries throughout Europe, the USA, Japan and Zimbabwe and produced sets of co-efficients specific to each population [122].

Another advantage of this quality of life tool is that it produces overall quality of life scores for individual participants, which can be used in health economic analyses using costs per quality adjusted life years (QALY's) (Chapter 5). Tools that do not produce overall scores are not amenable to such analyses.

Using this measure of quality of life, there was a gradual increase in quality of life over 12 weeks in the ONS group, with the increase being more marked between week six and week 12 than between baseline and week six. In addition to the significant increase at

week 12 of the trial, the average quality of life, over the course of the 12 week intervention was also significantly greater in the ONS than the dietary advice group. The differences between groups for these measures of quality of life were considered to be clinically significant in addition to being statistically significant.

The dietary advice group's quality of life gradually declined over the course of the 12 week intervention (Figure 4.5); a similar finding to that of the 12 week food fortification randomised controlled trial by Smoliner et al., 2008 which found a reduction in quality of life using SF-36 in 52 malnourished care home residents. In this trial, using the SF-36 physical disability dimension they found the score decreased significantly in both the intervention group (17.1 ± 22.7 to 10.7 ± 15.6, p=0.047) and the control group (24.0 ± 24.3 to 13.6 ± 13.9, p=0.001), although the decline in quality of life was smaller in the food fortification group than the control group (7 points versus 10 points), however, unlike the new trial, the difference between groups was not significant.

In this RCT approximately one third of the participants did not complete the intervention. The characteristics of those that did and did not complete the intervention were explored, and the reasons for drop outs were similar in the two groups. The proportion of residents that dropped out was not significantly different between groups (Tables 4.7 to 4.11) and the baseline characteristics of the two groups were similar (Tables 4.4 to 4.6 and 4.12 to 4.18). To confirm that the results were robust, an intention to treat analysis was undertaken using multiple imputation [127]. This technique for dealing with missing data is considered to be more robust than previous methods for dealing with missing data, such as carrying values forward or using mean values.

The use of the multiple imputation technique in the analysis of the primary outcome of this RCT resulted in similar values for quality of life to the per protocol analysis, with the magnitude of the difference between the groups being of a similar order, although the values were slightly lower than those produced by the per protocol analysis. The results were also very similar when considering the results at time points during the intervention, and the results averaged over the course of the 12 week intervention.

The only results from the EuroQol quality of life tool that did not remain significantly different when analysed using a multiple imputation model were the results of the Visual Analogue Scale. For this aspect of the EQ-5D the mean difference between the groups was 6.7 points using the intention to treat analysis rather than the 9.3 point difference produced in the per protocol analysis. A 6.7 point difference is still quite sizeable, however the standard errors in the pooled imputed data (ONS: 61.3 ± 4.5, DA: 54.6 ± 6.3) were approximately double that of the per protocol analysis (ONS: 66.3 ± 2.5, DA:

57.0 ± 3.2), which may help to explain why the difference was not significant for this aspect of quality of life.

Although there were significant differences in the overall scores for quality of life, using ED-5D TTO, VAS rescaled and VAS, it is worth considering participants' responses to the components of the EuroQoL questionnaire both in terms of mean scores for each component, and proportion of residents in each sub category of the components. When considered in terms of mean scores, the ONS group had consistently lower mean scores for all five components of the questionnaire, with the difference between the scores being significant for the self care component (Table 4.22). Lower scores indicated greater levels of independence in the ONS group for all five components, which would be in agreement with the increase in total TTO and VAS rescaled scores. This significant difference in the self care component could result in implications for the work load of care home staff, and potentially increase staff efficiency if residents are feeling better within themselves and more able to carry out tasks such as washing and dressing independently.

When considered in terms of the proportions in each subgroup of components (e.g. independent, needs some help, dependent) there were larger shifts in the dietary advice group than the ONS group in terms of participants not being able to complete their self care independently or they experienced greater levels of pain or discomfort (Table 4.23). This decline in certain components of the questionnaire would have resulted in participants being assigned a worse score, and would help to explain the decline in the mean score for the dietary advice group. The overall assigned score for individual participants also depended upon the combination of the five components. Although the distribution within some components remained relatively constant, there may have been shifts in levels of dependency within each component. Participants that experienced a decline in their ability to wash and dress, or experienced higher levels of pain may have also experienced greater levels of dependency within the remaining components, resulting in a much greater overall decline in total score for certain individuals. It is likely that the changes described above, were also observed in the imputed data, due to the nature of multiple imputation analysis techniques.

Given that EuroQol has not previously been reported in nutrition intervention trials in older people residing in care homes, it is important to consider the quality of life results presented in this trial with those of other trials that have used EuroQol in both chronically ill and healthy populations (Table 4.33). As observed from this comparison of this RCT with other trials (mean EQ-5D TTO: 0.56), the values for EuroQol reported in this RCT are similar to those reported by other RCT's measuring quality of life in chronic disease. Other studies have reported TTO values ranging from 0.46 in a RCT involving older

people (mean age 82.8 ± 7.48 years) after femoral neck fracture [128] to 0.72 in an RCT involving patients with diabetes [129].

Table 4.33 EQ-5D TTO scores for a range of health conditions and a healthy population

Patient group	EQ-5D TTO
Community nutrition support trial *(this study)*	0.56
Older people [128]	0.46
Chronic heart failure [123]	0.54
Mild to moderate depression [130]	0.59
Rheumatoid arthritis [129]	0.60
Chronic obstructive pulmonary disease [129]	0.62
Diabetes [129]	0.72
Healthy population (Adults - all ages) [129]	0.91

4.5.2 Energy and nutrient intake

The increases in quality of life observed over the course of the 12 week intervention mirrored the increases in energy and protein intake observed in the ONS group. The increase in nutritional intake, in combination with the increase in quality of life is suggestive that not only was the intervention taken by the ONS group, but that the increase in nutritional intake had a positive impact on the quality of life of malnourished care home residents.

The energy, protein and micronutrient intakes of the subjects were significantly different at the end of the 12 week intervention, favouring the ONS group. The increases in energy and protein intakes observed in the ONS group were similar to the increases in nutrient intakes observed in the ONS trials included in the systematic review of nutritional interventions [73-75].

The increase in energy and protein intake observed in the ONS group followed a similar pattern to that of the increases in quality of life scores within this group. There was a smaller change in intake between baseline and week six, than the larger change in intake that occurred between week six and week 12. This is suggestive that any intervention with ONS should be for a minimum of 12 weeks in order to gain benefits in quality of life.

The ONS group not only increased their intake of macronutrients during the intervention, but their intake of micronutrients also significantly increased. The increase in this range of macro and micronutrients may have impacted positively on their quality of life. It is possible that due to participants' low baseline intake of many key nutrients, the supplementation of their diet with ONS allowed them to increase their intake of key nutrients required for physiological processes such as immune function and cognition. For example, deficiencies in energy, protein and vitamins A, C, D, E, B6, B12, folate, biotin, zinc, copper, iron and selenium result in reduced T-cell differentiation [30]. As immune function is often linked to cognition in older people, it is possible that the supplementation of a range of nutrients may have impacted on their general health, and subsequently their perspective on their quality of life.

Interestingly, the provision of ONS was additive to food intake, and did not suppress habitual food intake at week 12. Over the course of the first six weeks of the intervention, the nutrient intake of the ONS group did increase, however their intake from food decreased slightly in this period. By the time intake was recorded again at week 12, their intake from food had returned to the same level as their baseline intake, with the ONS then being additive to their food intake. This therefore suggests that participants may take six weeks or more to establish a regime of taking the ONS that does not inhibit their intake from food.

In addition to ONS not suppressing food intake at week 12 of the intervention, participants that received ONS did not feel any fuller than those that received dietary advice, and possibly reported feeling less full during the day by the end of the intervention period, despite having a greater energy and nutrient intake. This additive effect of ONS to food intake has been observed by other trials of ONS, which have also shown that the provision of liquid supplements has less of an effect on satiety than the provision of solid food snacks [41].

Despite this increase in energy and nutrient intake over the twelve week intervention, it did not result in change in weight or function. It may be possible this could be explained by physiological changes, changes in activity levels or methodological limitations.

Given that the population studies in this RCT was very old, it is possible that undocumented underlying disease processes may have been occurring, which may have resulted in increases to their nutritional requirements through raised total energy expenditure. Limited information was gathered on activity levels and changes in mobility over the course of the intervention. The results suggested that there were some small changes in self perceived activity levels, however due to the lack of detail in the recording of activity levels, it is not possible to draw firm conclusions from these results.

The information on dietary intake was collected through 24 hour food recall at baseline, week six and week 12, which does have some limitations. This method of dietary record provides a snap shot of food intake over a 24 hour period, however it is not able to capture any information on trends in food intake [29]. The content of the diary depends entirely on whether the day of the record is typical for that person. In the case of this RCT the food consumed in the 24 hours prior to the visit was recorded by the dietitian, who collected as much information as possible on food intake from the resident, and cross checked it with information from members of staff and any available food charts. This cross checking of dietary information should have helped to reduce the potential inaccuracies in the reporting of food intake.

4.5.3 Compliance to the nutritional interventions

Compliance to the interventions is important to consider when assessing whether the participants were exposed to the intervention. It is an aspect of nutritional intervention studies that is often under reported, but crucially important to ascertaining whether participants were exposed to the intervention. The questionnaires on satisfaction to the ONS and dietary advice produced some interesting results, further supporting the increased intake observed in the ONS group. The results also suggested that exposure to the dietary advice intervention may have been more limited, therefore potentially reducing the opportunity for participants' quality of life to improve in this group.

4.5.3.1 Compliance to the ONS

From the 24 hour food recalls the ONS groups' mean energy intake from ONS was 333kcal/day, which equates approximately to one bottle of ONS per day. This is slightly lower than the recent systematic review of compliance to oral nutritional supplements which found a mean energy intake of 433kcal/day [131], but higher than the mean intake from ONS reported in the Chapter Three (123kcal/day).

Participants were generally very satisfied with the intervention they received, and approximately one third of the subjects reported liking the ONS more by the end of the 12 week intervention. This liking of the ONS is supported by the increase in nutrient intake observed in the trial. The nutritional intake data for week 6 and 12 was indicative that the increase in intake was more marked between weeks six and 12 than baseline and week six. Combined with an increased preference for the ONS by the end of the intervention, it suggests that residents took the first six weeks to establish their preferences and routine for taking the ONS.

Compliance to taking ONS may have been affected by a range of factors. The recent review of compliance to ONS indicated that the energy density, range of flavours and the provision of instructions with ONS all impact on compliance to taking ONS [131]. In this trial, all participants had access to energy dense supplements and were able to change the flavours they received if they did not like them. All residents were provided with instructions on how to take their ONS, which was provided to the resident and also the care staff. Other factors that can influence compliance include the residents' liking of the ONS, remembering to take them on a daily basis, and assistance from staff. With many residents experiencing reduced mobility and incontinence, many residents did not want to consume large volumes of fluids throughout the day, therefore it was important for supplements to have a high energy density. Residents were able to divide their ONS into smaller quantities where volume was problematic.

4.5.3.2 Compliance to the dietary advice

The results for satisfaction with the dietary advice provided were more varied. The majority of residents that received this intervention reported that they had not recently read the dietary sheet they were provided with, and only 45% reported making changes to their diet at week six and week 12. The majority of those that did make changes to their diets tended to add snacks between their meals, or have nourishing drinks. Some residents felt they were unable to make any further changes to their diet, as they felt they were already following the advice provided in the diet sheet. Although some residents reported making changes to their diets over the course of the intervention, the groups mean nutrient intake and weight did not increase significantly.

It is possible that this group may have encountered some barriers to making changes to their diet during the intervention, due to living in an institutional setting. Residents' control over the food and drinks they consumed may have been less than if they were living in their own home. Their ability to comply with the dietary advice was therefore more dependent on the kitchen staff being aware of the need to enrich people's meals and drinks. In this trial, those residents that were more independent tended to ensure they had a supply of snacks such as biscuits and cake in their rooms, in order to help them increase their food intake. This reliance on care home staff with the provision of dietary advice has also been reported by Simmons et al., 2008. Their study highlighted that the time nurses have to assist residents with their meals is limited, however this time spent assisting residents may be essential in order to help increase residents' intake from food. They suggested that between meal snacks may also be effective and require less staff input than assistance with meals.

Despite these improvements in quality of life, nutritional intake and the observed overall satisfaction with the intervention within the ONS group, no other significant results were observed over the course of the 12 week intervention. The range of clinical and functional outcomes measured in the trial is discussed below, including potential reasons as to why significant results were not observed.

4.5.4 Weight

Weight change is considered to be an important outcome in nutrition intervention trials [121]. It has been suggested that a weight change of at least 2kg would be considered to be clinically significant [70]. In this RCT, subjects' weight increased from 48.48kg ± 9.85 to 51.14 ± 0.44kg in the ONS group and decreased from 51.08kg ± 8.92 to 50.26 ± 0.56kg in the dietary advice group. However when the results were adjusted for the baseline imbalance in weight, the resulting change in weight was only 0.8kg between the groups, despite the improvements in energy and protein intake in the ONS group. This change in weight was lower than the mean weight change in the systematic review of nutritional interventions in care homes (1.30 ± 0.38kg), however even in this review the weight change ranged from only 0.40 ± 0.68kg in the 12 week food fortification versus trial [76] to 2.2kg in a 12 week ONS versus control trial [77]. This may suggest that if a control group had been used within this RCT, greater mean differences in weight between the groups may have been observed.

There are some methodological reasons that may also explain why the weight change was not greater over the 12 week intervention. Firstly, the scales used to weigh residents varied between care homes. Ideally, all residents would have been weighed using the University of Southampton approved weighing scales, which were digital, stand on scales. However, the majority of residents were unable to stand safely on the scales, therefore the care home sit on or hoist scales had to be used. Due to constraints within the care home, it was not always possible to assess the accuracy and precision of the care home scales against the University of Southampton scales. However, all residents were weighed using the same set of scales at each time point during the intervention, in order to minimize the variability of the weight measurements. There was also the potential for user error with the care home weighing scales, when care home staff were asked to weigh residents independently. It could be possible that residents may have been wearing excess clothing when they were weighed, or that residents could still have been leaning against supporting frames, not applying their full weight to the weighing scales. Although looked for by researchers at follow up visits, it is possible that residents may have experienced mild oedema, which was not possible to detect during the follow up

assessments. Weight measurements were conducted at different times of the day, which could also have resulted in differing weight measurements.

4.5.5 Functional outcomes

This trial, like many others reviewed in the systematic review of nutritional interventions in care homes failed to show any significant differences in functional outcomes between the ONS and dietary advice groups. It may be possible that an exercise component to a nutritional intervention trial is required in order to assist the formation of lean body tissue. Trials by Fiatarone Singh et al., 2000 and Zak et al., 2009 have reported that such changes are possible with the combination of ONS and resistance training in care home residents, however little is known as to whether similar effects would be observed with dietary advice.

4.5.6 Healthcare use

This trial did not result in any significant changes in healthcare use. It is likely that the sample size and duration of the intervention in this trial was insufficient to fully assess this outcome measure. The trial by Gil Gregorio et al., 2003 was suggestive that an intervention period of one year was necessary in order to observe changes in infection rates and mortality within a care home population.

4.5.7 Limitations of this randomised controlled trial

This trial was not without its limitations. These include the population studied, interventions used, the duration of the intervention, and the attrition rate during the intervention.

When considering the results of this RCT it is important to note that the trial took place within a subset of care home types within Hampshire. As discussed in Chapter two, this subset did not include homes exclusively for residents with advanced dementia, learning difficulties, or residents aged less than 50 years. The participating care homes included privately owned residential, nursing and dual registered homes of varying size and locality. Therefore, caution must be applied when considering whether the results of the RCT would be applicable to such populations.
The care homes that participated in the RCT were selected on a voluntary basis. It is possible that these homes had a greater interest in nutritional care and as a result took a

more active interest in ensuring residents received the ONS or dietary advice. As with any intervention, the compliance to the intervention in an institutional setting is dependent on the staff who administer the intervention being aware of how they should do this. Communication with staff was an important consideration in this care home setting, as many residents were dependent upon staff giving them their ONS at specified times, or ensuring they received enriched meals or snacks. In larger homes, with a high staff turnover it is possible to see that without clear guidance, compliance to nutritional interventions could be lower.

Just over 30% of residents that were recruited to the trial did not complete the 12 week intervention. The residents participating in the trial were very frail and old, with many participants experiencing some level of memory loss during the 12 week intervention period which meant that it was not possible to carry out follow up visits with them. Prior to taking consent to participate in the trial, residents' capacity to give informed consent was judged on the opinion of the care home manager or head of care, and the researcher having visited the potential subject on two separate occasions to discuss the project, in order to minimize the potential for residents failing to complete the intervention. However, it is possible that some participants may have had a greater level of memory loss at their baseline visit than was anticipated. Also, given the frail nature of residents at risk of malnutrition, some participants did not complete the intervention due to increasing frailty, illness or hospital admissions.

As with many nutritional intervention trials, it was not possible to blind research staff, participating residents or care home staff to the interventions the residents received. All participating residents were fully aware of why they were receiving the intervention, and that their wellbeing would be assessed at intervals throughout the intervention. It is possible that staff may have aided compliance to interventions as they were aware of the RCT taking place and the interventions residents received.

Another factor to consider regarding study design is the inclusion of a control group. In this RCT, a control group was not used, in order to compare to commonly used nutritional interventions. However, it is possible that the differences observed between groups may have been much greater if a control group had also been used. Any future studies may wish to consider having four groups, including ONS, dietary advice, placebo ONS and a control group receiving routine care. However, in order to use four groups within such a trial in care homes, a much larger population would be required.

It is possible that the improvements in quality of life observed in the RCT could also be attributed to the additional visits residents received as a result of the trial. As discussed in Chapter one, older people may experience some anxiety on moving to a care home. The

inclusion of social activities within the day is important in maintaining wellbeing. However, during the RCT, all residents that participated in the trial were visited on three occasions; baseline, week six and week 12. These visits took the same amount of time, regardless of intervention, therefore it is likely that the increase in quality of life observed in the ONS group was due to the increase in dietary intake within the ONS group, rather than researcher input.

Recruitment to the study was challenging due to the frail nature of care home residents. The strict inclusion and exclusion criteria resulted in the need to screen over 1400 care home residents for potential eligibility, in order to recruit 104 residents to the trial. Many residents were excluded from the trial due to short term memory loss and conditions such as dementia. The exclusion of those with short term memory loss was due to the primary outcome of this trial being quality of life. It was felt that residents with memory loss should not complete the EuroQol tool, due to it not being specific to people with dementia. Although other quality of life tools exist for the measurement of quality of life in people with dementia [132-135], they were not used in this study. This decision was taken in order to ensure that the results were comparable with other quality of life studies.

By excluding those with dementia it has meant that it is not known whether this RCT would have the same effects on quality of life and nutritional intake within these groups of care home residents. As seen from the audit of malnutrition risk in care homes, the prevalence of malnutrition risk in people with dementia is higher than the average figure, therefore suggesting that those with dementia may actually be in greater need of assistance with improving their nutritional status. Any future trial of nutritional interventions may need to consider the effects of ONS and dietary advice, or another type of oral nutrition support in both those with and without advanced memory loss, or dementia.

Residents that were not malnourished according to 'MUST' criteria were not included in this RCT, in order to assess the effects of nutrition support strategies in those with greatest needs. However, it is possible that implementing nutrition support strategies in those with higher BMI's, who are not considered at risk of malnutrition according to 'MUST' may also benefit from such strategies. Many of the RCT's included in the systematic review of nutritional interventions included mixed populations, with the mean BMI of participants in many studies being between 22 and 25kg/m^2 (Table 3.3).
The duration of the intervention is also an important factor to consider with nutrition support trials. As identified from the review of nutritional interventions, trial duration can vary from four days to one year. This RCT intervened for 12 weeks, and resulted in improvements in quality of life and intake. However, if it had only been a six week

intervention, the differences in quality of life would not have been significant. This therefore suggests that at least 12 weeks is required for this intervention to be effective at improving both nutritional intake and quality of life. It is not known whether these effects would continue to improve if the intervention was longer, or if the participants' nutritional intake and quality of life would decrease to baseline levels after the intervention stops.

The method of administration of the two nutritional interventions may have impacted on residents' compliance to the intervention. ONS are ready made drinks, which were provided for the participants. As with prescriptions for ONS, they were free of charge to participating residents. In contrast, the dietary advice sheet, as with dietary advice sheets provided by dietitians, relies on the care home to follow the advice in the sheet, providing extra snacks and enriching meals. Clearly there would be a cost implication for the care homes to follow this type of nutritional advice, and could therefore have impacted on residents' exposure to this intervention. It also relied upon kitchen staff to be able to produce the enriched meals, and the communication between the care staff and the kitchen staff of residents' preferences.

This trial also included residents receiving residential and nursing care, resulting in the inclusion of those with very few medical problems who just require assistance with personal care, through to those with chronic, debilitating health problems. It is possible that the severity of participants' health conditions may have impacted on their compliance to the interventions, and their quality of life. The type of care participants received was adjusted for when analysing the results. Further sub analysis of the results may provide some further information on whether ONS were more effective for subgroups within the population. It could be that those with fewer advanced health problems, but a low BMI are more able to benefit from ONS than those with more advanced disease, or vice versa.

This was an effectiveness trial, not an efficacy trial, therefore it is possible that if the interventions were followed more closely, greater changes within the dietary advice group may have been observed. However, the trial has highlighted that due to the more labour intensive nature of following a dietary advice intervention, it may not be most suited to the care home setting, unless the appropriate training and support can be delivered.

4.6 Conclusions

This randomised controlled trial of nutritional interventions in malnourished care home residents has shown that ONS are more effective than the provision of dietary advice at improving nutrient intake and quality of life over a 12 week intervention period. As with other studies of nutritional interventions in care homes, no significant changes in functional outcomes were observed. Due to the relatively small population and length of intervention in this study, no changes in healthcare use were observed.

This study can therefore suggest that ONS should be used to treat residents with malnutrition in care homes. There is also a need to carry out a larger randomised controlled trial in care homes, including a control group in addition to an ONS group and dietary advice groups. Further intervention trials should also consider the use of exercise and resistance training if changes in functional outcomes are to be observed.

Chapter Five: The Cost-Effectiveness of the Nutrition Intervention Trial

5.1 Introduction

In the current economic climate, the cost-effectiveness of interventions is being scrutinised, using techniques such as cost-utility analyses. In many countries throughout Europe, thresholds for cost-acceptability of interventions are set by the national health agencies [136]. In the UK, NICE are charged with the responsibility for evaluating the effectiveness of interventions and making recommendations on which interventions should be funded within the National Health Service. It has been a subject of much speculation in medical literature as to whether NICE use financial cut offs for the cost-acceptability of interventions, with there being inference that interventions costing less than £20,000 to £30,000 are more likely to be recommended for use within the NHS [137]. Cost-effectiveness analyses are used quite regularly to assess the potential cost-effectiveness of medical treatments and drug therapies [138], however very few have taken place in the area of nutrition support in the community.

