Nutrition in older adults: Factors influencing compliance to oral nutritional supplements and methods to improve compliance

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The candidate confirms that the work submitted is his/her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

'Nutrition screening of older adults living in care homes'

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ESA Norris applied for ethics, designed the study, collected the data, analysed the data and wrote the publication.

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MM Hetherington gave input to the ethics application, design of the study and edited the publication.

Assertion of moral rights:

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Abstract

Risk of malnutrition is prevalent in care home residents. Prescription of oral nutritional supplements is common practice in nutritional management of these residents; yet compliance rates in care homes are low. In the present studies risk of malnutrition was assessed, reasons for poor compliance investigated and an intervention developed to improve compliance in older adult care home residents. It was clear that nursing care residents were significantly more vulnerable to malnutrition risk than residential care; those with the lowest BMI experienced the greatest weight loss; and despite notification to carers, risk remained stable. Improvements in energy intake by enhancing meals with additional energy through food fortification or providing supplementation in covert versus overt presentation were assessed. There was no benefit of covert presentation relative to overt but food fortification and supplementation increased the energy density and nutrient quality of the meals consumed. ONS benefits depend on high compliance; carers acknowledged residents' need for additional support; residents wanted to exert control over the flavour and type of supplement given; and residents' knowledge about why they take ONS was identified as an important factor for compliance. These findings shaped the development of an intervention in which choice and variety were compared against motivation and education. In comparison with baseline, both arms of the intervention significantly improved compliance (from 60% to 93%). This indicates that personal choice which can enhance perceived efficacy and autonomy; motivation (through implementation intention and reward); and education (through information about the benefits of supplementation) can improve compliance. Therefore, compliance to ONS depends on three major components; the attributes of the resident taking the supplement; the support and education of the residents' carer; and the sensory properties of the products prescribed. The research confirmed the importance of the care environment in identification and action upon malnutrition risk, and that for the beneficial effects of ONS to be achieved, compliance must be enhanced through personal choice, variety, motivation and education.

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Abbreviations

ADL	Activities of daily living
BAPEN	British Association for Parenteral and Enteral Nutrition
BMI	Body mass index
BMR	Basal metabolic rate
BPSD	Biological and psychological symptoms of dementia
CCK	Cholecystokinin
COPD	Chronic obstructive pulmonary disease
DOH	Department of Health
EAR	Estimated average requirement
ED	Energy density
ESPEN	European Society for Clinical Nutrition and Metabolism
FFA	Free fatty acids
GI	Gastrointestinal
GP	General Practioner
HCP	Health care professional
HRQOL	Health related quality of life
LOS	Length of stay
LTC	Long term care
MUAC	Mid upper arm circumference
NHS	National health service
NICE	National Institute of Clinical Excellence
NPY	Neuropeptide Y
ONS	Oral nutritional supplements
PEM	Protein energy malnutrition
PTM	Protective theory model
QOL	Quality of life
RCT	Randomised control trial

RDA	Recommended daily allowance
SEM	Standard error of the mean
SD	Standard deviation
USDA	United States Department of Agriculture
VAS	Visual analogue scale

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Chapter 1: Introduction

"As for old age, embrace and love it. It abounds with pleasure if you know how to use it. The gradually declining years are among the sweetest in a man's life, and I maintain that, even when they have reached the extreme limit, they have their pleasure still"

(M A Seneca, Roman Philosopher)

1.1 Definitions of older people

The definition of old age is socially constructed with different interpretations. Numerous definitions exist for the classification, but in the case of this thesis, old age (older adults) refers to those who are ≥65 years. The characterisations of older people according to the Department of Health National Service Framework for Older People (2001) are described in table 1.1 below:

Table 1.1 Definitions of old age as accepted by the department of Health (2001)

Phase	Definition	Health and social care policy
Entering old age	Completed carer/child rearing. Can include people as young as 50 or official retirement age (60 for women and 65 for men). Active and independent.	Promote and extend healthy active life. Compress morbidity.
Transitional phase	Transition between healthy, active life and frailty. Often occurs between 70 and 80 years (can occur at any stage).	Identify emerging problems. Ensure effective responses to prevent problems. Reduce long term dependency.
Frail older people	Vulnerable due to health problems e.g. stroke, dementia, social care needs. Often seen in later stage life.	Anticipate and respond to problems, recognise interactions of physical, mental and social factors which affect independency and QOL.

1.2 The ageing population

Although we are living longer, we are not necessarily living in better health. The UK is experiencing a gradual increase in population age; the fastest growing age group being the oldest old (≥85 years). The Office for National Statistics (2011) projects that there will be more than a 50% increase in the number people living to this age group by 2035 (figure 1.1). This dramatic change in demographics impacts greatly on the health care systems causing a substantial economic cost (MacIntosh, Morley and Chapman, 2000) (figure 1.2).