Before considering the use of economic analyses in relation to nutrition support, it is important to consider which type of economic analysis is used, and their potential for use in evaluating the cost-effectiveness of nutritional interventions.

5.1.1 Health economic analyses

A variety of health economic analyses can be used to assess the cost-effectiveness of healthcare interventions, including cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses. All of which may be used in slightly different circumstances. For the purpose of this chapter, the economic analysis will focus on cost-utility analysis. As there are some similarities between cost-effectiveness analyses and cost-utility analyses, the differences between the two will first be clarified.

Both cost-effectiveness analyses and cost-utility analyses consider the costs involved in an intervention. Cost-effectiveness considers the effect in terms of a measurement in natural units e.g. weight (kg), number of complications or number of hospital admissions, whereas cost-utility considers the effect in terms of a measure such as Quality Adjusted Life Years (QALY's) or Disability Adjusted Life Years (DALY's). The results of both types of analyses are expressed in similar terms, with cost-effectiveness expressed as cost per

unit of effect and cost-utility in terms of cost per QALY gained. Cost-effectiveness outcomes tend to be single and programme specific, whereas cost-utility analyses can relate to single or multiple programmes and place a value on an outcome. Using a measure such as QALY's allows both the quantity and quality of life to be assessed. Cost-utility analysis also has the advantage of enabling a broad range of outcomes to be included by providing a method through which they can be combined into a comparable summary outcome, which can act as a common denominator between studies, and allows for weightings of important components of an outcome to be taken into account [139].

Therefore, as a cost-utility analysis requires both costs and a measure such as QALY's, a cost-utility analysis can be performed using healthcare costs of an intervention, and the health related quality of life of participants. For a quality of life outcome to be incorporated into a QALY analysis, a tool such as EuroQoL or Health Utilities Index (HUI), which produce overall scores for quality of life must be used in order to quantify the quality of life. Effectiveness of an intervention can be assessed through the measurement of parameters such as quality of life, as long as they use a scale between zero and one [139]. In the UK, the NICE guidance in this area recommends that EuroQol can be used for this [126].

When using a cost-utility analysis, judgements may need to be made regarding the cost effectiveness of a treatment if an intervention results in extra costs and extra QALY's. This normally involves the calculation of the extra cost/extra QALY gained (cost/QALY), which is often referred to as the Incremental Cost-Effectiveness Ratio (ICER).

The Incremental Cost-Effectiveness Ratio can be displayed graphically using the cost-effectiveness plane, which through this graphical representation can help decision makers to visualise whether treatments would be cost-effective [139]. In the graphical presentation of the cost-effectiveness plane, 'A' represents the intervention of interest, and 'O' represents the alternative treatment or control group. If point A is located in quadrants II or IV, the choice as to whether to carry out an intervention is clear, with quadrant II indicating that the intervention will be more effective and less costly than the alternative or control intervention (Figure 5.1). Conversely the alternative or control treatment is more effective and less costly in quadrant IV. The decision as to whether to adopt an intervention is less clear in quadrants I and III, and is dependent on the maximum acceptable cost-effectiveness ratio. The gradient of the line OA represents the cost-effectiveness ratio. When carrying out an incremental analysis, most interventions fall into quadrant I of the cost-effectiveness plane.

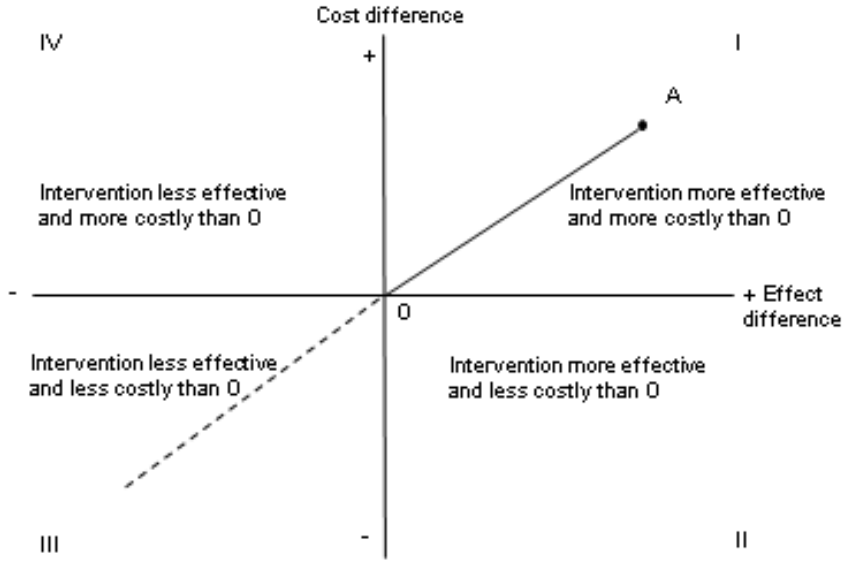


Figure 5.1 The cost-effectiveness plane [139]

There are some important considerations that must be taken into account when calculating ICER's. Firstly, it may be possible to calculate a negative ICER (i.e. an ICER that falls within quadrants II or IV of the cost-effectiveness plane). The value of the ICER is identical, however the planes represent very different outcomes. Secondly, if the difference in effects is zero, the ratio would be infinite, making the results more difficult to interpret. Thirdly, it is essential that differences in the baseline characteristics of the groups to be compared are adjusted prior to economic analysis taking place. In order to overcome potential uncertainty with ICER's it has been suggested the ICER should include both the observed effect size and the associated confidence interval, as the confidence interval will give an indication of the magnitude of the difference. In order to present this, a confidence region is often used. This may be in the form of a two dimensional confidence region, or alternatively using a confidence ellipse. The confidence ellipse has the advantage of being able to reflect the co-variance in cost and effect differences, rather than assuming independence in these two parts of the ICER. With a confidence ellipse, the exact shape of the confidence region depends upon the co-variation between cost and effect. For the ellipses to be produced, the assumption is made that there is a normal distribution both in the cost and effect of the intervention. The width of the ellipses depends upon the correlation between cost and effect. As there are potential difficulties in producing exact confidence intervals using traditional methods based on the central limit theorem, non-parametric bootstrapping may be used to derive confidence intervals [140]. Using this method, re-samples of the original data are collected in order to build a sampling distribution of the ICER. These bootstrapped results can be overlaid on the confidence ellipses in order to see how well the two methods match each other [139].

Having calculated an ICER, the Incremental Net Benefit (INB) may be considered in the expression of the cost-effectiveness of interventions. INB moves away from the use of ratios, and considers placing the costs and effects of an intervention on a single scale. This is most often expressed as net monetary benefit, rather than net health benefit. Net monetary benefit rescales the difference between the effects of the two interventions into a monetary value. The term 'willingness to pay' is used as the unit of effect, and the difference in costs between the options is subtracted from this value.

In addition to the use of net monetary benefit, cost-effectiveness acceptability curves (CEAC) may also be used. The CEAC expresses the probability that one intervention is more cost-effective than the other [140]. As with net monetary benefit, CEAC presents data in a willingness to pay format and can be produced using results from a traditional central limit theorem analysis and the non-parametric percentile bootstrapping technique [140].

Displaying the results of a cost-utility analysis using the net monetary benefit or CEAC allows commissioners of interventions to assess whether they would be willing to pay for interventions, and the level of certainty they are willing to accept that the intervention will cost less than a given sum of money. The use of CEAC in the assessment of whether to fund interventions in the UK has been recommended by NICE [126].

Although the techniques described above for the cost-utility analysis of interventions have existed for many years, and UK guidance recommends the use of cost-effectiveness acceptability curves in the assessment of funding of interventions, currently very few cost-utility analyses have been reported in the area of nutrition support in the community. Of these community trials, none were conducted on the use of oral nutritional interventions in residential and nursing homes. Only three cost-utility analyses of nutritional interventions in the community have been identified, with the cost/QALY ranging from £12,817 (95% CI £10,351 to £16,826) in an evaluation of enteral tube feeding at home and in nursing homes [141] to £70,000 in an evaluation of home parenteral nutrition [142]. An interdisciplinary community based COPD management trial involving nutrition support in conjunction with exercise, smoking cessation and education resulted in an intermediate cost/QALY of 32,425 Euros [143]. Interestingly, the paper by Hoogendoorn et al., 2010 was the only paper to report their results using a cost-effectiveness acceptability curve.

5.2 Aim

Given the lack of information on the cost-effectiveness of oral nutritional interventions in the community, particularly in care homes, there is a need to assess the cost-effectiveness of such interventions, in terms of the incremental cost-effectiveness ratio, net monetary benefit, and cost-effectiveness acceptability curve.

The aim of this chapter is therefore to perform a cost-utility analysis, using cost per QALY's for the nutrition intervention trial presented in the previous chapter, as information on the quality of life and healthcare use of residents that participated in the intervention trial was collected.

5.3 Methods

5.3.1 Subjects and design

104 residents at risk of malnutrition in residential and nursing homes in Hampshire were randomised to receive either oral nutritional supplements (n=53) or dietary advice (n=51). See Section 4.3.8 for further details of the nutritional interventions. The inclusion and exclusion criteria for the trial can be found in Sections 4.3.4.1 and 4.3.4.2. Participants received the intervention for 12 weeks, with measurements being recorded at baseline, week six and week 12 (Figure 4.1).

5.3.2 Health outcomes

In order to assess the cost-effectiveness of the interventions, information on healthcare use (Healthcare Professional visits and hospital admissions) and quality of life (EQ-5D TTO and VAS rescaled) was collected at participants' baseline, week six and week 12 visits. The costs of the interventions were also assigned, having recorded information on the dietetic time spent with each resident, and the number of bottles of ONS consumed. Using this information the cost and effectiveness (QALY's) were assigned.

5.3.3 Assignment of costs

Healthcare Professional and General Practitioner visits were recorded for the three months prior to the baseline visit, and at the week six and week 12 visits. Where possible, the duration and reason for their visits was also recorded. Admissions to hospital were also noted during the same time periods. Details of the type of admission (emergency or elective), duration of stay, reason for admission and type of ward admitted to, were also noted where the information was available. Standard costs were assigned to the visits and hospital admissions using values from Curtis, 2009 (Table 5.1).

5.3.3.1 Cost of the intervention

All participants received two, thirty minute periods of advice from a dietitian regarding the intervention they received, at their baseline and week six visits. The standard cost of a community dietetic visit was assigned to this (£32.70 per visit). In the case of those residents that received ONS, their individual mean daily intake over the course of the 12 week intervention was calculated. A unit cost for the ONS was assigned (£1.85 per bottle) and multiplied by the number of days the participant completed (either 84 days if the intervention was completed, or the number of days before the participant died).

Table 5.1 Cost of healthcare use [144]

Healthcare Use	Cost
Visits to the care home	
Audiologist	£144/visit
Chiropodist	£21/visit
Dietitian	£32.70/visit (30 minutes)
District nurse	£27/home visit
GP	£117/visit
Optician	£45/visit
Phlebotomist	£27/visit
Physiotherapist	£48/visit
GP practice visits	
Practice nurse	£11/consultation
Outpatients appointments	
Accident and Emergency visit, but not admitted	£93/visit
Consultant physician outpatients appointment	£144/consultation
Endoscopy	£185
Gastroenterology outpatients appointment	£144/consultation
Ophthalmology outpatients appointment	£144/consultation
Orthopaedics outpatients appointment	£144/consultation
Parkinson's outpatients appointment	£152/consultation
Radiographer	£16/appointment (20 minutes)
Hospital Admissions	
Hospital Admission (Short stay, Emergency†)	£493/admission

† There were 3 admissions during the intervention, with the mean length of stay being 2.17 days (range 0.5 to 4 days)

5.3.4 Effectiveness of the intervention: Quality Adjusted Life Years (QALY's)

Quality of life was measured using the EuroQol (EQ-5D) at baseline, week six and week 12 of the intervention (section 4.3.9.2). EQ-5D TTO and VAS rescaled scores were calculated using the standard weightings for the UK population (Tables 4.1 and 4.2) [122]. These values were then used to calculate QALY's.

Due to baseline imbalances in the EQ-5D Visual Analogue Scale between the intervention groups (Table 4.13) adjusted quality adjusted life years (QALY's) were calculated [139]. As the intervention took place over three months rather than one year, the QALY's based on EQ-5D TTO and VAS rescaled scores were divided by four. Where participants did not complete the 12 week intervention, their QALY was also multiplied by the proportion of the trial each resident had completed.

5.3.5 Cost-effectiveness

Cost-effectiveness was expressed as the incremental cost-effectiveness ratio (ICER), which was calculated as the difference in mean costs between the ONS and dietary advice groups divided by the difference in mean QALY (TTO and VAS rescaled) [140]. Cost-effectiveness acceptability curve and an incremental net benefit analysis were also considered.

5.3.6 Statistical analysis

The analysis was performed according to a per protocol and an intention to treat analysis. Differences in baseline characteristics of participants that completed the intervention and drop outs were statistically tested using independent sample unpaired t-tests for continuous data and Chi squared tests for categorical variables.

In order to account for costs and quality of life scores that were missing due to residents dropping out of the intervention and the additional uncertainty that these missing values introduced, the multiple imputation technique was used. Each missing value was replaced by five simulated values produced using the multiple imputation method, SPSS version 18.0. The multiple imputation method implied that for participants who dropped out, values were imputed that were randomly drawn from the data of participants who completed the intervention, but had similar baseline characteristics. For example, participants that had a worse health status that dropped out of the trial, random draws of data of participants with a similar health status who did not drop out were imputed. The imputation model included a range of independent variables from baseline, week six and week 12 (Table 5.2).

Table 5.2 Independent variables from baseline and the intervention period that were used in the Multiple Imputation Model

	Variables	
	Baseline	During the Intervention
Completed the Intervention	EQ-5D TTO	QALY TTO 3months
RIP	EQ-5d VAS rescaled	QALY VAS Rescaled 3months
Percentage of intervention completed	ED-5D VAS	Cost 3 months
Designated Intervention	Cost of HCP and Hospital in the 3 months prior to intervention	
'MUST' Category		
Type of care		
Age		
Sex		

Constraints were placed on the QALY TTO and VAS rescaled 3 month variables, with the minimum values constrained to zero and the maximum values to 0.25 and the Cost 3 month variable was constrained to a minimum value of zero but no maximum value was assigned. The QALY TTO and VAS rescaled 3 month variables were constrained in order to produce imputed results in line with the QALY scale.

The CEAC and the associated confidence ellipses and net incremental benefit were established using the method of Nixon et al., 2010 which employed two models; one using the central limit theorem (CLT) and the other non-parametric bootstrapping (percentile method). The non-parametric bootstrapping method involved using 1,000 bootstraps per dataset. The 95% confidence interval around the difference in mean costs and QALY was determined by taking the 2.5th and 97.5th percentile of these bootstrap replications [140]. The bootstrap replicates were plotted in cost-effectiveness planes. By plotting all bootstrap replicates, the uncertainty around the point estimates of the ICER was displayed. In addition, the information in the cost-effectiveness planes was displayed in terms of incremental net benefit and cost-effectiveness acceptability curves, with the

CEAC showing the probability that the ICER falls below various ceiling ratios of willingness to pay [140].

5.3.7 Sensitivity analysis

The CEAC curve, which expressed results in relation to probability, can be regarded as a type of sensitivity analysis [139]. A separate type of sensitivity analysis was undertaken using alternative costs, based upon information from UK healthcare data[145], which suggested that hospital admission costs in 2008 ranged from +21% to -47% from the mean cost of hospital admissions. As hospital admissions were the second largest contributor to the healthcare costs, the sensitivity analysis used costs 20% above and below the mean costs. Using these costs, alternative ICER's were produced for the per protocol and intention to treat datasets.

5.4 Results

5.4.1 Participants

A total of 70 residents completed with intervention. The 34 residents that did not complete the intervention included six people that died (two residents in the ONS group, four residents in the dietary advice group) and 28 residents that failed to complete the intervention due to ill health or declining memory, which resulted in them not being able to remember the detail of the project. As discussed in the previous chapter, there were no significant differences between the characteristics of those that did or did not complete the trial (Tables 4.8 to 4.12).

5.4.2 Costs included in the cost-utility analysis

There were no significant differences in healthcare costs between the ONS and control group, both in terms of the total costs of Healthcare Professional visits and hospital admissions (Table 5.3) and the components of the total healthcare costs (Table 5.4). The majority of the costs were attributed to GP visits, closely followed by hospital admissions (Table 5.4). The cost of the intervention was significantly higher in the ONS group than the dietary advice group, resulting in the total costs used in the cost-utility analysis being significantly greater in the ONS group than the dietary advice group (Table 5.3).

Table 5.3 Total costs (per resident completing the protocol) used in the cost-utility analysis, according to intervention group

	Intervention		P value
Costs (£)	ONS	Dietary Advice	
Healthcare Professional visits and Hospital admissions	153.62 ± 208.44	127.27 ± 250.03	0.639
Cost of the Intervention	173.71 ± 126.06	39.75 ± 32.25	<0.0001
Total cost (Healthcare use and Intervention)	375.70 ± 213.78	173.85 ± 240.15	<0.0001

Table 5.4 Components of the costs related to Healthcare Professional visits and hospital admissions (per resident completing the protocol), according to intervention

	Baseline		P value	Intervention		P value
Costs of healthcare use (£)	ONS	Dietary Advice		ONS	Dietary Advice	
GP	121.42 ± 155.56	75.71 ± 140.01	0.119	92.72 ± 147.56	43.59 ± 114.54	0.061
Practice Nurse	0	0		0	0.22 ± 1.54	0.310
District Nurse	30.06 ± 105.86	5.29 ± 16.22	0.102	5.09 ± 37.09	4.76 ± 23.36	0.957
Phlebotomist	0	0		0.51 ± 3.71	0.53 ± 3.78	0.978
Dietitian	0.62 ± 4.49	0	0.329	0	0	
Physiotherapist	1.81 ± 9.23	5.65 ± 40.33	0.502	0	6.59 ± 40.75	0.242
Chiropodist	0.79 ± 4.04	0.82 ± 4.12	0.969	0	0	
Optician	1.70 ± 8.66	2.65 ± 13.98	0.677	0	0	
Audiology Outpatient	0	0		2.72 ± 19.78	0	0.329
Consultant Physician Outpatient	0	5.96 ± 29.80	0.148	0	0	
Endoscopy Outpatient	3.49 ± 25.41	3.63 ± 25.91	0.978	0	0	
Gastroenterology Outpatient	0	2.82 ± 20.16	0.310	0	0	
Ophthalmology Outpatient	8.15 ± 33.59	2.82 ± 20.16	0.331	5.43 ± 39.56	0	0.329
Orthopaedics Outpatient	2.72 ± 19.78	0	0.329	0	0	
Parkinson's Outpatient	0	5.96 ± 29.80	0.148	0	0	
Radiographer Outpatient	0	0.63 ± 3.14	0.148	0.30 ± 2.20	0.31 ± 2.24	0.978
Respiratory Outpatient	0	0		2.72 ± 19.78	0	0.329
A+E visit – no admission	0	0		0	1.82 ± 13.02	0.310
Hospital Admissions	0	29.00 ± 117.15	0.074	12.64 ± 78.94	31.81 ± 123.12	0.432

5.4.3 Quality Adjusted Life Years (QALY's)

The calculation of QALY's using TTO and VAS rescaled co-efficients of the EQ-5D questionnaire, resulted in their being significant differences in QALY's between the intervention groups. The ONS group had a greater QALY than the dietary advice group, both with a per protocol and an intention to treat analysis (Table 5.5).

Table 5.5 Adjusted results for QALY TTO and VAS rescaled (three month period), using residents that completed the intervention (per protocol) and intention to treat analyses

	Intervention		P value
	ONS	Dietary Advice	
QALY TTO			
Per protocol	0.14 ± 0.04	0.12 ± 0.03	0.023
Intention to treat			
Imputation 1	0.13 ± 0.04	0.11 ± 0.04	0.018
Imputation 2	0.14 ± 0.04	0.12 ± 0.04	0.021
Imputation 3	0.13 ± 0.04	0.11 ± 0.04	0.027
Imputation 4	0.12 ± 0.05	0.11 ± 0.05	0.063
Imputation 5	0.13 ± 0.03	0.12 ± 0.03	0.010
QALY VAS rescaled			
Per protocol	0.15 ± 0.03	0.13 ± 0.03	0.016
Intention to treat			
Imputation 1	0.13 ± 0.04	0.11 ± 0.04	0.011
Imputation 2	0.14 ± 0.03	0.12 ± 0.03	0.005
Imputation 3	0.13 ± 0.04	0.11 ± 0.04	0.021
Imputation 4	0.13 ± 0.04	0.11 ± 0.04	0.065
Imputation 5	0.14 ± 0.03	0.12 ± 0.03	0.009

5.4.4 Cost-Effectiveness: Incremental Cost-Effectiveness Ratio (ICER)

The Incremental cost-effectiveness ratio, calculated using a per protocol analysis for the cost/QALY (EQ-5D TTO and VAS rescaled) produced similar results, with the mean ICER being £10,698 (95% CI: £3793 to £76932) for cost/QALY (TTO) and £12,557 (95% CI: £4684 to £67562) for cost/QALY (VAS rescaled) (Table 5.6). With both cost-utility analyses the confidence limits for the ICER's were extremely similar when produced using both the central limit theorem and bootstrapping methods (Figures 5.2 to 5.7). The cost-effectiveness planes for cost/QALY (TTO) and cost/QALY (VAS rescaled) showed that the majority of bootstrap replications fell in the upper right quadrant, indicating that the nutrition intervention trial resulted in higher costs using ONS but that more participants had a higher gain in QALY's.

Table 5.6 The average Incremental Cost-Effectiveness Ratio and percentile values† (cost/QALY (EQ-5D TTO) and cost/QALY (EQ-5D VAS rescaled)), according to per protocol and intention to treat (imputed) analyses

		Confidence Interval					
	Mean ICER (£)	2.5%	5%	10%	90%	95%	97.5%
Cost/QALY (TTO)							
Per protocol	10698	3793	4552	5529	26389	41014	76932
Intention to treat							
Imputation 1	12052	5382	6087	7012	27251	40591	69822
Imputation 2	9423	3546	4202	5042	22401	34205	62165
Imputation 3	7758	2676	3256	3988	19347	30939	63937
Imputation 4	10872	4271	4913	5769	35403	90079	258473
Imputation 5	9269	3606	4248	5070	20148	28161	42226
Cost/QALY (VAS rescaled)							
Per protocol	12577	4684	5583	6727	28594	41590	67562
Intention to treat							
Imputation 1	10874	5140	5772	6589	22350	30973	46353
Imputation 2	9846	3927	4643	5539	19434	25400	34198
Imputation 3	7816	2807	3393	4127	18290	27627	49388
Imputation 4	11390	4585	5248	6129	37257	99282	211827
Imputation 5	10071	4251	4937	5802	20559	27964	40447

† The percentile values can be used to establish confidence intervals

e.g. Per protocol Cost/QALY (TTO): 90% CI (5%-95%) £4551 to £41014

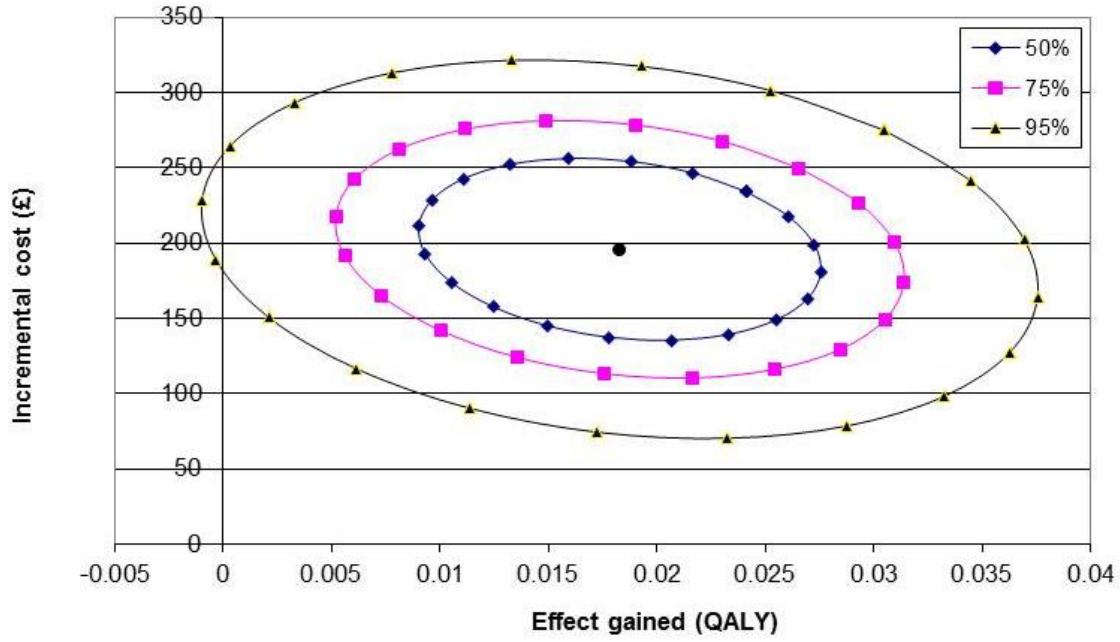


Figure 5.2 Confidence ellipses based on the central limit theorem for the per protocol Incremental Cost-Effectiveness Ratio, using Cost/QALY (TTO)

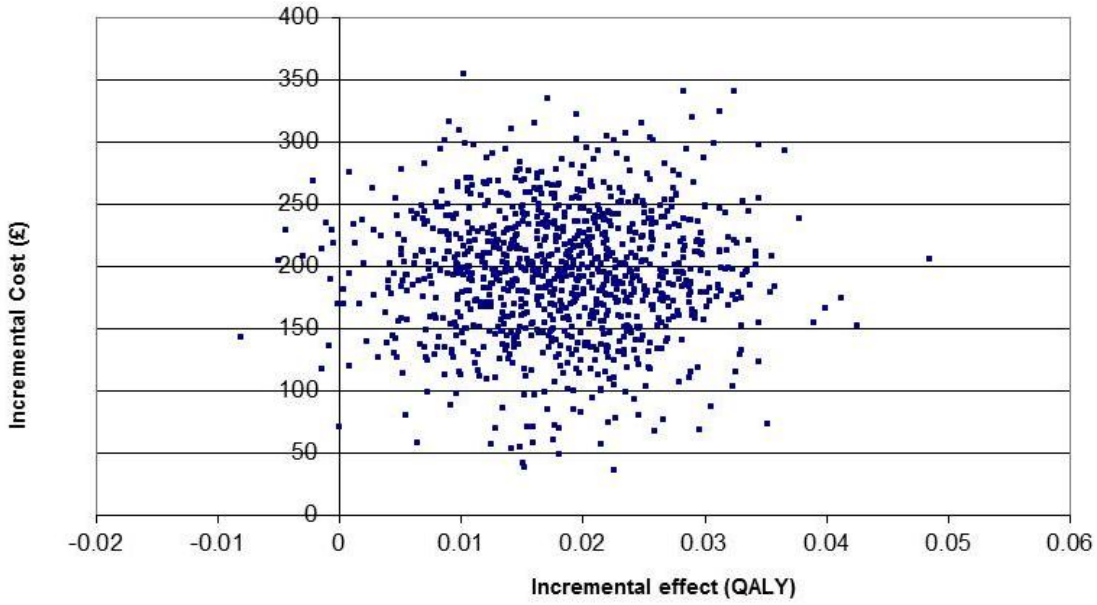


Figure 5.3 Bootstrap distribution (1000 resamples) of the per protocol Incremental Cost-Effectiveness Ratio, using Cost/QALY (TTO)

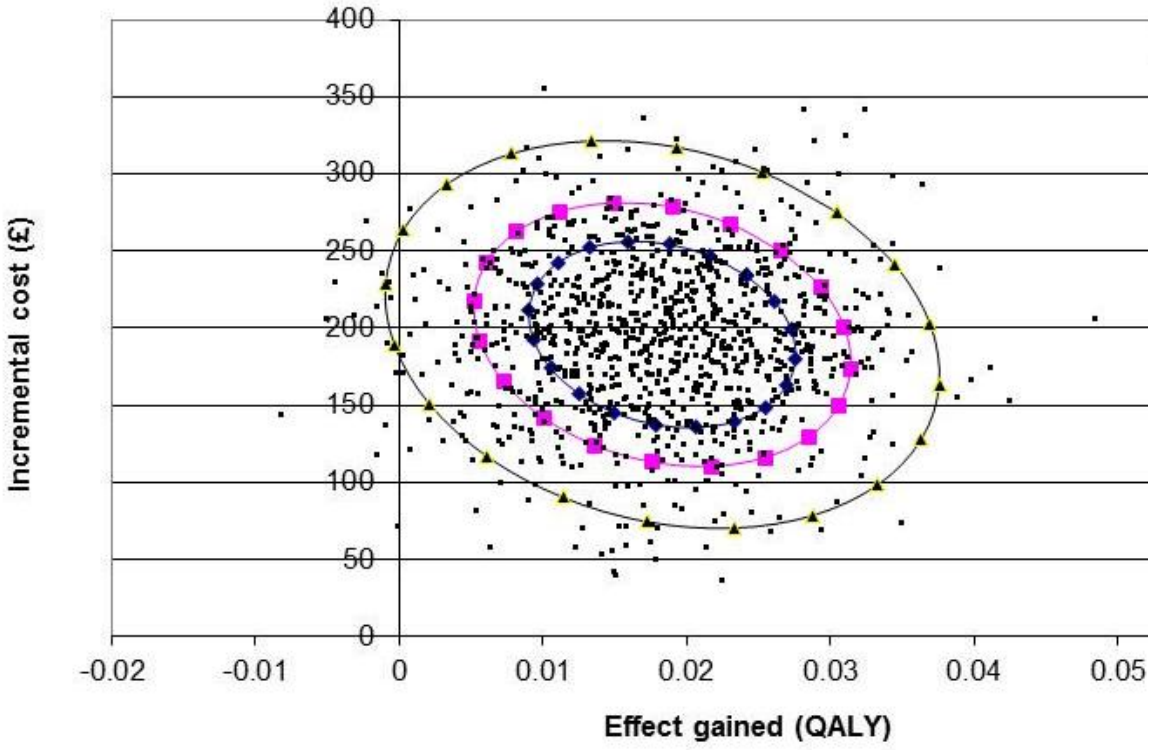


Figure 5.4 Confidence intervals based on the central limit theorem and Bootstrap distribution (1000 resamples) of the per protocol Incremental Cost-Effectiveness Ratio, using Cost/QALY (TTO)

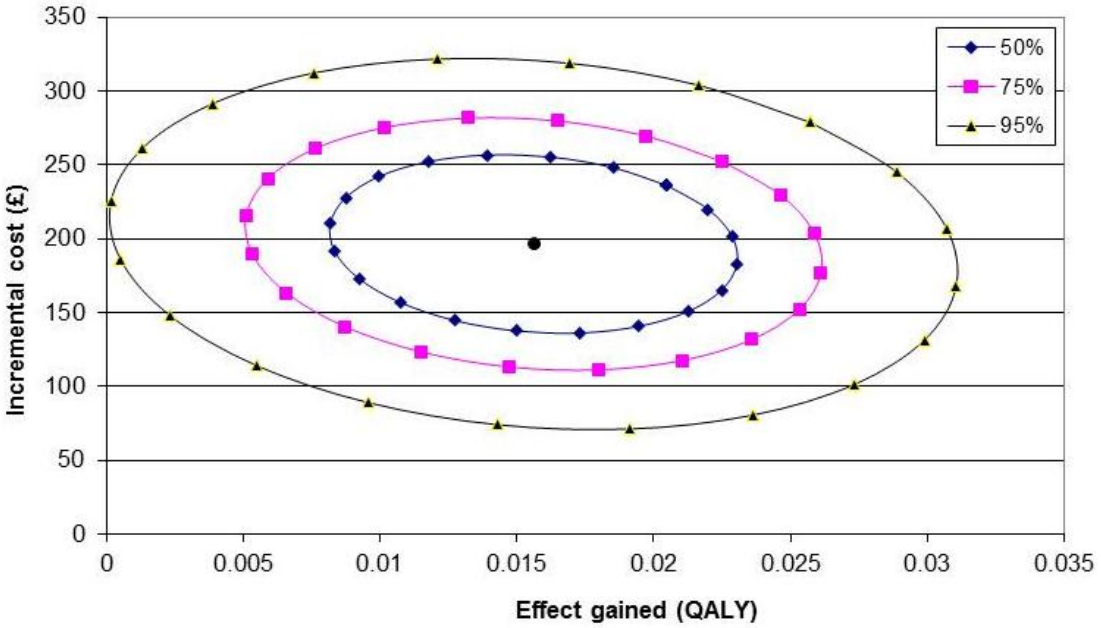


Figure 5.5 Confidence ellipses based on the central limit theorem for the per protocol Incremental Cost-Effectiveness Ratio, using Cost/QALY (VAS rescaled)

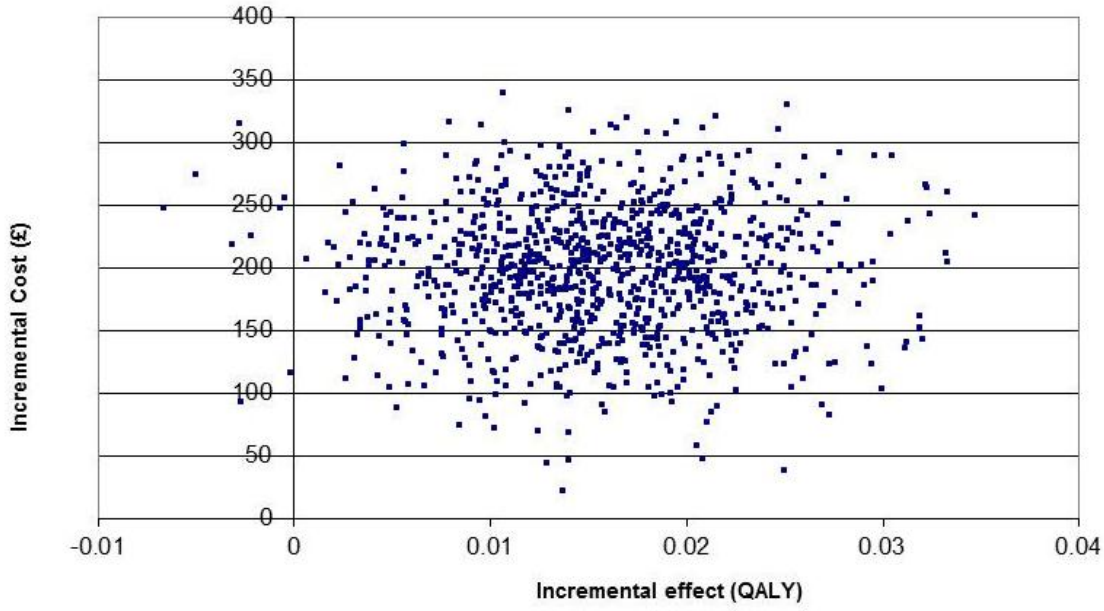


Figure 5.6 Bootstrap distribution (1000 resamples) of the per protocol Incremental Cost-Effectiveness Ratio, using Cost/QALY (VAS rescaled)

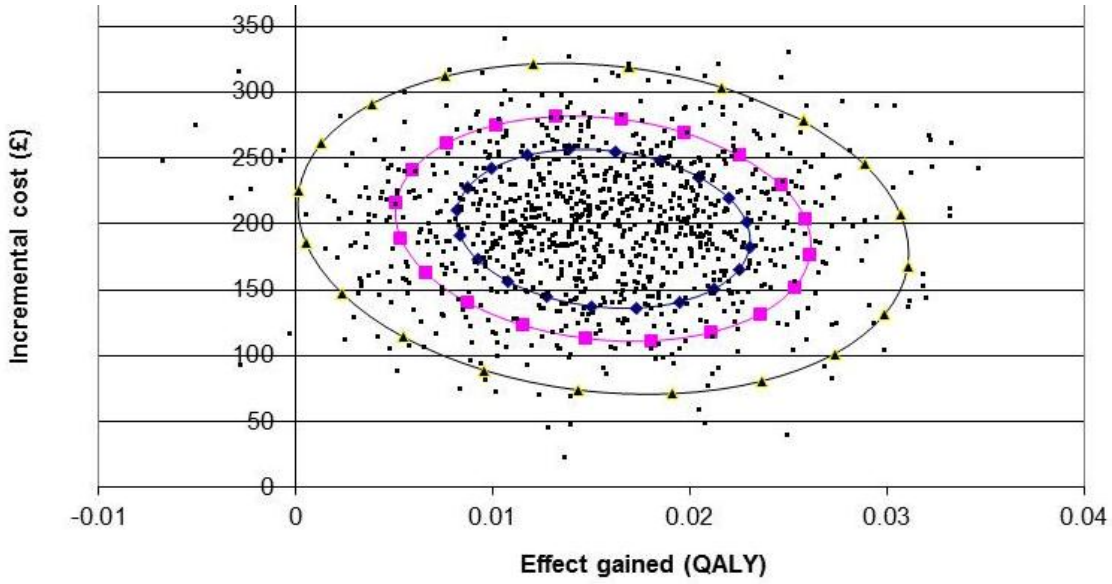


Figure 5.7 Confidence intervals based on the central limit theorem and Bootstrap distribution (1000 resamples) of the Incremental Cost-Effectiveness Ratio, Cost/QALY (VAS rescaled)

5.4.5 Willingness to Pay

Having produced the ICER's for the nutrition intervention trial using Cost/QALY's for EQ-5D TTO and VAS rescaled, the willingness to pay was assessed, using incremental net benefit (Figures 5.8 and 5.10) and cost-effectiveness acceptability curves (Figures 5.9 and 5.11). The probability that the provision of ONS is cost-effective at a willingness to pay of between £20,000 to £30,000 per QALY gained was 84.4% to 92.0% for cost/QALY (TTO) and 79.1% to 90.9% for cost/QALY (VAS rescaled) (Table 5.7). Similar results were produced for the imputed datasets.

Table 5.7 Percentage of trials that would fall within the willingness to pay of £20,000 to £30,000 for the ICER (Cost/QALY (TTO)) and ICER (Cost/QALY (VAS rescaled)), using both the per protocol and intention to treat analyses

	% of trials that would fall within willingness to pay	
	£20,000	£30,000
Cost/QALY (TTO)		
Per protocol	83.4	92.0
Intention to treat		
Imputation 1	81.4	91.7
Imputation 2	87.7	93.9
Imputation 3	90.5	94.8
Imputation 4	80.0	88.0
Imputation 5	89.8	95.6
Cost/QALY (VAS rescaled)		
Per protocol	79.1	90.9
Intention to treat		
Imputation 1	87.1	94.7
Imputation 2	90.7	96.7
Imputation 3	91.5	95.6
Imputation 4	78.2	87.3
Imputation 5	89.3	95.7

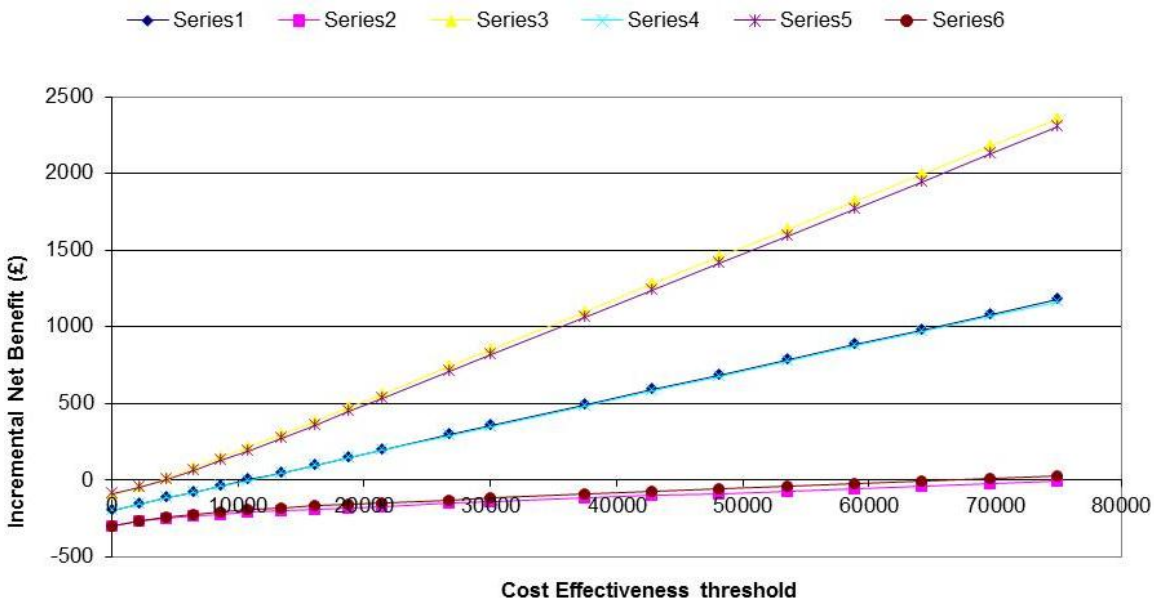


Figure 5.8 Incremental net benefit (INB) with Cost/QALY (TTO), using the central limit theorem (CLT) and bootstrap (BS) techniques indicating the 95% confidence interval Series 1: INB CLT, Series 2: INB CLT upper 95% CI, Series 3: INB CLT lower 95% CI, Series 4: INB BS, Series 5: INB BS upper 95% CI, Series 6: INB BS lower 95% CI

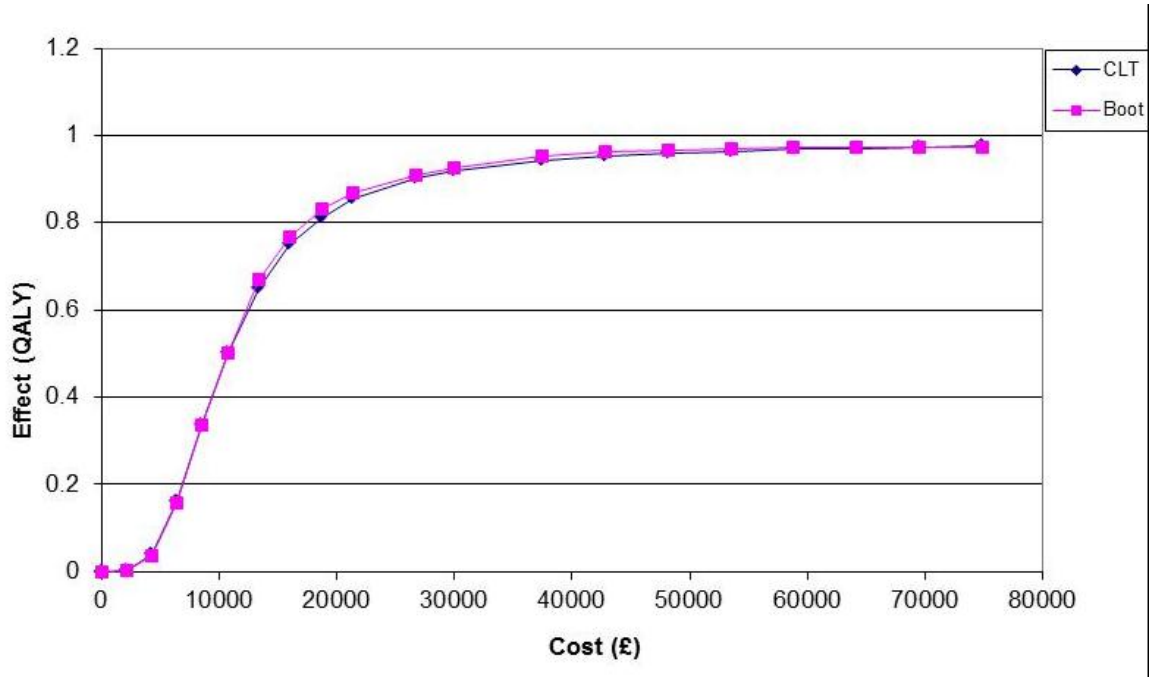


Figure 5.9 Cost effectiveness acceptability curve for the cost/QALY (TTO), using the central limit theorem (CLT – blue line) and bootstrap techniques (Boot – pink line)

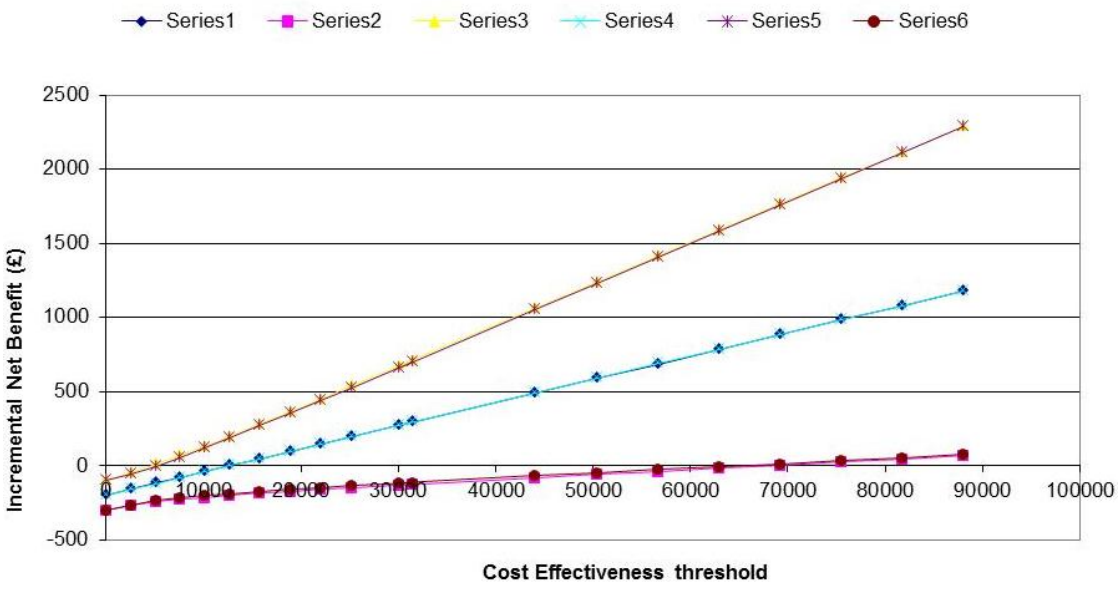


Figure 5.10 Incremental net benefit (INB) with Cost/QALY (VAS rescaled), using the central limit theorem (CLT) and bootstrap (BS) techniques indicating the 95% confidence interval Series 1: INB CLT, Series 2: INB CLT upper 95% CI, Series 3: INB CLT lower 95% CI, Series 4: INB BS, Series 5: INB BS upper 95% CI, Series 6: INB BS lower 95% CI

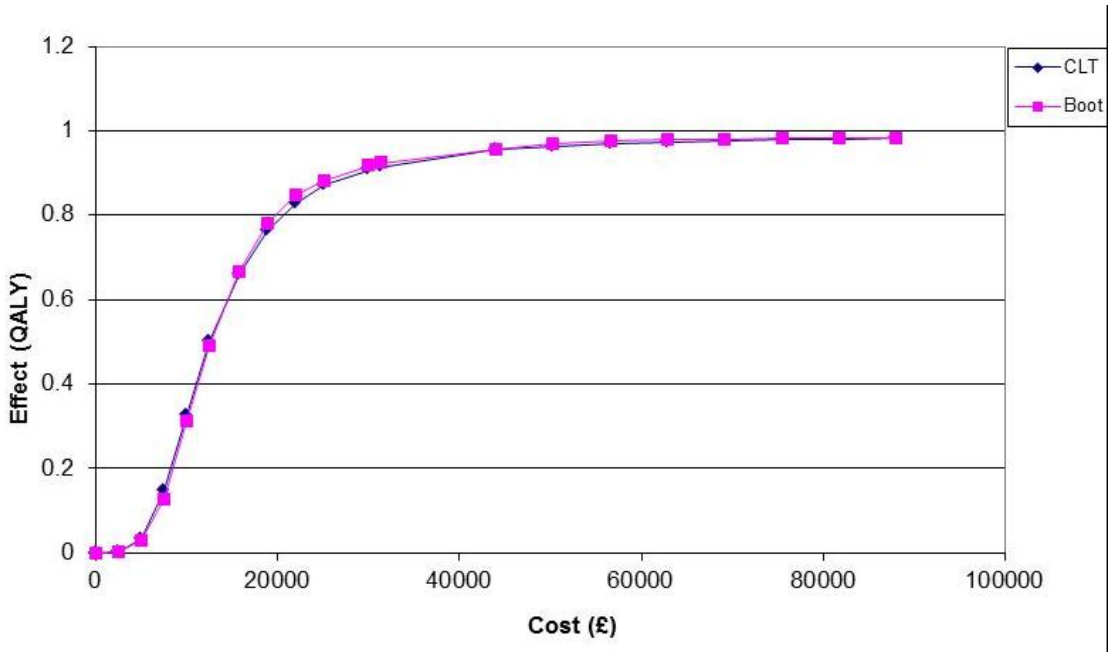


Figure 5.11 Cost effectiveness acceptability curve for the cost/QALY (VAS rescaled), using the central limit theorem (CLT – blue line) and bootstrap techniques (Boot – pink line)

5.4.6 Sensitivity Analysis

Results for the sensitivity analysis showed that when costs were increased, or decreased by 20%, the costs/QALY were comparable to the base case analysis (Table 5.8).

Table 5.8 Per protocol average Incremental Cost-Effectiveness Ratio (ICER) and 95% Confidence Interval for Cost/QALY (TTO) and Cost/QALY (VAS rescaled) when costs were increased or decreased by 20%

ICER (£)	Original	Costs -20%	Costs +20%
Cost/QALY (TTO)	10698 (3793 to 76932)	8558 (3034 to 61546)	12838 (4552 to 92319)
Cost/QALY (VAS rescaled)	12577 (4684 to 67562)	10032 (3727 to 53910)	15049 (5590 to 80865)

5.5 Discussion

This is the first cost-utility analysis of ONS versus dietary advice in malnourished care home residents to be completed, and also the first to consider the economic implications of this combination of nutritional interventions. The health economic analysis has shown that such an intervention with ONS in comparison with dietary advice can significantly improve quality of life at a relatively low cost, according to cost/QALY TTO (£10,698) and cost per QALY VAS rescaled (£12,577).

For both cost/QALY analyses (TTO and VAS rescaled) the per protocol and imputed ICER results were in good agreement, and there was approximately a 90% probability that 90% of interventions would cost less than the £30,000 threshold for cost-effectiveness speculated to be suggested by NICE [137]. Even when a sensitivity analysis was conducted, increasing the costs by 20%, the ICER's still remained well below this £30,000 threshold. The cost/QALY's reported for this intervention were also much lower than those reported by the nutrition intervention trial in COPD (32,425 Euros) [143], the home enteral nutrition trial (£12,817) [141] and the parenteral nutrition trial (£70,000) [142]. From a search of the CEA database, this trial also represents a cost-utility analysis in one of the oldest, if not the oldest populations enrolled into a nutrition intervention trial, with the mean age being 88.47 ± 7.86 years.

5.5.1 Limitations

This study does have some limitations, which are discussed here, including the attrition rate of participants in the trial, type of model used, the duration of the intervention and the co-efficients used to calculate quality of life.

In the nutrition intervention trial, comparing ONS with dietary advice, approximately 30% of trial participants did not complete the intervention, therefore multiple imputation methods were employed in order to produce a complete dataset for healthcare costs and quality of life scores. As discussed earlier in this chapter, a range of imputation methods exist, including carrying values forward and using the mean values for variables, however multiple imputation methods are considered one of the most robust ways of inserting missing data points [127]. The analysis found that the cost-effectiveness acceptability curves were almost identical using traditional methods of analysis and bootstrapping techniques.

It is also important to consider the components of the cost-utility analysis as the results were in the right upper quadrant, suggesting that there would be increased costs but also increased effects with this intervention. The costs included both healthcare use and intervention costs, based on standard UK costs in 2009. The costs from 2009 were applied as that was the period in which the majority of healthcare costs took place. The healthcare use figures were recorded from both residents' notes and cross checked with the residents and staff. This cross checking of information helped to ensure all information on healthcare use, and duration of hospital admissions was collected. Information on use of ONS was collected in a similar way at each visit, to minimise the misreporting of compliance to this intervention. It is possible that some costs relating to the dietary advice and ONS groups may not have been accounted for, including the cost to the care home of administering the interventions. This was not included in the model as the provision of food and delivering ONS to the residents was deemed to be a routine cost for the care home. Also with regards to the dietary advice group, it was more difficult to ascertain the effectiveness of this intervention, as less than 50% of this group reported making any changes to their diet. There was very little change in the nutritional intake and quality of life within this group, which suggests they may have only had limited exposure to this intervention.

It is also important to consider the duration of this intervention. The QALY's used in the model did not incorporate any QALY's for the three months prior to baseline, as consent to participate and randomisation to the intervention groups occurred at baseline. If this had occurred three months prior to the intervention starting, then the effect of no intervention on cost/QALY could have also been assessed. Due to the small number of deaths that occurred during the intervention period, it is also evident that the quality of life score (TTO or VAS rescaled) was the predominant factor in the production of the QALY's. Also, there is no indication in the RCT as to what happens to participants' quality of life after the intervention.

In addition to this, care must be taken with the extrapolation of this data as the co-efficients used to produce quality of life scores were based on the UK dataset for EQ-5D. Other datasets exist for other countries within Europe, and also the USA, Japan and Zimbabwe as countries place different weightings on the components of EuroQol according to the importance people in these countries place on the components [122].

The use of QALY's in this cost-utility analysis has been widely debated, and there are some centres that disagree with the use of QALY's [136]. Questions have been raised as to whether QALY's truly represent a utility, and also whether they adequately represent public preferences for rationing. QALY's tend to place preferences on middle aged people, rather

than the young or very old, which raises questions as to whether it is the most appropriate measure to use in very old populations [146]. Some groups have suggested that different weightings could be used for the young, very old or chronically ill, or that equity weightings could be used. Williams, 1997 has suggested that equity weightings for QALY's that take into account people's age in order to ensure all people receive a "fair innings" and have the opportunity to live a "full lifespan". There has been discussion as to whether it is more important to improve an individual's quality of life score from 0.8 to 0.9 or from 0.1 to 0.2 [146].

Greater emphasis needs to be placed on improving the policies under which decision makers use cost-effectiveness analysis, rather than on improvements in technique for calculating QALY's. It is, therefore, important for policy makers, and commissioners of services to be reminded of the comments by Gold et al., 1996, that cost-effectiveness analyses should be used to inform policy, rather than replace other methods, as this type of analysis cannot incorporate all the values relevant to policy making decisions.

5.6 Conclusions

This was the first cost-utility analysis to consider the cost-effectiveness of oral nutritional interventions in malnourished care home residents. It also, quite possibly, included one of the oldest populations that have ever been used in a health economic analysis.

The relatively low ICER's produced in this nutrition intervention trial therefore suggest that funding a relatively low cost intervention with ONS in malnourished care home residents would result in improvements in their quality of life. It is clear that cost-effectiveness analyses should be used to inform decision makers and that they can be used as a technique for obtaining better value though the efficient targeting of resources. As this nutrition intervention trial has suggested that improvements in quality of life and cost per QALY are possible through a 12 week intervention with ONS, future policy for nutrition support in malnourished care home residents may wish to consider the use of such an intervention.

Chapter Six: Final Summary and Conclusions

6.1 Introduction

This thesis set out to explore the routine nutritional care provided by privately owned care homes in Hampshire, and prevalence of malnutrition in this setting, in addition to conducting a randomised controlled trial of the effectiveness of oral nutritional interventions on improvements in quality of life, clinical, functional and healthcare outcomes in malnourished care home residents.

The topic of nutritional support for older people is extremely important, given the rising population of older people within the UK. Older people are more frequently expressing their wish to stay in their own homes for as long as possible, therefore Health Professionals have a responsibility to ensure older peoples' health problems, including malnutrition are detected and treated at an early stage in order to attenuate the decline in their wellbeing. When assessing and treating older peoples' nutritional needs, healthcare professionals must take into consideration the range of physiological, psychological and social changes that occur with aging. Frail older people are at risk of macro and micronutrient deficiencies, and it is important that these are identified and treated in order to prevent health complications such as infections and pressure sores.

In recent years guidance on nutritional screening and nutrition support has been produced for hospitals and the community. However, in the community, the regulation of such processes is more complex, given the sheer number of providing organisations and the range of types of ownerships of care homes. The increasing level of regulation of both residential and nursing homes by the Care Quality Commission should help to ensure minimum standards of nutritional care are adhered to, however minimum standards of care do not necessarily equate to 'best practice'.

The community health care workforce, from General Practitioners through to care workers have a responsibility to understand the nutritional needs of their clients, many of whom are frail, vulnerable residents. A recent survey of General Practitioners has suggested that the majority have not received any further training in nutrition since their medical degree, and many were unaware of the NICE guidance for nutrition support [147, 148]. Other work with nurses in Scotland has found that providing education and training on malnutrition and

nutrition support led to a greater number of completed nutrition screening tools, and appropriate use of nutrition interventions [61].

It is important for General Practitioners to work with community nurses and dietitians to ensure people at risk of malnutrition are meeting their nutritional needs, however in the care home setting little is known regarding the effectiveness of such nutritional interventions.

In order for General Practitioners and commissioners to provide good quality, evidence based nutritional services in the community, they need to be aware of the prevalence of malnutrition, the interventions available to treat malnutrition and their effectiveness, including their cost effectiveness.

6.2 Nutritional screening and the use of nutritional interventions

The audit of nutritional care in Hampshire care homes highlighted that practice is variable across this sector, with national guidance for the identification and treatment of malnutrition not always being followed in all care homes that participated in the survey.

Use of nutrition screening tools varied, with them being used more often in nursing than residential homes, however guidance on the use of nutrition screening tools in residential care homes was only introduced during the period in which this survey took place. Therefore, it is unsurprising that some care providers were not using nutritional screening tools. Where nutrition screening tools were used, ‘MUST’ was used most frequently, which suggests that homes using a nutrition screening tool were following NICE guidance for nutritional screening. Despite the variation in the use of tools, the prevalence of malnutrition did not vary significantly between homes that did or did not use a nutrition screening tool. This could suggest that although in some homes residents were being identified as being at risk of malnutrition, nutritional interventions were not being put in place for those residents identified as being at risk.

The prevalence of malnutrition was also found to vary considerably according to age and the presence of certain diseases; with the prevalence of malnutrition being much higher amongst those with cancer than those with cardiovascular disease. This finding is not surprising considering the aetiology of the diseases. Those with cancer tend to be in a catabolic state,

whereas diets high in calories and saturated fat and sedentary lifestyles are associated with the development of cardiovascular disease.

Interestingly, the prevalence of malnutrition was not associated with the deprivation score of the locality of the care home, with those residents living in more deprived areas of Hampshire having the same risk of malnutrition as those in less deprived areas. However, some caution must be taken in interpreting these figures as the deprivation score relates to the locality of the care home rather than residents' previous home postcode.

These trends in the use of nutrition screening tools and the prevalence of malnutrition, suggest that there is a great need for care homes to ensure that nutrition screening is taking place and that those at highest risk are identified. Some research has taken place into the effect of staff knowledge and understanding of malnutrition and how best to treat this condition in care homes, and has shown that, through comprehensive training of nurses the identification and treatment of malnutrition in this setting can be improved.

In addition to investigating the prevalence of malnutrition, the use of oral nutritional supplements in Hampshire care home residents was actually surprisingly low. In the care homes of this county that were studied, only 8% of residents received ONS, with 2.2% of those at low risk, 8.0% of those at medium risk and 23.8% of those at high risk of malnutrition, according to 'MUST', being prescribed ONS. This therefore suggests that, in this county, use of ONS was low amongst those at low risk, but also low amongst those residents who may benefit from receiving ONS. Combined with the relatively low reported use of nutrition screening tools and limited use of oral nutritional supplements in this county, it suggests that there is a need to ensure appropriate care plans are implemented, monitored and reviewed for residents at risk of malnutrition, with appropriate nutrition support strategies being used.

6.3 Systematic review of nutritional interventions in care homes

There are a range of nutritional interventions available for the treatment of malnutrition in the community, including oral nutritional supplements, dietary advice, changing the ambience of the mealtime environment and providing assistance with meals. As reported in Chapter One of this thesis, the evidence to support the use of oral nutritional supplements

and dietary advice, two common first line treatments for malnutrition in the UK and Europe, has been reviewed for the wider community, but not specifically for use in care homes. A review of the use of oral nutritional supplements in nursing homes has since been published, however it did not include residential homes, and did not include the full range of papers included in the review presented in this thesis [149].

Having ascertained through the survey of nutritional practice in Hampshire care homes that the use of oral nutrition support strategies varied, a systematic review was conducted to assess the effect of nutritional interventions in this sector. This review highlighted the limited amount of evidence to support the use of nutritional interventions, particularly with malnourished populations in care homes, with the evidence being greater for oral nutritional supplements than food fortification or dietary advice.

The review could only identify a relatively small number of articles for inclusion, with their population sizes and outcome measures varying considerably. This made it quite difficult to combine the results from the trials. Very few trials included in the review included any information on the compliance to the interventions, which makes it difficult to ascertain whether participants were exposed to the intervention. Trials that included functional measures did not find any significant differences between the intervention groups. This may have occurred due to inadequate power, exposure to the intervention and the timescale for the intervention.

Given that changes to residents' diets are required in order to improve nutritional status, there is a need to further assess the impact of a range of nutritional interventions on improving nutritional status. Interventions that include aspects of staff training, mealtime assistance, exercise and changing the ambience of the dining environment may need to be considered in addition to the provision of oral nutritional supplements, food fortification or dietary advice. It is quite possible that some of the interventions listed above may need to be used in combination in order to improve outcomes.

The systematic review also highlighted the need to standardise the interventions used in care homes, and to consider the time period over which the interventions are carried out. Residents' exposure to interventions also needs to be documented. Many of the randomised controlled trials included in the review did not record this, therefore making it more difficult to establish the effectiveness of the interventions used.

6.4 Nutrition Intervention Trial

Having considered some of the key questions raised from conducting the systematic review, the randomised controlled trial of oral nutritional supplements versus dietary advice attempted to answer some of these key research questions.

The systematic review identified that previous trials had tended to use mixed populations including both malnourished and non malnourished participants, making it difficult to elucidate who would benefit most from a nutritional intervention within this older age group. In the UK, current guidance suggests that only those people that are at risk of malnutrition should receive nutritional interventions, therefore the cohort used in this study included only those at risk of malnutrition, and followed them over a 12 week period to assess the effects of the interventions. A 12 week intervention period was used in this trial, in order to follow commonly used review periods for nutritional interventions in the UK.

This was the first RCT to consider this combination of interventions, and the first to measure quality of life in residents receiving ONS. Over the course of this 12 week intervention trial ONS improved residents' quality of life more effectively than dietary advice, with their energy, protein and micronutrient intake also improving significantly over this time. These results were suggestive that ONS should be prescribed for a minimum of 12 weeks in order to observe benefits in quality of life. Ideally, measurements would have also been taken after the intervention had stopped in order to assess whether the effect of the ONS continued to improve residents' quality of life beyond 12 weeks, or whether their quality of life decreased after the intervention stopped.

If a larger sample size could be recruited and followed up over a longer period, it would be interesting to explore the effects of such interventions on outcomes such as mortality. However there are some special considerations to bear in mind when working with care home residents. Due to their advancing chronic disease, the average length of stay in care homes may be limited (in the Hampshire survey the average was 2.2 years), which may limit the duration of interventions in this setting.

Thought must also be given to the combination of interventions used in any further trial, the types of measurements to be taken, and the timeframe that is required for research visits. This RCT did not include a control group, and if it were possible to carry out a larger scale trial, researchers may consider using four groups (ONS, dietary advice, food fortification and a control). Of course, other combinations of intervention groups are possible, and future

studies may also wish to consider the effect of the care giving environment and ways to improve the activity levels of residents. When designing a care home trial it is also very important to note that care home residents may be frail and elderly, and as a result may tire quickly during research visits. This should be taken into consideration when considering the types of measures and the frequency of measurements. Alternative forms of data collection i.e. from care plan notes and staff interviews may be appropriate in some instances.

The trial did not find any significant differences in anthropometric or functional outcomes between the two intervention groups. A range of factors may have contributed to this. It is possible that participants had underlying catabolic disease processes that they were unaware of, which would have resulted in greater nutritional requirements. The addition of an extra 333kcal/day to their diet may not have been sufficient to aid weight gain in these cases. It has been suggested that older people find it more difficult to regain lean tissue after periods of chronic under nourishment. Any gain in body mass is likely to include a higher proportion of fat than muscle. If this occurred, it would explain why there were no significant improvements in measures such as handgrip strength. It is possible that resistance training is required in addition to the use of ONS in order to improve functional outcomes amongst a group of frail older people, many of whom had limited mobility.

Further to this, residents may have misreported compliance to the intervention. There are limitations to the use of 24 hour food recall, and residents may have over or under estimated their intake. Drug nutrient interactions may also have occurred, which could have affected their ability to absorb the extra nutrients they received from the interventions. Measurement error could also have affected the results, however the accuracy and precision of measurements were checked at regular intervals throughout the project.

This RCT does pose some questions for future research as to whether the same effects would be observed in a population with more severe cognitive impairment or dementia. It is possible that those with dementia would stand to benefit most from a nutritional intervention in care homes. The prevalence of malnutrition amongst this group was greater than the general care home population, and it is well reported within the medical literature that those with advanced dementia tend to lose weight as the disease progresses due to alterations in taste preferences, loss of the ability to feed themselves, and the possibility for increased nutritional requirements due to increased movement. If a similar trial took place in for residents with advanced dementia, the use of an alternative quality of life tool would need to be considered, as EuroQol was not designed for use with people with dementia. Consideration would also need to be given to the form of intervention given, and any

directions for the interventions would need to be explained thoroughly to staff. The measurement of dietary intake and compliance to interventions would also require careful consideration as residents would not be able to recall their intake. Staff would need to complete an accurate food diary or researchers would need to be present to weigh plate waste at mealtimes.

It is possible that ONS may provide some benefit to those residents with a BMI greater than 20kg/m^2. Many of the trials included in the systematic review of nutritional interventions (Chapter Three) included populations with a BMI greater than 20kg/m^2. There could be a rationale for providing ONS to this group, if they are unable to meet their nutritional requirements through food alone. It is possible that theories such as the obesity paradox also apply to the care home population, in that those of a greater BMI have a lower risk of mortality than those with a lower BMI. As the prevalence of obesity increases amongst younger and middle age people, it is possible in coming years that more residents in care homes may experience 'silent malnutrition' as their appetite gradually decreases. Further research is required to assess the potential benefit of ONS, or other nutritional interventions, to people with a BMI greater than 20kg/m^2.

6.5 The cost-effectiveness of the nutrition intervention trial

Further to the RCT, the cost-utility analysis found that the provision of ONS is a cost-effective treatment in the management of malnutrition in this setting. It was the first cost-utility analysis of oral nutrition support strategies in care homes, and as such has demonstrated that it is possible to carry out such analyses if the necessary outcomes are measured in a nutrition support RCT. The results of the analysis, were in good agreement using data for those that completed the intervention, and imputed data where residents did not complete the trial. The cost of funding such an intervention would only cost approximately £10,000 to £12,000 in order to produce benefits in quality adjusted life years. In addition to this, the improvements in quality of life observed in the RCT included improvements in perceived ability to wash and dress oneself, which may also indicate potential for improvements in staff efficiency with personal care if residents are feeling stronger and require less help with this daily activity. However, as discussed in the previous chapter, cost-utility analyses should not be seen as the only method for deciding whether to commission services, but should be seen as an effective tool in aiding this process.

6.6 Implications for future practice

The results of this project suggest that improvements are required to the system of nutritional care provided in care homes in Hampshire. Although national guidance for care homes includes requirements for the nutritional screening of all care home residents, it was evident at the time of this project that this was not occurring in all homes, particularly residential homes. As a result of residents not being screened for malnutrition risk, many were not receiving nutritional interventions or dietary advice from dietitians.

General Practitioners are ultimately responsible for the medical care of residents in care homes, and it is important for them to work collaboratively with care homes to ensure staff are aware of the importance of nutritional screening. Without the proper detection of malnutrition many residents are left vulnerable to infections, pressure sores and have a greater risk of mortality. All care homes should have a system in place whereby all residents are screened for malnutrition on admission, and rescreened on a monthly basis. Further work is required with care homes to ascertain their needs in relation to ensuring the necessary infrastructure is in place for the detection of malnutrition, and that staff are appropriately trained. In order for this to occur, support is required from community Health Professionals.

Further to nutritional screening, appropriate care plans need to be put in place. For those at risk of malnutrition, their intake from food should be optimised, and residents should be referred to their General Practitioner, community nurse or dietitian for further nutritional assessment. This RCT has shown that ONS are a cost-effective intervention for improving the quality of life of malnourished care home residents and General Practitioners should therefore consider prescribing ONS for care home residents at risk of malnutrition. Care home staff should work with residents requiring ONS to ascertain their preferences for flavours of ONS, type of ONS and timing of ONS. Care home staff need to monitor residents' compliance to the intervention, and ensure the resident is reviewed at three monthly intervals by the prescriber. If problems with tolerance to the ONS are identified in the interim periods, care home staff must feel that they can report this to the GP, district nurse or dietitian, and alternative arrangements be put in place.

General Practitioners need to work with community healthcare professionals to establish standard guidance on the use of ONS, and other nutrition interventions, in order to ensure all those that require nutritional interventions receive them, and are monitored and reviewed at timely intervals. Education programmes for malnutrition training should be accessed, and all staff working with older people should have a good knowledge of the signs and symptoms of

malnutrition, and how to treat it. Without community Health Professionals and care home staff working together to identify and treat malnutrition, it will continue to be under identified and under treated amongst care home residents.

6.7 Conclusions

The body of work included in this thesis has addressed some key research questions that were raised by NICE in relation to nutrition support in adults. The audit of nutritional care has demonstrated that the identification of malnutrition in care homes in Hampshire is variable, and there is a need to ensure all care homes screen for this condition, and implement and review nutritional care plans for every resident. The use of nutritional interventions was also variable, and the systematic review has highlighted the need for further good quality randomised controlled trials of ONS, food fortification, dietary advice, or a combination of these interventions. RCT's of nutrition support need to include a wider range of outcomes, and include more details on the effectiveness, or compliance to the interventions. The RCT of ONS versus dietary advice has suggested that ONS may be more effective at improving quality of life than dietary advice, and that the provision of ONS is a cost effective intervention.

Chapter Seven: References

1. *Projecting Older People Population Information*. Institute of Public Care 2010.
2. *Nutrition Support for Adults:Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition* 2006, National Institute for Clinical Excellence: London.
3. Elia, M., L. Zellipour, and R.J. Stratton, *To screen or not to screen for adult malnutrition?* Clin Nutr, 2005. **24**(6): p. 867-84.
4. Russell, C.A. and M. Elia, *Malnutrition in the UK: where does it begin?* Proc Nutr Soc, 2010. **69**(4): p. 465-9.
5. Meijers, J.M., et al., *Malnutrition prevalence in The Netherlands: results of the annual dutch national prevalence measurement of care problems.* Br J Nutr, 2009. **101**(3): p. 417-23.
6. Russell, C.A. and M. Elia, *Nutrition screening survey in the UK and Republic of Ireland in 2010*. 2011, BAPEN: Redditch.
7. Morley, J.E., *Anorexia and weight loss in older persons.* J Gerontol A Biol Sci Med Sci, 2003. **58**(2): p. 131-7.
8. Johnsen, C., J.M. East, and P. Glassman, *Management of malnutrition in the elderly and the appropriate use of commercially manufactured oral nutritional supplements.* J Nutr Health Aging, 2000. **4**(1): p. 42-6.
9. Hickson, M., *Malnutrition and ageing*. Postgrad Med J, 2006. **82**(963): p. 2-8.
10. Roubenoff, R., *Sarcopenia: effects on body composition and function.* J Gerontol A Biol Sci Med Sci, 2003. **58**(11): p. 1012-7.
11. MacIntosh, C., J.E. Morley, and I.M. Chapman, *The anorexia of aging.* Nutrition, 2000. **16**(10): p. 983-995.
12. Matthews, F.E. and T. Dening, *Prevalence of dementia in institutional care.* Lancet, 2002. **360**(9328): p. 225-6.
13. Mowe, M. and T. Bohmer, *Reduced appetite. A predictor for undernutrition in aged people.* J Nutr Health Aging, 2002. **6**(1): p. 81-3.
14. Wikby, K. and A. Fagerskiold, *The willingness to eat. An investigation of appetite among elderly people.* Scand J Caring Sci, 2004. **18**(2): p. 120-7.
15. Crogan, N.L. and A. Pasvogel, *The influence of protein-calorie malnutrition on quality of life in nursing homes.* J Gerontol A Biol Sci Med Sci, 2003. **58**(2): p. 159-64.
16. Elia, M. and C. Russell, *Combatting Malnutrition: Recommendations for Action*, in *Report from the Advisory Group on Malnutrition, Led by BAPEN*, M. Elia and C.A. Russell, Editors. 2009, BAPEN. p. 1-7.
17. Stratton, R.J., et al., *'Malnutrition Universal Screening Tool' predicts mortality and length of hospital stay in acutely ill elderly.* Br J Nutr, 2006. **95**(2): p. 325-30.
18. Lennard-Jones, J.E., *A positive approach to nutrition as treatment*. 1992, Kings Fund London.
19. *The state of social care in England 2006-2007*. 2008, Centre for Social Care Inspection.
20. *SCIE Guide 15: Dignity in Care*. 2006, Social Care Institute for Excellence.
21. *Care homes for older people: national minimum standards and the Care Homes Regulations: third edition (revised)*. 2003, Department of Health.
22. *Nutrition Action Plan*. 2007, Department of Health and the Nutrition Summit stakeholder group.
23. Elia, M., *The 'MUST' Report*. 2003.
24. Nestle. *MNA User Guide*. 1991 [cited 2011; Available from: http://www.mna-elderly.com/default.html.
25. Kondrup, J., et al., *Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials.* Clinical Nutrition, 2003. **22**(3): p. 321-336.
26. Kruizenga, H.M., et al., *Development and validation of a hospital screening tool for malnutrition: the short nutritional assessment questionnaire (SNAQ).* Clin Nutr, 2005. **24**(1): p. 75-82.

27. Russell, C.A. and M. Elia, *Nutrition screening survey in the UK in 2007*. 2008, BAPEN: Redditch.
28. Russell, C.A. and M. Elia, *Nutrition screening survey in the UK in 2008*. 2009, BAPEN: Redditch.
29. Thomas, B. and J. Bishop, eds. *Manual of Dietetic Practice*. 4 ed. 2007, Wiley – Blackwell.
30. Stanner, S., R. Thompson, and J.L. Buttriss, eds. *Healthy Aging; The Role of Nutrition and Lifestyle*. 2009, Wiley-Blackwell: UK.
31. DH, *National diet and nutrition survey: people aged 65 years and over*. 1998, Department of Health.
32. Leslie, W.S., et al., *Unidentified under-nutrition: dietary intake and anthropometric indices in a residential care home population.* J Hum Nutr Diet, 2006. **19**(5): p. 343-7.
33. *Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. Report on Health and Social Subjects*. Vol. No.41. 1991, London: Department of Health.
34. Baldwin, C. and T.J. Parsons, *Dietary advice and nutritional supplements in the management of illness-related malnutrition: systematic review.* Clinical Nutrition, 2004. **23**(6): p. 1267-1279.
35. Baldwin, C., T. Parsons, and S. Logan, *Dietary advice for illness-related malnutrition in adults.* Cochrane Database Syst Rev, 2007(1): p. CD002008.
36. Wong, S.Y., et al., *Is dietary counselling effective in increasing dietary calcium, protein and energy intake in patients with osteoporotic fractures? A randomized controlled clinical trial.* J Hum Nutr Diet, 2004. **17**(4): p. 359-64.
37. Hickson, M., et al., *Does additional feeding support provided by health care assistants improve nutritional status and outcome in acutely ill older in-patients?--a randomised control trial.* Clin Nutr, 2004. **23**(1): p. 69-77.
38. Gray-Donald, K., H. Payette, and V. Boutier, *Randomized clinical trial of nutritional supplementation shows little effect on functional status among free-living frail elderly.* J Nutr, 1995. **125**(12): p. 2965-71.
39. Kalnins, D., et al., *Failure of conventional strategies to improve nutritional status in malnourished adolescents and adults with cystic fibrosis.* J Pediatr, 2005. **147**(3): p. 399-401.
40. Schwenk, A., H. Steuck, and G. Kremer, *Oral supplements as adjunctive treatment to nutritional counseling in malnourished HIV-infected patients: randomized controlled trial.* Clin Nutr, 1999. **18**(6): p. 371-4.
41. Turic, A., et al., *Nutrition supplementation enables elderly residents of long-term-care facilities to meet or exceed RDAs without displacing energy or nutrient intakes from meals.* J Am Diet Assoc, 1998. **98**(12): p. 1457-9.
42. *Dietary foods for special medical purposes. L91.* Official Journal of the European Communities, 1999. **42**: p. 29-36.
43. *British National Formulary*. 42 ed, ed. British Medical Association and Royal Pharmaceutical Society of Great Britain. 2006, London.
44. Stratton, R.J. and M. Elia, *Encouraging appropriate, evidence-based use of oral nutritional supplements.* Proc Nutr Soc, 2010. **69**(4): p. 477-87.
45. Elia M, S.R., Russell C, Green CJ, Pang F. , *The cost of disease related malnutrition in the UK and economic considerations for the use of oral nutritional supplements (ONS) in adults.* 2005, BAPEN: Redditch, UK.
46. Volkert, D., et al., *ESPEN guidelines on enteral nutrition: Geriatrics.* Clinical Nutrition, 2006. **25**(2): p. 330-360.
47. Stratton, R.J. and M. Elia, *Who benefits from nutritional support: what is the evidence?* Eur J Gastroenterol Hepatol, 2007. **19**(5): p. 353-8.
48. Stratton, R.J., *Elucidating effective ways to identify and treat malnutrition.* Proc Nutr Soc, 2005. **64**(3): p. 305-11.
49. Milne, A.C., A. Avenell, and J. Potter, *Meta-analysis: Protein and energy supplementation in older people.* Annals of Internal Medicine, 2006. **144**(1): p. 37-48.

50. Edington, J., et al., *A prospective randomised controlled trial of nutritional supplementation in malnourished elderly in the community: clinical and health economic outcomes.* Clin Nutr, 2004. **23**(2): p. 195-204.
51. Cawood, A.L., et al., *Prevalence of malnutrition and use of nutritional support in Peterborough Primary Care Trust.* Journal of Human Nutrition and Dietetics, 2008. **21**(4): p. 384-384.
52. Stratton, R.J. and M. Elia, *Deprivation linked to malnutrition risk and mortality in hospital.* Br J Nutr, 2006. **96**(5): p. 870-6.
53. Collins, P.F., et al., *The influence of deprivation on malnutrition risk in outpatients with chronic obstructive pulmonary disease.* Clin Nutr, 2010. **5**(2): p. 165.
54. *Patient weighing scales*. 2008, Department of Health.
55. *Oral nutritional supplement prescribing review*, QIPP, 2010.
56. Noble, M., et al., *The English Indices of Deprivation*, Office for National Statistics Editor. 2008: London.
57. *Essential standards of quality and safety*. 2010, Care Quality Commission: London.
58. Suominen, M., et al., *Malnutrition and associated factors among aged residents in all nursing homes in Helsinki.* European Journal of Clinical Nutrition, 2005. **59**(4): p. 578-583.
59. Meijers, J.M., et al., *Malnutrition in Dutch health care: Prevalence, prevention, treatment, and quality indicators.* Nutrition, 2009.
60. Suominen, M.H., et al., *How well do nurses recognize malnutrition in elderly patients?* Eur J Clin Nutr, 2007.
61. Molyneux, A., H. Hogan, and A. Burns, *Implementation of a nursing home care management pathway developed to facilitate the use of The Malnutrition Universal Screening Tool.* Proc Nutr Soc (In Press), 2011.
62. *Projecting Older People Population Information System (POPPI)*. 2012 27/4/12]; Available from: www.poppi.org.uk.
63. Arnaud-Battandier, F., et al., *Use of oral supplements in malnourished elderly patients living in the community: a pharmaco-economic study.* Clin Nutr, 2004. **23**(5): p. 1096-103.
64. Collins, C.E., J. Kershaw, and S. Brockington, *Effect of nutritional supplements on wound healing in home-nursed elderly: A randomized trial.* Nutrition, 2005. **21**(2): p. 147-155.
65. Loane, D., et al., *Nutrition in the community - an exploratory study of oral nutritional supplements in a health board area in Ireland.* Journal of Human Nutrition and Dietetics, 2004. **17**(3): p. 257-266.
66. Thomas, B. and J. Bishop, *Manual of dietetic practice*. 4 ed. 2007: Blackwell Publishing.
67. Milne, A.C., et al., *Protein and energy supplementation in elderly people at risk from malnutrition.* Cochrane Database Syst Rev, 2009(2): p. CD003288.
68. Higgins, J. and S. Green, *Cochrane Handbook for Systematic Reviews of Interventions*. 5.1.0 ed. 2011: Cochrane.
69. Clarke, M., *The QUORUM statement.* Lancet, 2000. **355**(9205): p. 756-7.
70. Stratton, R.J., C.J. Green, and M. Elia, *Disease-related malnutrition: An evidence-based approach to treatment*. 2003: CABI publishing.
71. Jadad, A.R., et al., *Assessing the quality of reports of randomized clinical trials: is blinding necessary?* Control Clin Trials, 1996. **17**(1): p. 1-12.
72. Kwok, T., J. Woo, and M. Kwan, *Does low lactose milk powder improve the nutritional intake and nutritional status of frail older Chinese people living in nursing homes?* J Nutr Health Aging, 2001. **5**(1): p. 17-21.
73. Fiatarone Singh, M.A., et al., *The effect of oral nutritional supplements on habitual dietary quality and quantity in frail elders.* J Nutr Health Aging, 2000. **4**(1): p. 5-12.
74. Lauque, S., et al., *Protein-energy oral supplementation in malnourished nursing-home residents. A controlled trial.* Age Ageing, 2000. **29**(1): p. 51-6.

75. Manders, M., et al., *Effect of a nutrient-enriched drink on dietary intake and nutritional status in institutionalised elderly.* Eur J Clin Nutr, 2009. **63**(10): p. 1241-50.
76. Smoliner, C., et al., *Effects of food fortification on nutritional and functional status in frail elderly nursing home residents at risk of malnutrition.* Nutrition, 2008. **24**(11-12): p. 1139-44.
77. Wouters-Wesseling, W., et al., *Study of the effect of a liquid nutrition supplement on the nutritional status of psycho-geriatric nursing home patients.* Eur J Clin Nutr, 2002. **56**(3): p. 245-51.
78. Gil Gregorio, P., S.P. Ramirez Diaz, and J.M. Ribera Casado, *Dementia and Nutrition. Intervention study in institutionalized patients with Alzheimer disease.* J Nutr Health Aging, 2003. **7**(5): p. 304-8.
79. Cluskey, M. and N. Dunton, *Serving meals of reduced portion size did not improve appetite among elderly in a personal-care section of a long-term-care community.* J Am Diet Assoc, 1999. **99**(6): p. 733-5.
80. Nijs, K.A., et al., *Effect of family style mealtimes on quality of life, physical performance, and body weight of nursing home residents: cluster randomised controlled trial.* BMJ, 2006. **332**(7551): p. 1180-4.
81. Nijs, K.A., et al., *Effect of family-style meals on energy intake and risk of malnutrition in dutch nursing home residents: a randomized controlled trial.* J Gerontol A Biol Sci Med Sci, 2006. **61**(9): p. 935-42.
82. Ramseyer, K., *Finger food for patients with dementia.* Ernahrungs-Umschau, 2008. **55**(2): p. 74-77.
83. Remsburg, R.E., et al., *Impact of a buffet-style dining program on weight and biochemical indicators of nutritional status in nursing home residents: a pilot study.* J Am Diet Assoc, 2001. **101**(12): p. 1460-3.
84. Cruz-Jentoft, A.J., et al., *Compliance with an oral hyperproteic supplement with fibre in nursing home residents.* J Nutr Health Aging, 2008. **12**(9): p. 669-73.
85. Kayser-Jones, J., et al., *A prospective study of the use of liquid oral dietary supplements in nursing homes.* J Am Geriatr Soc, 1998. **46**(11): p. 1378-86.
86. Remsburg, R.E., et al., *Does a liquid supplement improve energy and protein consumption in nursing home residents?* Geriatr Nurs, 2001. **22**(6): p. 331-5.
87. McCormick, S.E., et al., *The efficacy of pre-thickened fluids on total fluid and nutrient consumption among extended care residents requiring thickened fluids due to risk of aspiration.* Age Ageing, 2008. **37**(6): p. 714-5.
88. Crogan, N.L., C. Alvine, and A. Pasvogel, *Improving nutrition care for nursing home residents using the INRx process.* J Nutr Elder, 2006. **25**(3-4): p. 89-103.
89. Kikutani, T., et al., *Effects of oral functional training for nutritional improvement in Japanese older people requiring long-term care.* Gerodontology, 2006. **23**(2): p. 93-8.
90. Levinson, Y., et al., *Is it possible to increase weight and maintain the protein status of debilitated elderly residents of nursing homes?* J Gerontol A Biol Sci Med Sci, 2005. **60**(7): p. 878-81.
91. Cereda, E., et al., *Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial.* J Am Geriatr Soc, 2009. **57**(8): p. 1395-402.
92. Kittrell, J.B., *The effect of vitamin, mineral, and nutritional supplement in the aged.* J Ark Med Soc, 1984. **81**(1): p. 73-4.
93. Tomoe, M., et al., *Improved nutritional status of the elderly given an nutrient supplement drink.* Japanese Journal of Nutrition and Dietetics, 2005. **63 (2)**: p. 89-95.
94. Beck, A.M., K. Damkjaer, and N. Beyer, *Multifaceted nutritional intervention among nursing-home residents has a positive influence on nutrition and function.* Nutrition, 2008. **24**(11-12): p. 1073-80.
95. Beck, A.M., K. Damkjaer, and L.W. Sorbye, *Physical and social functional abilities seem to be maintained by a multifaceted randomized controlled nutritional intervention*

among old (>65 years) Danish nursing home residents. Arch Gerontol Geriatr, 2010. **50**(3): p. 351-5.
96. Fiatarone, M.A., et al., *The Boston FICSIT study: the effects of resistance training and nutritional supplementation on physical frailty in the oldest old.* J Am Geriatr Soc, 1993. **41**(3): p. 333-7.
97. Fiatarone, M.A., et al., *Exercise training and nutritional supplementation for physical frailty in very elderly people.* N Engl J Med, 1994. **330**(25): p. 1769-75.
98. Rosendahl, E., et al., *High-intensity functional exercise program and protein-enriched energy supplement for older persons dependent in activities of daily living: a randomised controlled trial.* Aust J Physiother, 2006. **52**(2): p. 105-13.
99. Zak, M., C. Swine, and T. Grodzicki, *Combined effects of functionally-oriented exercise regimens and nutritional supplementation on both the institutionalised and free-living frail elderly (double-blind, randomised clinical trial).* BMC Public Health, 2009. **9**: p. 39.
100. Manders, M., *Nutritional care in old age: the effect of supplementation on nutritional status and performance*. 2006.
101. Beck, A.M., L. Ovesen, and M. Schroll, *Home-made oral supplement as nutritional support of old nursing home residents, who are undernourished or at risk of undernutrition based on the MNA. A pilot trial.* Aging Clinical and Experimental Research, 2002. **14**(3): p. 212-215.
102. Castellanos, V.H., M.V. Marra, and P. Johnson, *Enhancement of select foods at breakfast and lunch increases energy intakes of nursing home residents with low meal intakes.* J Am Diet Assoc, 2009. **109**(3): p. 445-51.
103. Simmons, S.F., et al., *Prevention of unintentional weight loss in nursing home residents: a controlled trial of feeding assistance.* J Am Geriatr Soc, 2008. **56**(8): p. 1466-73.
104. Johnson, L.E., P.A. Dooley, and J.B. Gleick, *Oral nutritional supplement use in elderly nursing home patients.* J Am Geriatr Soc, 1993. **41**(9): p. 947-52.
105. Lee, S.K., et al., *Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial.* Adv Skin Wound Care, 2006. **19**(2): p. 92-6.
106. Manders, M., et al., *The effect of a nutrient dense drink on mental and physical function in institutionalized elderly people.* J Nutr Health Aging, 2009. **13**(9): p. 760-7.
107. Young, K.W., et al., *Providing nutrition supplements to institutionalized seniors with probable Alzheimer's disease is least beneficial to those with low body weight status.* J Am Geriatr Soc, 2004. **52**(8): p. 1305-12.
108. Parrott, M.D., K.W. Young, and C.E. Greenwood, *Energy-containing nutritional supplements can affect usual energy intake postsupplementation in institutionalized seniors with probable Alzheimer's disease.* J Am Geriatr Soc, 2006. **54**(9): p. 1382-7.
109. Wouters-Wesseling, W., et al., *Early nutritional supplementation immediately after diagnosis of infectious disease improves body weight in psychogeriatric nursing home residents.* Aging Clin Exp Res, 2006. **18**(1): p. 70-4.
110. Young, K.W., et al., *A randomized, crossover trial of high-carbohydrate foods in nursing home residents with Alzheimer's disease: associations among intervention response, body mass index, and behavioral and cognitive function.* J Gerontol A Biol Sci Med Sci, 2005. **60**(8): p. 1039-45.
111. Schiffrin, E.J., et al., *Systemic inflammatory markers in older persons: the effect of oral nutritional supplementation with prebiotics.* J Nutr Health Aging, 2007. **11**(6): p. 475-9.
112. Carlsson, M., et al., *The feasibility of serving liquid yoghurt supplemented with probiotic bacteria, Lactobacillus rhamnosus LB 21, and Lactococcus lactis L1A--a pilot study among old people with dementia in a residential care facility.* J Nutr Health Aging, 2009. **13**(9): p. 813-9.

113. Christensson, L., A.C. Ek, and M. Unosson, *Individually adjusted meals for older people with protein-energy malnutrition: a single-case study.* J Clin Nurs, 2001. **10**(4): p. 491-502.
114. Odlund Olin, A., et al., *Energy-dense meals improve energy intake in elderly residents in a nursing home.* Clin Nutr, 2003. **22**(2): p. 125-31.
115. Faxen-Irving, G., et al., *The effect of nutritional intervention in elderly subjects residing in group-living for the demented.* Eur J Clin Nutr, 2002. **56**(3): p. 221-7.
116. Heyman, H., et al., *Benefits of an oral nutritional supplement on pressure ulcer healing in long-term care residents.* J Wound Care, 2008. **17**(11): p. 476-8, 480.
117. Welch, P.K., M. Dowson, and J.M. Endres, *The effect of nutrient supplements on high risk long term care residents receiving pureed diets.* J Nutr Elder, 1991. **10**(3): p. 49-62.
118. Breslow, R.A., et al., *The importance of dietary protein in healing pressure ulcers.* J Am Geriatr Soc, 1993. **41**(4): p. 357-62.
119. Harril, I., M. Kunz, and A. Kylen, *Dietary supplementation and nutritional status in elderly women.* Journal of nutrition for the elderly, 1982. **1**: p. 3-14.
120. Beck, A.M., L. Ovesen, and M. Schroll, *Home-made oral supplement as nutritional support of old nursing home residents, who are undernourished or at risk of undernutrition based on the MNA. A pilot trial. Mini Nutritional Assessment.* Aging Clin Exp Res, 2002. **14**(3): p. 212-5.
121. Stratton, R.J., Green, C. J. & Elia, M *Disease-related malnutrition: an evidence-based approach to treatment*. 2003: CABI Publishing.
122. Szende, A., M. Oppe, and N. Devlin, *EQ-5D Value Sets: Inventory, Comparative Review and User Guide*. EuroQol Group Monographs. Vol. 2. 2007.
123. Rivas, B., et al., *Health-related quality of life in unselected outpatients with heart failure across Spain in two different health care levels. Magnitude and determinants of impairment: The INCA study.* Quality of Life Research, 2008. **17**: p. 1229-1238.
124. Durnin, J.V.G.A. and J. Womersley, *Body fat assessed from total body density and its estimation from skinfold thickness: measurements on 481 men and women aged from 16 to 72 years.* British Journal of Nutrition, 1974. **32**: p. 77-97.
125. Stubbs, R.J., et al., *The use of visual analogue scales to assess motivation to eat in human subjects: a review of their reliability and validity with an evaluation of new hand-held computerized systems for temporal tracking of appetite ratings.* Br J Nutr, 2000. **84**(4): p. 405-15.
126. *Guide to the methods of technological appraisal*, National Institute for Health and Clinical Excellence, Editor. 2004: London.
127. Altman, D.G., *Missing outcomes in randomized trials: addressing the dilemma.* Open Medicine, 2009. **3**(2): p. 51-53.
128. Frihagen, F., et al., *Outcome after femoral neck fractures: a comparison of Harris Hip Score, Eq-5d and Barthel Index.* Injury, 2008. **39**(10): p. 1147-56.
129. Arne, M., et al., *Physical activity and quality of life in subjects with chronic disease: Chronic obstructive pulmonary disease compared with rheumatoid arthritis and diabetes mellitus.* Scandinavian Journal of Primary Health Care, 2009. **27**: p. 141-147.
130. Jonkers, C.C.M., et al., *Economic evaluation of a minimal psychological intervention in chronically ill elderly patients with minor or mild to moderate depression: A randomised trial (the DELTA-study).* International Journal of Technology Assessment in Health Care, 2009. **25** (4): p. 497-504.
131. Hubbard, G.P., et al., *A systematic review of compliance to oral nutritional supplements.* Clin Nutr, 2012.
132. Trigg, R., R.W. Jones, and S.M. Skevington, *Can people with mild to moderate dementia provide reliable answers about their quality of life?* Age Ageing, 2007. **36**(6): p. 663-9.
133. Trigg, R., S.M. Skevington, and R.W. Jones, *How can we best assess the quality of life of people with dementia? the Bath Assessment of Subjective Quality of Life in Dementia (BASQID).* Gerontologist, 2007. **47**(6): p. 789-97.

134. Bryan, S., et al., *Proxy completion of EQ-5D in patients with dementia.* Qual Life Res, 2005. **14**(1): p. 107-18.
135. Missotten, P., et al., *Quality of life in older Belgian people: comparison between people with dementia, mild cognitive impairment, and controls.* Int J Geriatr Psychiatry, 2008. **23**(11): p. 1103-9.
136. McPake, B., L. Kumaranayake, and C. Normand, *Health Economics - An International Perspective*. 2002: Routledge Publishing.
137. Towse, A., C. Pritchard, and N. Devlin, *Cost Effectiveness Thresholds: economic and ethical issues*, ed. O.o.h. economics. 2003, London.
138. Neumann, P.J., *Using cost-effectiveness analysis to improve healthcare opportunities and barriers*. 2005, Oxford: Oxford University Press.
139. Drummond, M.F., et al., *Methods for the Economic Evaluation of Health Care Programmes*. Third Edition ed. 2005, Oxford: Oxford University Press.
140. Nixon, R.M., D. Wonderling, and R.D. Grieve, *Non-parametric methods for cost-effectiveness analysis: the central limit theorem and the bootstrap compared.* Health Econ, 2010. **19**(3): p. 316-33.
141. Stratton, R.J. and M. Elia, *A cost-utility analysis in patients receiving enteral tube feeding at home and in nursing homes.* Proc Nutr Soc, 2008. **67**(OCE): p. E111.
142. Richards, D.M. and M.H. Irving, *Cost-utility analysis of home parenteral nutrition.* Br J Surg, 1996. **83**(9): p. 1226-9.
143. Hoogendoorn, M., et al., *Is INTERdisciplinary COMmunity-based COPD management (INTERCOM) cost-effective?* Eur Respir J, 2010. **35**(1): p. 79-87.
144. Curtis, L., *Unit Costs of Health and Social Care 2009*. 2009, University of Kent.
145. DH, *UK Healthcare Data*. 2008, Department of Health.
146. Williams, A., *Intergenerational equity: an exploration of the 'fair innings' argument.* Health Econ, 1997. **6**(2): p. 117-32.
147. Cook, W.B., A.L. Cawood, and R.J. Stratton, *A national survey of General Practitioners understanding and awareness of malnutrition.* Proc Nutr Soc (In Press), 2011.
148. Chapman, C.M.C. and G.K. Grimble, *Attitude of British General Practitioners towards nutritional counselling and treatment of malnutrition.* Proc Nutr Soc (In Press), 2011.
149. Nieuwenhuizen, W.F., et al., *Older adults and patients in need of nutritional support: review of current treatment options and factors influencing nutritional intake.* Clin Nutr, 2010. **29**(2): p. 160-9.

Chapter Eight: Conference Abstracts

Prevalence of malnutrition risk in care homes in Hampshire

International Association of Gerontology and Geriatrics, July 2009
E. L. Parsons[1], R. J. Stratton[1], H. Warwick[2], A. L. Cawood[1], M. Elia[1]
[1]Institute of Human Nutrition, University of Southampton, [2]Nutrition and Dietetics, Southampton University Hospitals NHS Trust, Southampton, United Kingdom

Introduction: Reported prevalence of malnutrition in care homes (12-100%) varies due to the use of different criteria to identify malnutrition and differences in the types of homes and residents screened (1).

Methods: Using 'MUST' ('Malnutrition Universal Screening Tool) (see (2) for methods), this cross-sectional survey aimed to establish the prevalence of malnutrition in care homes according to the type of care (nursing, residential) and the age, diagnosis and duration of stay of residents. 25 care homes in Hampshire England (10 nursing, 10 residential, 5 dual registered) involving 552 residents (27% male, 73% female; median age 87 (57-105) y) were included. Three quarters of residents received nursing and the remainder residential care.

Results: Overall prevalence of malnutrition was 40% (14% medium risk; 26% at high risk), with a similar prevalence in nursing (41% (13% medium risk; 28% high risk) and residential homes (37% (16% medium risk; 21% high risk). Prevalence of malnutrition progressively increased with age (27% in 60-70y, 52% in >90y, p=0.002 Chi-squared) and varied with diagnosis, being higher in cancer (69%) and dementia (53%) and lower in endocrine disorders (27%) and cardiovascular disease (36%). The prevalence of malnutrition was not significantly related to the number of health problems (0-7/resident) or the duration of stay in a care home (4 categories: <1 y; 1-1.9 y; 2-2.9 y; >3 y).
Conclusion: This survey shows malnutrition is common in both residential and nursing homes but the oldest residents and those with cancer and dementia are particularly vulnerable. The prevalence of malnutrition was not significantly related to duration of stay or number of health problems. A larger survey is required to fully assess the prevalence of malnutrition in care homes.
References: (1) Stratton et al (2003) Disease-related malnutrition. CABI Publishing, Oxford; (2) Elia (2003) The 'MUST' report, BAPEN, Redditch (www.bapen.org.uk)

Inequalities in malnutrition screening and use of oral nutritional supplements in care homes

European Society for Clinical Nutrition and Metabolism, August 2009

E. L. Parsons[1], R. J. Stratton[1], H. Warwick[2], A. L. Cawood[1], T. Smith[3], M. Elia[1]
[1]Institute of Human Nutrition, University of Southampton, [2]Nutrition and Dietetics, Southampton University Hospitals NHS Trust, Southampton, [3]Gastroenterology, Royal Bournemouth Hospital, Bournemouth, United Kingdom

Rationale: Information is lacking on inequalities in the use of screening and nutrition support. This survey aimed to investigate any differences in screening practices, malnutrition prevalence and the use of oral nutritional supplements (ONS) in care homes in Hampshire UK.

Methods: In this cross-sectional survey of 43 care homes in Hampshire, UK (17 nursing, 18 residential, 8 dual registered, 1176 residents, mean age 86.5y SD 8.7y) information was collected on the use of a screening tool, the prevalence of malnutrition assessed using 'MUST' ('Malnutrition Universal Screening Tool') (1) and the use of all types of prescribable and non prescribable ONS (powders, liquids, single and multi-nutrient).

Results: 8% of residential homes used a nutrition screening tool compared with 39% of nursing homes and 88% of dual registered homes. Using MUST, there were no significant differences in malnutrition risk between the two types of care (nursing vs. residential: 40% vs. 36%) or between care homes that did (38%) and did not (38%) use a screening tool. Despite this, use of ONS was greater in residents receiving nursing vs. residential care (12.5% vs. 2.5%; $p<0.001$) and in care homes that did vs. did not use a screening tool (13.9% vs. 5.2%, $p<0.001$). According to 'MUST' malnutrition risk category, ONS were used in 2.4% of low risk, 7.5% of medium risk and 24% of high risk residents.

Conclusion: This cross sectional survey shows that there are inequalities in screening practices and the use of ONS in care homes. Strategies are required to tackle such inequalities and further evaluation is needed to investigate if inequalities exist in the use of other forms of nutrition support in care homes.
Reference: 1) Elia (2003) The 'MUST' report, BAPEN, Redditch

An audit of the use of oral nutritional supplements in care homes in Hampshire

British Association for Parenteral and Enteral Nutrition, October 2009

By E.L.PARSONS, R.J. STRATTON AND M. ELIA, *Institute of Human Nutrition, University of Southampton, Southampton, SO16 6YD*

Introduction: A variety of nutrition support strategies are currently used to optimise nutrition in care homes. This audit aimed to establish the use of oral nutritional supplements (ONS) according to malnutrition risk, BMI and unintentional weight loss in residents of care homes.

Methods: In this audit of 43 care homes in Hampshire (17 nursing, 18 residential, 8 dual registered, 1176 residents (mean age 86.5 (SD 8.7) y, mean BMI 22.80 (SD 4.99) kg/m^2) information was collected on the use of all types of prescribable and non-prescribable ONS (powders, liquids, single and multi-nutrient supplements) over the previous 4 weeks. ONS use was related to the residents' malnutrition risk category (low, medium, high) using the 'Malnutrition Universal Screening Tool' 'MUST' (www.bapen.org.uk; Elia, 2003), BMI and percentage unintentional weight loss.

Results: Although 39% of residents were at risk of malnutrition (14% medium and 25% high risk), only 8.2% of all residents received ONS in the 4 weeks prior to the audit. ONS usage increased according to 'MUST' category; 2.5% of residents at low risk, 7.4% at medium risk and 19.1% at high risk of malnutrition.

ONS use in the 4 weeks prior to the audit varied with BMI: 28% in those with a BMI<18.5kg/m^2; 40% in those with a BMI<16.0kg/m^2; and 50% in those with a BMI<14.0kg/m^2. Weight loss in the previous 3-6 months occurred in all these low BMI categories and increased as BMI decreased (3.6 (SD 5.1)% in those with a BMI<18.5kg/m^2, 6.0 (SD 6.7)% in those with a BMI<16.0kg/m^2 and 6.7 (SD 6.6)% in those with BMI<14.0kg/m^2). Among those who lost more than 10% body weight in the previous 3-6 months, 15% received ONS in previous 4 weeks. None of the residents were under the care of a dietitian.

Conclusion: The audit indicates that most residents with malnutrition do not receive ONS, and therefore there is a need to assess the extent to which other forms of nutritional support, if any, are given to malnourished residents in care homes.

Reference: Elia (2003) The 'MUST' report, BAPEN, Redditch (www.bapen.org.uk)

Malnutrition risk varies according to nutrition intervention in care homes

European Society for Clinical Nutrition and Metabolism, September 2010

E. L. Parsons[1], A. L. Cawood[2], H. Warwick[3], T. R. Smith[4], M. Elia[1], R. J. Stratton[1]

[1]Institute of Human Nutrition, UNIVERSITY OF SOUTHAMPTON, Southampton, [2]Medical Affairs, Nutricia, Trowbridge, [3]Nutrition and Dietetics, [4]Gastroenterology, Southampton University Hospitals NHS Trust, Southampton, United Kingdom

Rationale: There is little information about how the prevalence of malnutrition in care homes varies according to the type of nutritional support provided. This study aimed to examine the extent to which malnutrition in residents receiving oral nutritional supplements (ONS) and enteral tube feeding through a percutaneous endoscopic gastrostomy (PEG) differs from the general care home population, and whether dietetic input is provided.

Methods: 1322 residents (mean age 86.7 (SD 8.7)y, mean BMI 23.0 (SD 5.1)kg/m2) from 51 care homes (24 nursing, 19 residential 8 dual registered) participated. Malnutrition was assessed using 'MUST' ('Malnutrition Universal Screening Tool') (1) and related to the use of ONS (in the 4 weeks prior to the survey), PEG feeding, as well as the provision of dietetic input.

Results: 8% of the care home population received ONS and 2% PEG feeding. Those receiving ONS resided predominantly in nursing homes (61%), and to a lesser extent in residential (10%) and dual registered homes (29%). All residents with a PEG resided in nursing homes. Overall 37% of residents were at risk of malnutrition (13% medium risk, 24% high risk) but this varied according to the type of nutritional support provided. Dietetic input was provided to 0.3% of the population. Results according to ONS and PEG are shown in the table.

	ONS	PEG	Other
%malnutrition† (medium+high)	85 (14 + 71)	23 (8 + 15)	34 (14 + 20)
% receiving dietetic input	2	8	0

† $p<0.0001$ (Chi^2)

Conclusion: Despite the particularly high prevalence of malnutrition in care home residents who do and do not receive nutritional support, dietetic input in this locality is extremely limited.

Reference(s): (1) Elia (2003) The 'MUST' report, BAPEN, Redditch

Deprivation is not associated with malnutrition risk in care homes in Hampshire, UK

European Society for Clinical Nutrition and Metabolism, September 2010

E.L. Parsons[1], R.J. Stratton[1], M. Elia[1]
[1]Institute of Human Nutrition, University of Southampton, Southampton, United Kingdom

Rationale: There is wide variation in the prevalence of malnutrition between care homes, but the extent to which this is related to deprivation is uncertain. The aim of this cross sectional survey was to examine whether malnutrition risk is linked to deprivation according to the geographic location of the care home.

Methods: 51 care homes (24 nursing, 19 residential and 8 dual registered) participated, including 1322 residents [mean age 86.7 y (SD 8.7), mean BMI 23.0 kg/m2 (SD 5.1)]. Information was collected on the prevalence of malnutrition with 'MUST' ('Malnutrition Universal Screening Tool') [1]. Deprivation (including seven components: income, employment, health, education, housing, crime and living environment) was assessed using the Index of Multiple Deprivation (IMD) ranks for each care home (based on postcode) [2]. High IMD ranks relate to low levels of deprivation (total range 1 32,482).

Results: The prevalence of malnutrition in individual care homes ranged from 10% to 78% (mean 38±12.7; median 37%), and IMD rank ranged from 4,837 to 32,374 (mean 24,440±6,499; median 26,930). There was no significant association between prevalence of malnutrition risk in care homes and deprivation rank before ($r = 0.177$, $p = 0.214$) or after adjustment for care home type (residential, nursing) ($r = 0.185$, $p = 0.179$). None of the individual components of deprivation were significantly associated with the prevalence of malnutrition.

Conclusion: There was no evidence of a relationship between malnutrition and deprivation in care homes, however this survey did not take into account the location residents had been admitted from.

References: [1] Elia (2003) The 'MUST' report, BAPEN, Redditch

Systematic review of the effects of oral nutritional interventions in care homes

British Association for Parenteral and Enteral Nutrition, November 2010

By E.L. Parsons, R.J. Stratton and M. Elia, Institute of Human Nutrition, University of Southampton, Southampton SO16 6YD, UK

Rationale: There is some uncertainty about the effectiveness of different forms of oral nutrition support in the management of malnutrition in care homes. A systematic review was undertaken to investigate the evidence for the use of oral nutritional interventions (dietary advice, food fortification, oral nutritional supplements (ONS)) on nutritional, functional and clinical outcomes in care home residents.

Methods: The systematic review was undertaken following accepted methodology, including the systematic searching of databases (PubMed, CAB abstracts, Ovid, Embase) and bibliographies (up to December 2009). A total of 20 randomised controlled trials (RCT) in care homes (n=1046) were identified that compared either food fortification (8 RCT, n=366) or ONS (10 RCT, n=612) with routine care. No trials of dietary advice vs. routine care were found and 1 RCT (n=68) compared food fortification with ONS. The duration of intervention was 6 days to 1 year. Food fortification strategies included use of energy-rich ingredients and food snacks. ONS were mostly multi-nutrient, ready-made liquids. Outcomes assessed were; energy intake, body weight, body function (e.g., quality of life, muscle strength) and clinical outcomes (e.g. infections). Analysis was undertaken using Meta-analysis (Comprehensive Meta-Analysis v2.0) where possible, and combined analysis of the difference in the mean changes on a paired basis (paired t-test) (SPSS v17.0).

Results: One food fortification trial reported small, non significant changes in energy intake. A meta-analysis of body weight found no significant effects of food fortification vs. a control group (2 RCT, n=79, 0.39 (95% CI 0.8, 1.6)kg (p=0.52, random effects model). Few food fortification trials reported functional outcomes, with no significant differences being observed and there was insufficient data for meta-analysis. No food fortification trials reported clinical outcomes. Combined analysis of 2 ONS RCT (n=264) showed improvements in energy intake (mean difference 255kcal ± 33, range 232 to 278kcal, p=0.057). Meta-analysis of 2 ONS RCT (n= 212) found a significant difference in body weight (2.08 (95% CI 0.82, 3.34)kg, p=0.001, random effects model). No studies reported significant functional

changes. One RCT reported significant reductions in infections (ONS; 53% – no infections, control; 44% – no infections, p=0.001 (calculated using published data)), and bed days (ONS: 7.5 ± 2.1 vs. control: 17.3 ± 5.6, p<0.001 (calculated using published data)) over 12 months of ONS and another reported improvements in pressure ulcer healing with 8 weeks of ONS (change in pressure ulcer score; 5.56 vs. 2.85, p<0.05). There was insufficient functional and clinical outcome data for meta-analysis. The one RCT of food snacks vs. ONS reported significantly greater nutritional intakes with ONS (mean difference 275kcal, p<0.01) but no functional or clinical outcomes were measured.

Conclusion: This systematic review of studies in care homes suggests that: (i) there is extremely little evidence for the use of food fortification and no evidence for dietary advice; (ii) there is some evidence that ONS can improve energy intake, body weight and clinical outcomes. More research in well designed trials is needed to investigate the effects of different kinds of oral nutritional support in care homes.

Randomised controlled trial in care homes residents shows improved quality of life (QOL) with oral nutritional supplements

European Society for Clinical Nutrition and Metabolism, September 2011

E. L. Parsons[1],*, R. J. Stratton[1], A. L. Cawood[2], T. R. Smith[3], H. Warwick[3], M. Elia[1]
[1]UNIVERSITY OF SOUTHAMPTON, Southampton, [2]Nutricia, Trowbridge, [3]Southampton NHS Trust, Southampton, United Kingdom

Rationale: As few trials have explored the effect of nutrition support on quality of life (QOL) in care homes, this has become a research priority (1). This study examined the hypothesis that oral nutritional supplements (ONS) can be more effective than dietary advice (DA) at improving QOL in care home residents.

Methods: 104 residents (57 residential, 47 nursing, mean age 88.3±7.7y, mean BMI 9.1±2.7kg/m2, 86% female) at risk of malnutrition (using Malnutrition Universal Screening Tool 'MUST') were randomised to receive ONS with guidance on how to use (Nutricia range; mean intake 333kcal±237/d; n=53) for 12 weeks or written and verbal DA (n=51). QOL was measured at baseline and at 12 weeks using EuroQol (EQ-5D), including a time trade off (TTO) (range -0.073 to 1) and a visual analogue scale (VAS) (score 0 to 100) for self perceived health. Results were analysed using per-protocol and intention to treat analysis.

Results: QOL (adjusted for baseline, malnutrition risk, type of care (nursing, residential)) was significantly higher in the ONS than the DA group. Using per protocol analysis (n =70) the EQ-5D TTO scores (mean±SD) were 0.60±0.23 vs. 0.56±0.25 (p=0.004) and VAS scores 67.4±15.2 vs. 57.3±23.1 (p=0.027) for ONS vs. DA. With intention to treat analysis, EQ-5D TTO (mean±SE) (0.70±0.03 vs. 0.61±0.03; p=0.009) and VAS (66.4±5.1 vs. 56.5±9.5; p=0.05) scores remained significant.

Conclusion: This is the first study in care homes to indicate that ONS in malnourished residents can improve quality of life more effectively than dietary advice.

Reference(s): (1)NICE (2006) CG32 Nutrition Support for Adults. London.

Randomised controlled trial shows greater total nutritional intakes with liquid supplements than dietary advice in care home residents

European Society for Clinical Nutrition and Metabolism, September 2011

E. L. Parsons[1], M. Elia[1], A. L. Cawood[2], T. R. Smith[3], H. Warwick[3], R. J. Stratton[1]
[1]UNIVERSITY OF SOUTHAMPTON, Southampton, [2]Nutricia, Trowbridge, [3]Southampton NHS Trust, Southampton, United Kingdom

Rationale: Few trials have compared the effectiveness of oral nutritional supplements (ONS) with dietary advice (DA) in care homes (1). This trial examined the hypothesis that ONS can be more effective at improving nutritional intake than DA in care home residents.

Methods: 104 residents (57 residential, 47 nursing, mean age 88.3±7.7y, mean BMI 19.1±2.7kg/m2, 86% female) at risk of malnutrition (using Malnutrition Universal Screening Tool 'MUST') were randomised to receive ONS with guidance on how to use (Nutricia range; mean intake 333kcal±237/d; n=53); or written and verbal DA (n=51) for 12 weeks. At baseline and 12 weeks, nutritional intake (energy and protein) was measured by a dietitian (24h recalls; analysed with WISP) and appetite (hunger, desire to eat) assessed with 100mm visual analogue scales. Results were analysed using per-protocol regression analysis.

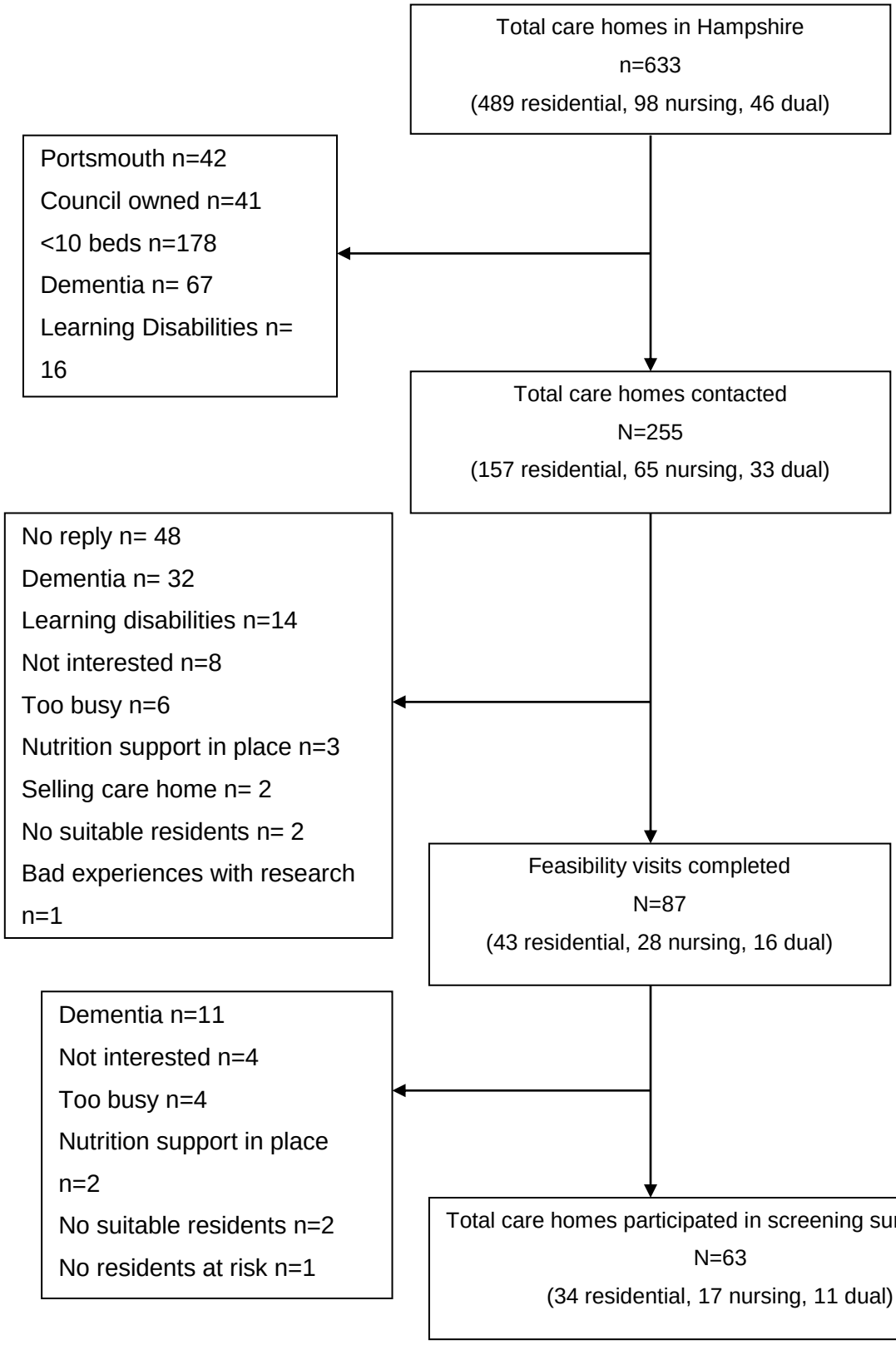
Results: Total energy and protein intakes (adjusted for baseline, malnutrition risk, type of care (nursing, residential)) were significantly higher in the ONS than the DA group (1655±502kcal vs. 1253±469kcal, p=0.001; 62.1±18.4g vs. 49.6±19.9g, p=0.004). Appetite sensations were not significantly different between the ONS and DA groups (hunger: 39±21mm vs. 33±28mm, n=57; desire to eat: 46.6±19mm vs. 49.7±27.3mm, n=54).

Conclusion: This RCT indicates that ONS can be more effective at increasing total energy and protein intakes than dietary advice with ONS having little effect on the appetite of care home residents.

Reference(s): (1) Parsons EL et al (2011) Systematic review of the effects of oral nutritional interventions in care homes, Proc Nutr Soc (in press)

Chapter Nine: Appendices

Appendix 1: Reasons for non-participation in the randomised controlled trial of oral nutritional supplements versus dietary advice in care homes



Appendix 2: Nutritional practice in care homes

Community Nutrition Research Project.

GENERAL DETAILS.

Name of care home	
Name of manager	
Number of beds	
Private / NHS	
Contact Details	
Previous participation in research	
Any current research in home	
Associated hospital	
Date of visit	
Visit undertaken by	

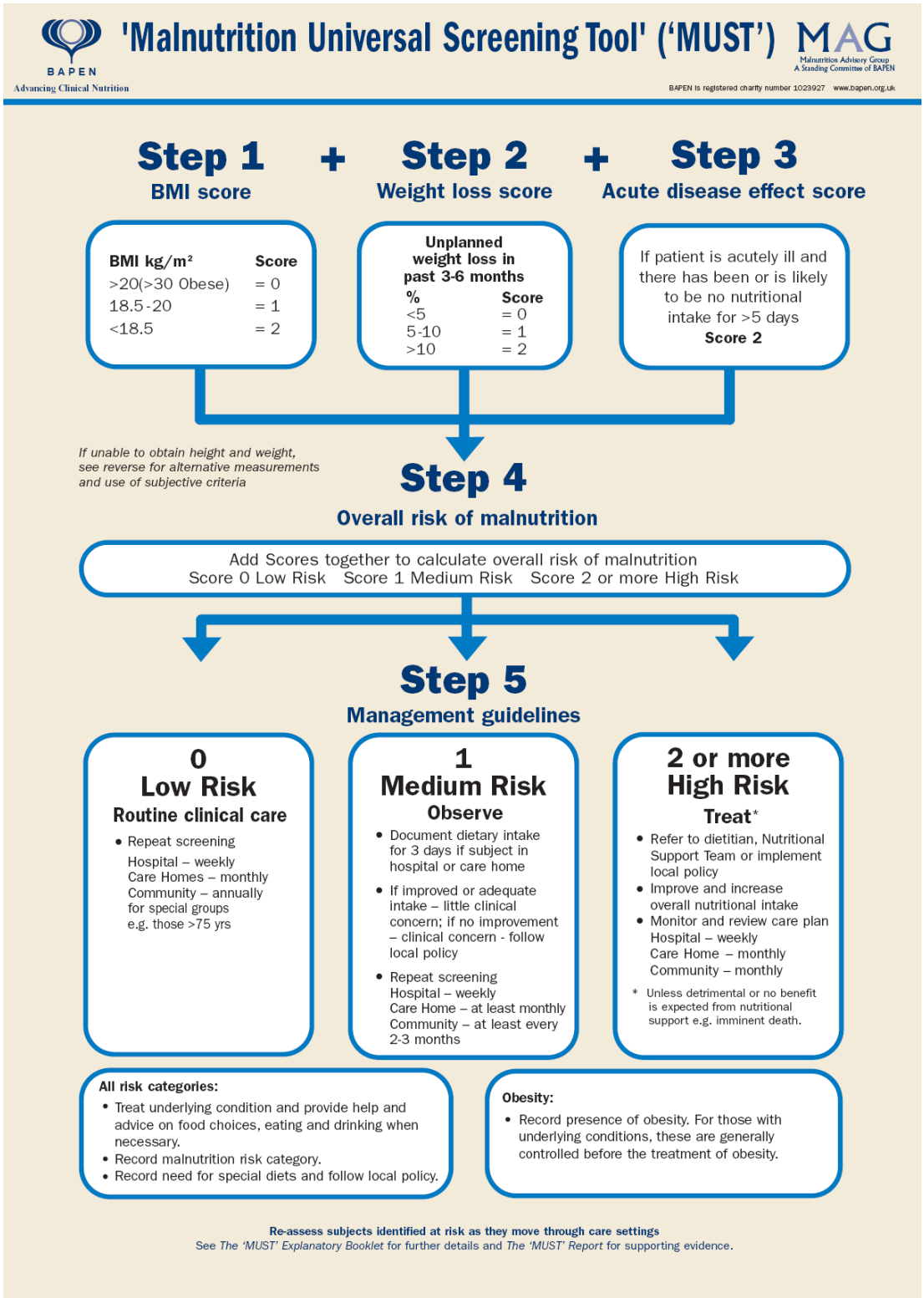
OVERVIEW OF RESIDENTS

Types of patients	
Age range of patients	
Average length of stay	
Primary Diagnosis	
Turnover of patients	
Malignancy	
Able to consent	
GP input	

NUTRITION

Currently Screening? How often	
Use of MUST?	
% malnourished	
Dietetic Input into home?	
% ONS	
% Tube feeders	
Food fortification / special menus	
Equipment and facilities	

Appendix 3: 'Malnutrition Universal Screening Tool' ('MUST')



BAPEN
Advancing Clinical Nutrition

'Malnutrition Universal Screening Tool' ('MUST')

MAG
Malnutrition Advisory Group
A Standing Committee of BAPEN

BAPEN is registered charity number 1023927 www.bapen.org.uk

Step 2 – Weight loss score

Weight before weight loss (kg)

	SCORE 0 Wt Loss <5%	SCORE 1 Wt Loss 5-10%	SCORE 2 Wt Loss > 10%
34 kg	<1.70	1.70 – 3.40	>3.40
36 kg	<1.80	1.80 – 3.60	>3.60
38 kg	<1.90	1.90 – 3.80	>3.80
40 kg	<2.00	2.00 – 4.00	>4.00
42 kg	<2.10	2.10 – 4.20	>4.20
44 kg	<2.20	2.20 – 4.40	>4.40
46 kg	<2.30	2.30 – 4.60	>4.60
48 kg	<2.40	2.40 – 4.80	>4.80
50 kg	<2.50	2.50 – 5.00	>5.00
52 kg	<2.60	2.60 – 5.20	>5.20
54 kg	<2.70	2.70 – 5.40	>5.40
56 kg	<2.80	2.80 – 5.60	>5.60
58 kg	<2.90	2.90 – 5.80	>5.80
60 kg	<3.00	3.00 – 6.00	>6.00
62 kg	<3.10	3.10 – 6.20	>6.20
64 kg	<3.20	3.20 – 6.40	>6.40
66 kg	<3.30	3.30 – 6.60	>6.60
68 kg	<3.40	3.40 – 6.80	>6.80
70 kg	<3.50	3.50 – 7.00	>7.00
72 kg	<3.60	3.60 – 7.20	>7.20
74 kg	<3.70	3.70 – 7.40	>7.40
76 kg	<3.80	3.80 – 7.60	>7.60
78 kg	<3.90	3.90 – 7.80	>7.80
80 kg	<4.00	4.00 – 8.00	>8.00
82 kg	<4.10	4.10 – 8.20	>8.20
84 kg	<4.20	4.20 – 8.40	>8.40
86 kg	<4.30	4.30 – 8.60	>8.60
88 kg	<4.40	4.40 – 8.80	>8.80
90 kg	<4.50	4.50 – 9.00	>9.00
92 kg	<4.60	4.60 – 9.20	>9.20
94 kg	<4.70	4.70 – 9.40	>9.40
96 kg	<4.80	4.80 – 9.60	>9.60
98 kg	<4.90	4.90 – 9.80	>9.80
100 kg	<5.00	5.00 – 10.00	>10.00
102 kg	<5.10	5.10 – 10.20	>10.20
104 kg	<5.20	5.20 – 10.40	>10.40
106 kg	<5.30	5.30 – 10.60	>10.60
108 kg	<5.40	5.40 – 10.80	>10.80
110 kg	<5.50	5.50 – 11.00	>11.00
112 kg	<5.60	5.60 – 11.20	>11.20
114 kg	<5.70	5.70 – 11.40	>11.40
116 kg	<5.80	5.80 – 11.60	>11.60
118 kg	<5.90	5.90 – 11.80	>11.80
120 kg	<6.00	6.00 – 12.00	>12.00
122 kg	<6.10	6.10 – 12.20	>12.20
124 kg	<6.20	6.20 – 12.40	>12.40
126 kg	<6.30	6.30 – 12.60	>12.60

Weight before weight loss (st lb)

	SCORE 0 Wt Loss <5%	SCORE 1 Wt Loss 5-10%	SCORE 2 Wt Loss >10%
5st 4lb	<4lb	4lb – 7lb	>7lb
5st 7lb	<4lb	4lb – 8lb	>8lb
5st 11lb	<4lb	4lb – 8lb	>8lb
6st	<4lb	4lb – 8lb	>8lb
6st 4lb	<4lb	4lb – 9lb	>9lb
6st 7lb	<5lb	5lb – 9lb	>9lb
6st 11lb	<5lb	5lb – 10lb	>10lb
7st	<5lb	5lb – 10lb	>10lb
7st 4lb	<5lb	5lb – 10lb	>10lb
7st 7lb	<5lb	5lb – 11lb	>11lb
7st 11lb	<5lb	5lb – 11lb	>11lb
8st	<6lb	6lb – 11lb	>11lb
8st 4lb	<6lb	6lb – 12lb	>12lb
8st 7lb	<6lb	6lb – 12lb	>12lb
8st 11lb	<6lb	6lb – 12lb	>12lb
9st	<6lb	6lb – 13lb	>13lb
9st 4lb	<7lb	7lb – 13lb	>13lb
9st 7lb	<7lb	7lb – 13lb	>13lb
9st 11lb	<7lb	7lb – 1st 0lb	>1st 0lb
10st	<7lb	7lb – 1st 0lb	>1st 0lb
10st 4lb	<7lb	7lb – 1st 0lb	>1st 0lb
10st 7lb	<7lb	7lb – 1st 1lb	>1st 1lb
10st 11lb	<8lb	8lb – 1st 1lb	>1st 1lb
11st	<8lb	8lb – 1st 1lb	>1st 1lb
11st 4lb	<8lb	8lb – 1st 2lb	>1st 2lb
11st 7lb	<8lb	8lb – 1st 2lb	>1st 2lb
11st 11lb	<8lb	8lb – 1st 3lb	>1st 3lb
12st	<8lb	8lb – 1st 3lb	>1st 3lb
12st 4lb	<9lb	9lb – 1st 3lb	>1st 3lb
12st 7lb	<9lb	9lb – 1st 4lb	>1st 4lb
12st 11lb	<9lb	9lb – 1st 4lb	>1st 4lb
13st	<9lb	9lb – 1st 4lb	>1st 4lb
13st 4lb	<9lb	9lb – 1st 5lb	>1st 5lb
13st 7lb	<9lb	9lb – 1st 5lb	>1st 5lb
13st 11lb	<10lb	10lb – 1st 5lb	>1st 5lb
14st	<10lb	10lb – 1st 6lb	>1st 6lb
14st 4lb	<10lb	10lb – 1st 6lb	>1st 6lb
14st 7lb	<10lb	10lb – 1st 6lb	>1st 6lb
14st 11lb	<10lb	10lb – 1st 7lb	>1st 7lb
15st	<11lb	11lb – 1st 7lb	>1st 7lb
15st 4lb	<11lb	11lb – 1st 7lb	>1st 7lb
15st 7lb	<11lb	11lb – 1st 8lb	>1st 8lb
15st 11lb	<11lb	11lb – 1st 8lb	>1st 8lb
16st	<11lb	11lb – 1st 8lb	>1st 8lb
16st 4lb	<11lb	11lb – 1st 9lb	>1st 9lb
16st 7lb	<12lb	12lb – 1st 9lb	>1st 9lb

BAPEN
Advancing Clinical Nutrition

'Malnutrition Universal Screening Tool' ('MUST')

MAG
Malnutrition Advisory Group
A Standing Committee of BAPEN

BAPEN is registered charity number 1023927 www.bapen.org.uk

Alternative measurements and considerations

Step 1: BMI (body mass index)

If height cannot be measured

- Use recently documented or self-reported height (if reliable and realistic).
- If the subject does not know or is unable to report their height, use one of the alternative measurements to estimate height (ulna, knee height or demispan).

If height & weight cannot be obtained

- Use mid upper arm circumference (MUAC) measurement to estimate BMI category.

Step 2: Recent unplanned weight loss

If recent weight loss cannot be calculated, use self-reported weight loss (if reliable and realistic).

Subjective criteria

If height, weight or BMI cannot be obtained, the following criteria which relate to them can assist your professional judgement of the subject's nutritional risk.

1. BMI

- Clinical impression – thin, acceptable weight, overweight. Obvious wasting (very thin) and obesity (very overweight) can also be noted.

2. Unplanned weight loss

- Clothes and/or jewellery have become loose fitting (weight loss).
- History of decreased food intake, reduced appetite or swallowing problems over 3-6 months and underlying disease or psycho-social/physical disabilities likely to cause weight loss.

3. Acute disease effect

- No nutritional intake or likelihood of no intake for more than 5 days.

Further details on taking alternative measurements, special circumstances and subjective criteria can be found in *The 'MUST' Explanatory Booklet*. A copy can be downloaded at www.bapen.org.uk or purchased from the BAPEN office. The full evidence-base for 'MUST' is contained in *The 'MUST' Report* and is also available for purchase from the BAPEN office.

BAPEN Office, Secure Hold Business Centre, Studley Road, Redditch, Worcs, B98 7LG. Tel: 01527 457 850. Fax: 01527 458 718.
bapen@sovereignconference.co.uk BAPEN is registered charity number 1023927. www.bapen.org.uk

 ISBN 1 899467 85 8 Price £2.00

Royal College of Nursing

THE BRITISH DIETETIC ASSOCIATION

Published November 2003 by MAG the Malnutrition Advisory Group, a Standing Committee of BAPEN. *Review date December 2004 and annually thereafter.*
'MUST' is supported by the British Dietetic Association, the Royal College of Nursing and the Registered Nursing Home Association.

BAPEN
Advancing Clinical Nutrition

'Malnutrition Universal Screening Tool' ('MUST')

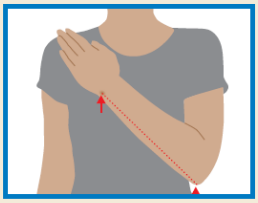
MAG
Malnutrition Advisory Group
A Standing Committee of BAPEN

BAPEN is registered charity number 1023927 www.bapen.org.uk

Alternative measurements: instructions and tables

If height cannot be obtained, use length of forearm (ulna) to calculate height using tables below.
(See The 'MUST' Explanatory Booklet for details of other alternative measurements (knee height and demispan) that can also be used to estimate height).

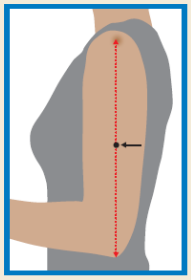
Estimating height from ulna length



Measure between the point of the elbow (olecranon process) and the midpoint of the prominent bone of the wrist (styloid process) (left side if possible).

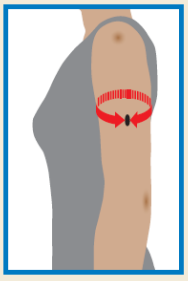
HEIGHT (m)	Men (<65 years)	1.94	1.93	1.91	1.89	1.87	1.85	1.84	1.82	1.80	1.78	1.76	1.75	1.73	1.71
	Men (>65 years)	1.87	1.86	1.84	1.82	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.67
	Ulna length (cm)	32.0	31.5	31.0	30.5	30.0	29.5	29.0	28.5	28.0	27.5	27.0	26.5	26.0	25.5
HEIGHT (m)	Women (<65 years)	1.84	1.83	1.81	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.70	1.69	1.68	1.66
	Women (>65 years)	1.84	1.83	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.66	1.65	1.63
HEIGHT (m)	Men (<65 years)	1.69	1.67	1.66	1.64	1.62	1.60	1.58	1.57	1.55	1.53	1.51	1.49	1.48	1.46
	Men (>65 years)	1.65	1.63	1.62	1.60	1.59	1.57	1.56	1.54	1.52	1.51	1.49	1.48	1.46	1.45
	Ulna length (cm)	25.0	24.5	24.0	23.5	23.0	22.5	22.0	21.5	21.0	20.5	20.0	19.5	19.0	18.5
HEIGHT (m)	Women (<65 years)	1.65	1.63	1.62	1.61	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47
	Women (>65 years)	1.61	1.60	1.58	1.56	1.55	1.53	1.52	1.50	1.48	1.47	1.45	1.44	1.42	1.40

Estimating BMI category from mid upper arm circumference (MUAC)



The subject's left arm should be bent at the elbow at a 90 degree angle, with the upper arm held parallel to the side of the body. Measure the distance between the bony protrusion on the shoulder (acromion) and the point of the elbow (olecranon process). Mark the mid-point.

Ask the subject to let arm hang loose and measure around the upper arm at the mid-point, making sure that the tape measure is snug but not tight.



If MUAC is < 23.5 cm, BMI is likely to be <20 kg/m².
If MUAC is > 32.0 cm, BMI is likely to be >30 kg/m².

Appendix 4: Invitation to participate in the randomised controlled trial (care home manager to residents)

Invitation to take part in research.

We are currently involved in a nutrition research project with the University of Southampton.

This research aims to find out the best way of giving nutrition to elderly people who are thin, losing weight, or have a poor appetite. The research will assess the effects of nutritional drinks and dietary advice on your quality of life, strength, mobility, and appetite.

Tackling nutrition in care homes has recently been highlighted by many national bodies.

Each person, who is willing and suitable for the research, will be given nutrition drinks or dietary advice for 3 months and followed up for 3-6 months. Participation is voluntary and you would be free to withdraw from the research at any time.

If you are interested and would like to discuss this further, please let me know so that we can arrange for you to meet a member of the research team.

THE CARE HOME MANAGER.

University of Southampton

IHN Institute of Human Nutrition

Appendix 5: GCP Protocol for Obtaining Informed Consent

Researchers see the potential subjects in an unhurried, private atmosphere where the subject has time to review the documents and ask questions.

The researcher introduces themselves to the subject by name and role, stating the purpose of their communication.

- The researcher should determine the ability of the subject to understand the information and give consent before proceeding further. This can be discussed with other healthcare professionals caring for the potential participant.
- The researcher should inform the subject about the study, using the participant information sheet. If necessary this can be in the presence of an impartial witness.
- An impartial witness can be any individual who is not a member of the Research Team.
- Researchers ensure that the subject understands the nature of the study, why the research is being done, the key benefits, and why they are being asked to participate.
- The subject should have time to read and understand the Participant Information Sheet, and ask any questions.
- If the subject is prepared to participate, complete the Consent Form. The subject needs to:
  - read each statement
  - initial each box
  - personally print their name, sign and date the Consent Form.
- The researcher taking consent must also print their name, sign and date the Consent Form.
- If the subject cannot read or sign the Consent Form, but is indeed in a condition to provide verbal consent, then there should be an impartial witness present during the entire discussion. After all the written information has been explained to the potential participant, and after they have given oral consent to participate in the study, then the witness must sign and date the back of the Consent Form. By signing the form, the impartial witness declares that the information was

explained to, and understood by, the subject and that the subject has given his/her consent out of his/her own free will.

- This form must be copied, one to be given to the subject, one to be put in the subjects notes, and the original to be kept in the site master file.
- Information on the subject's participation in the trial, the day consent was taken, and the intervention should be documented in the subject's notes.
- Participants are free to withdraw from the trial at any time without the need to give reasons.

Appendix 6: Randomisation code list

	Medium risk / Residential care	High risk / Residential care	Medium risk / Nursing care	High risk / Nursing care
1	1	0	1	1
2	0	1	1	0
3	0	1	0	1
4	1	1	1	1
5	1	0	1	0
6	1	1	0	0
7	1	0	1	0
8	1	0	0	0
9	1	0	0	0
10	0	1	1	0
11	0	1	0	1
12	0	1	1	1
13	1	0	0	1
14	0	0	1	0
15	1	0	1	0
16	0	1	1	0
17	0	0	1	1
18	1	0	0	0
19	0	0	1	0
20	1	1	1	0
21	0	1	0	0
22	1	1	0	0
23	1	0	0	1
24	0	0	1	0
25	1	0	0	1
26	1	1	1	1
27	1	1	0	1
28	1	1	1	0
29	0	1	0	1
30	1	1	1	1
31	1	1	0	0
32	0	0	1	0

33	0	1	1	0
34	0	1	1	1
35	1	1	1	1
36	1	0	0	0
37	1	0	1	1
38	1	0	0	0
39	0	1	0	1
40	1	1	1	0
41	0	0	0	1
42	1	0	1	1
43	0	1	0	0
44	0	0	1	1
45	1	0	1	1
46	0	1	0	1
47	1	0	0	0
48	0	1	1	1
49	0	0	1	0
50	1	0	0	1
51	1	1	1	0
52	0	1	0	0
53	1	0	0	1
54	0	0	0	1
55	1	1	0	0
56	0	1	1	1
57	0	0	1	0
58	0	1	1	0
59	1	0	0	1
60	0	0	0	0
61	1	0	0	0
62	0	1	0	1
63	0	1	0	0
64	1	0	0	1
65	0	0	0	0
66	0	0	0	0
67	0	0	1	1
68	0	1	1	0

69	1	1	0	1
70	1	0	1	1
71	1	0	0	0
72	0	1	0	1
73	1	1	0	0
74	0	1	0	1
75	0	1	0	1

Appendix 7: Nutritional content of ONS

Product	Volume	kcal per bottle / carton	g Protein bottle / carton
Fortisip Extra	200ml	320	20
Fortisip Protein	200ml	300	20
Fortisip bottle	200ml	300	12
Fortisip Yogurt Style	200ml	300	12
Fortifresh	200ml	300	12
Fortisip Multifibre	200ml	300	12
Fortijuce	200ml	300	8
Fortimel	200ml	200	20
Renilon 7.5	125ml	250	9.4
Fortisip Savoury Multi Fibre	200ml	300	15
Fortisip Fruit Dessert	150g	200	10.5
Forticreme Complete	125g	200	11.8
Scandishake + full fat milk	85g powder + 240ml milk	598	11.7
Calogen Recommended dose = 3 x 30ml per day	200ml or 500ml bottle	405kcal per 90ml	0

Appendix 8: MHRA Letter

Safeguarding public health

MHRA

Ms Rachel Bolch
Nutricia Clinical Care
White Horse Business Park
Trowbridge
Whiltshire
BA14 0XQ

Date 26 January 2007

Ref: AE/2007/000088/000084/000053/000052

Direct Line: 020 7084 2361
Direct Fax: 020 7084 2439
e-mail: alexis.edwards@mhra.gsi.gov.uk

Dear Ms Bolch

Re Fortisip and oral nutritional supplement range

Thank you for your recent correspondence. On the basis of the information presently available about the above named product, and on the understanding that information relating to specific adverse medical conditions are available only to medical practitioners and not available to the public, the Agency has concluded that the sale or supply of this product would not be subject to the licensing and other provisions of The Medicines For Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I.1994/3144).

The Agency reserves the right to change its view in the event of any information or evidence which has a bearing on the status of the products, including the way in which they are promoted if medicinal claims are made for them.

These products are likely to be regarded as foods and subject to the food labelling regulations which contain detailed provisions for both the labelling and advertising of food. In particular, any claim that a food has the property of preventing, treating or curing human disease is prohibited. This prohibition covers *any implication* that a foodstuff is capable of protecting against disease, infection or other adverse condition or relieving symptoms. Food safety law is administered and enforced locally on behalf of the Food Standards Agency by the Trading Standards Service.

If you intend to market these products as foods you should consult the appropriate regulatory authority about the products' acceptability.

Yours sincerely

Alexis Edwards
Assistant Classifier
Medicines Borderline Section

Medicines and Healthcare products Regulatory Agency
Market Towers 1 Nine Elms Lane London SW8 5NQ
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

Appendix 9: Nutrition drinks advice sheet

NUTRITION DRINKS

Nutrition drinks are palatable, ready-made drinks packed full of calories, protein, vitamins and minerals.

You should aim to have 2 or more drinks per day.

Continue to eat as much food as you can.

The drinks are best served chilled and can be poured into a glass or drunk through a straw from the bottle.

You can have a variety of nutrition drinks as there are many styles and flavours to choose from during the trial.

If you wish to change the nutrition drinks you are taking let us know.

YOUR NUTRITION DRINKS:

- _____
- _____

Appendix 10: Build Up Diet Sheet

BUILD YOURSELF UP

A GUIDE TO HELP INCREASE THE CALORIES AND PROTEIN IN YOUR DIET

This is not a "special diet", but just some practical tips on how to build yourself up.

This advice will help you to get your energy back and keep your strength up. If you have lost weight these tips may help you to put some pounds back on.

WHEN SHOULD I EAT?

Try to eat something between your meals. This is particularly important if you have a reduced appetite and can only manage small meals.

Aim to eat something, or have a milky drink, six times per day, i.e.:

- Breakfast
- Mid-morning snack
- Lunch
- Mid-afternoon snack
- Evening meal
- Bedtime snack

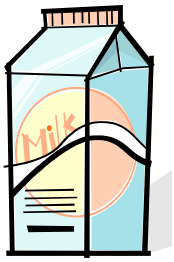
Everyone's appetite varies between good and bad days and from hour to hour. Make the most of the good times by eating and treating yourself to your favourite foods.

ARE THERE ANY FOODS I SHOULD AVOID?

There are no particular foods you should avoid or foods that you must eat, unless you are allergic to something. Everyone is different: if you find that certain foods upset you, avoid them! Try to have as wide a variety of foods as possible.

Often people, when they are well, are told to avoid fat and sugar. This is not relevant to you. In fact, it is these foods that will help you put some pounds back on if you have lost weight.
Smoking tends to reduce your appetite. If you are off your food, cutting back on smoking will help.

HOW CAN I INCREASE THE CALORIES AND PROTEIN IN THE FOODS THAT I EAT?



MILK: Drink full cream milk or milky drinks (like ovaltine or milky coffee). Choose milky puddings like custards, blancmanges and rice puddings.

BREAKFAST CEREALS: Use plenty of milk, and add sugar, honey or syrup freely. Many people enjoy breakfast cereals as between meal snacks and at bedtime.

CASSEROLES AND SOUPS: Have casseroles or soups that contain minced meat, lentils, beans or noodles.

MEAT POULTRY AND FISH: These foods are very good for you as they are an excellent source of protein. Choose meat, poultry and fish dishes that are served with sauces such as cheese, white or parsley, for added protein and calories. Sauces are particularly helpful if you have a dry or a sore mouth.

POTATO: Add butter or margarine to potatoes or sprinkle cheese on top.

VEGETABLES: Melt butter or margarine on top of hot vegetables or ask for some grated cheese to be sprinkled on top.

Sauces such as cheese or white sauce are tasty on cauliflower, leeks and marrow and represent another good way to fortify vegetables. Mayonnaise and salad cream can also add extra calories to salads.

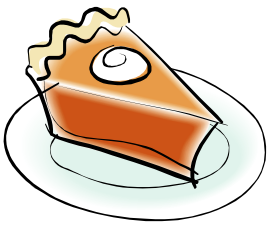
DESSERTS: Try to have a dessert after meals. If necessary wait a while between the main course and dessert. Add ice-cream, cream or evaporated milk to puddings.

Use sugar, honey or syrup liberally. Thick and creamy yoghurts or fromage frais and cream cakes are excellent sources of extra calories.

DRINKS: Milky drinks are better than just tea between meals. Use plenty of milk when making coffee and milky drinks. Milk shakes are a useful source of calories and protein and are very good as between meal snacks.

Fresh fruit juice is a good source of vitamins particularly if you are not eating much fruit.

NIBBLES: Enjoy snacks like nuts, fruit, crisps, biscuits, sweets and chocolate between meals.



WHAT CAN I DO IF I HAVE LOST MY APPETITE?

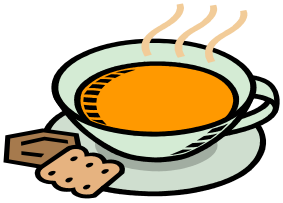
The following list may give you some ideas of the types of food you may prefer to eat if you do not fancy a main meal.

ON TOAST: Cheese, baked beans, scrambled eggs, sardines, pilchards, mackerel, pate, spaghetti, ravioli, tinned mushrooms, toast toppers.

SANDWICHES AND FILLED ROLLS: Try fillings such as cheese, cheese spreads, tuna or other fish, egg mayonnaise, pate, cold meats (e.g. corned beef, ham, beef), bacon, peanut butter, jam, marmalade, banana.

BAKED POTATOES: Butter, cheese, baked beans, tuna coleslaw

FILLED OMELETTES: Ham, cheese, mushroom



SOUPS: Soups can make quick nutritious meals

SNACKS: Your care home may provide a variety of snacks for you to have between meals that can help when you have a poor appetite. These could include pasties, pies, biscuits, cakes, scones, chocolates, nuts, crisps and dried fruit.

ALCOHOL: If you have lost your appetite, a glass of sherry or brandy before a meal may stimulate your appetite.

SAMPLE MEAL PLAN:

Breakfast

Porridge or cereal and milk with sugar or honey

Cooked breakfast e.g. bacon, sausage and tomato

Bread/toast with butter and marmalade

Mid-morning

Snack and/or drink e.g. milky coffee with a piece of cake

Glass of milk and a sandwich

Crisps or biscuits

Lunch

Soup

Large portion of meat, fish, egg or cheese

Vegetables

Potatoes with butter or margarine

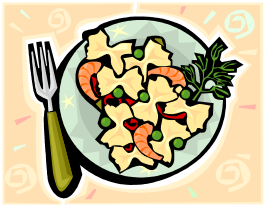
Dessert

Cheese and biscuits

Mid-afternoon

Snack with drink e.g. scone and tea

Fruit juice with toast or a sandwich



Dinner

As lunch, or sandwich with fillings such as meat, fish cheese or egg

Dessert or yoghurt

Bedtime

Hot chocolate or Horlicks made with milk

Biscuit, cake, toast or cereal

Appendix 11: EuroQol Questionnaire

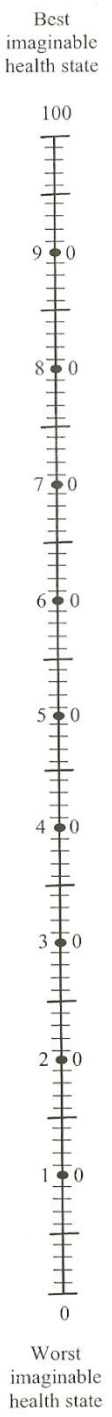
Mobility		
I have no problems in walking about	❑	1
I have some problems in walking about	❑	2
I am confined to bed	❑	3
Self-Care		
I have no problems with self-care	❑	1
I have some problems washing or dressing myself	❑	2
I am unable to wash or dress myself	❑	3
Usual Activities (e.g. work, study, housework, family or leisure activities)		
I have no problems with performing by usual activities	❑	1
I have some problems with performing my usual activities	❑	2
I am unable to perform my usual activities	❑	3
Pain/Discomfort		
I have no pain or discomfort	❑	1
I have moderate pain or discomfort	❑	2
I have extreme pain or discomfort	❑	3
Anxiety/Depression		
I am not anxious or depressed	❑	1
I am moderately anxious or depressed	❑	2
I am extremely anxious or depressed	❑	3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

Designated score

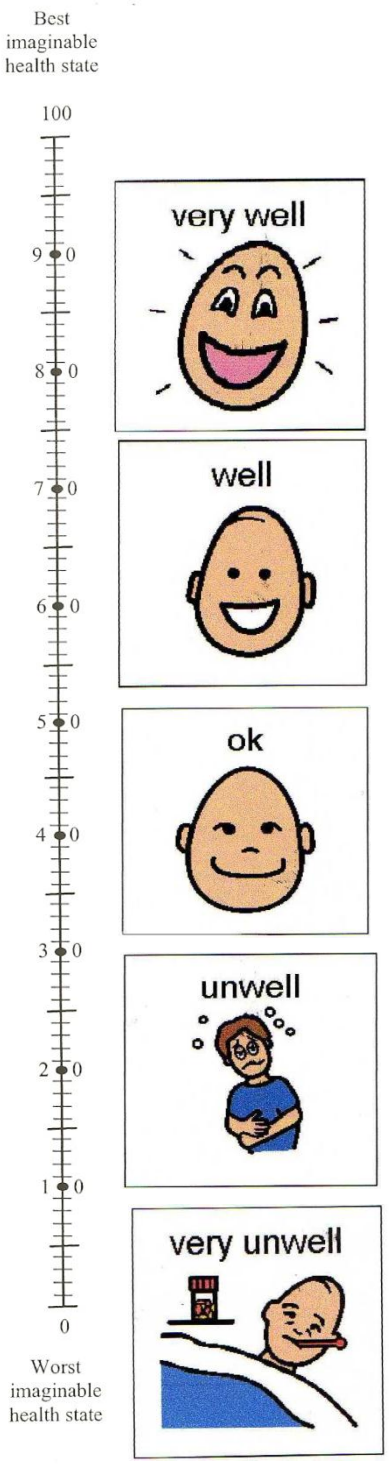


Appendix 12: EuroQol Visual Analogue Scale Aid

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



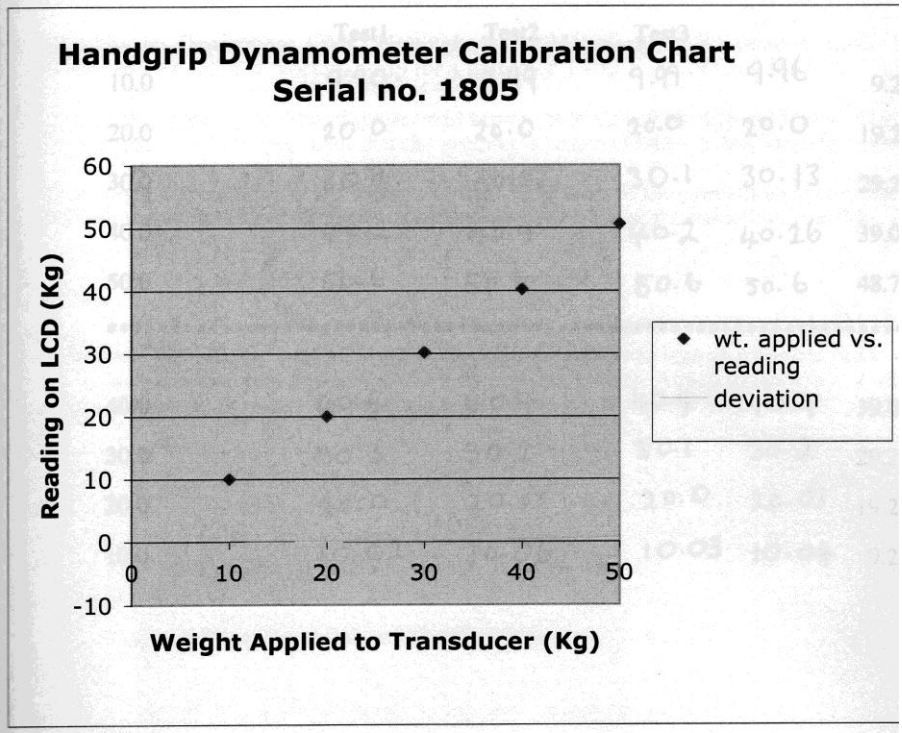
Appendix 13: Barthel's index of activities of daily living

The highest score, 20, indicates that the patient is fully independent in physical function; the lowest score, 0, represents a totally dependent, bedridden state.

		Score
1. Bowel status	0 points – Incontinent (or need to be given enema) 1 point – Occasional accident (once a week) 2 points – Fully Continent	
2. Bladder status	0 points – Incontinent or catherized and unable to manage 1 point – Occasional accident (Max one per 24 hours) 2 points – Fully Continent	
3. Grooming	0 points – Need help with person care: face/hair/teeth/shaving 1 point – Independent (implements provided)	
4. Toilet Use	0 points – Dependent 1 point – Needs some help but can do something alone 2 points – Independent (on and off / wiping / dressing)	
5. Feeding	0 points – Unable 1 point – Needs help in cutting / spreading butter etc) 2 points – Independent (food provided within reach)	
6. Transfer	0 points – Unable (as no sitting balance) 1 point – Major help (physical one or two people) 2 points – Can sit minor help (verbal or physical) 3 points – Independent	
7. Mobility	0 points – Immobile 1 point – Wheelchair – independent (including corners etc) 2 points – Walks with help of one person (verbal or physical) 3 points – Independent	
8. Dressing	0 points – Dependent 1 point – Needs help but can do about half unaided 2 points – Independent (including button / zips / laces / etc)	
9. Stairs	0 points – Dependent 1 point – Needs help but can do about half unaided 2 points – Independent (including button / zips / laces / etc)	
10. Bathing	0 points – Dependent 1 point – Independent bathing or showering	

Appendix 14: Calibration results for the Hand Grip Dynamometer

Weight Applied (kg)	Reading on LCD(kg)	Deviation (kg)
10	9.96	-0.04
20	20	0
30	30.13	0.13
40	40.26	0.26
50	50.6	0.6



Medical Physics Department
Queen's Medical Centre
Nottingham NG7 2UH

WORK INSTRUCTION W26

Handgrip Dynamometer Test and Calibration Procedure

4.2 System Calibration Chart

Instrument Serial no. 1805 Transducer Serial no. 1805

Start Temperature 23°c End Temperature Limits (20C to 25C)

Before Adjustment :

Applied Force (kg)	Instrument Reading			Average	Limits
	Test1	Test2	Test3		
10.0	9.90	9.99	9.99	9.96	9.2-10.8
20.0	20.0	20.0	20.0	20.0	19.2-20.8
30.0	30.1	30.2	30.1	30.13	29.2-30.8
40.0	40.2	40.4	40.2	40.26	39.0-41.0
50.0	50.6	50.6	50.6	50.6	48.7-51.3
**********					
40.0	40.4	40.4	40.4	40.4	39.0-41.0
30.0	30.3	30.2	30.1	30.2	29.2-30.8
20.0	20.0	20.1	20.0	20.03	19.2-20.8
10.0	10.02	10.06	10.03	10.04	9.2-10.8

Appendix 15: Food chart

Time	Food or drink consumed Indicate quantity: scoop, tablespoon, whole plate, bowl	Supplements or snacks consumed Indicate quantity: ¼, ½, ¾ all
Breakfast		
Mid-morning		
Lunch		
Mid-afternoon		
Evening meal		
During evening		
Bedtime		
NOTES		

The checklist below is used to ensure foods from the main groups are included:

- Bread / Cereals
- Fruit / Vegetables / Fruit Juice
- Meat / Fish
- Fats/ Oils
- Milk / Dairy
- Crisps & nuts
- Sweets & Chocolate
- Cakes & Biscuits
- Sugar
- Drinks
- Alcohol
- Vitamin Supplements
- Functional Foods

Appendix 16: Appetite Questionnaire

Please mark on the visual analogue scale (0-10) to indicate strength of appetite sensations.

Have you felt hungry today? **Yes ☐ No ☐**

How hungry do you feel?

Not at all hungry 0 ——————————— 10 As hungry as I have ever felt

Have you felt full today? **Yes ☐ No ☐**

How full do you feel?

Not at all full 0 ——————————— 10 As full as I have ever felt

Have you had a desire to eat today? **Yes ☐ No ☐**

How strong is your desire to eat?

Very weak 0 ——————————— Very strong 10

Appendix 17: Definitions of Adverse Events and Serious Adverse Events

An Adverse Event (AE) is any unfavourable unintended symptom or sign (objective or subjective), whether deemed study product related or not ('unintended' should be considered relative to the condition or the situation of the subject), that:

- occurs in the subject between first study product administration and study completion, and
- was not present prior to exposure to the study products or has worsened in intensity or frequency following administration of the study product.

A Serious Adverse Event (SAE) is an AE or untoward medical occurrence that at any dose:

- results in death or is life threatening;
- results in persistent or significant disability/ incapacity;
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- is a congenital anomaly/ birth defect.

The intensity of the AE must be scored:

1. Mild: awareness of sign, symptom or events, but easily tolerated;
2. Moderate: discomfort enough to cause interference with usual activity and may warrant intervention;
3. Severe: incapacitating with inability to do usual activities or significantly affects clinical status and warrants intervention.

The relationship of the AE to the study product must be assessed:
Not related; Probably not related; Possibly related; Probably related; Highly probably related.

The researcher is responsible for completing the adverse event form and the chief investigator will review all adverse event forms.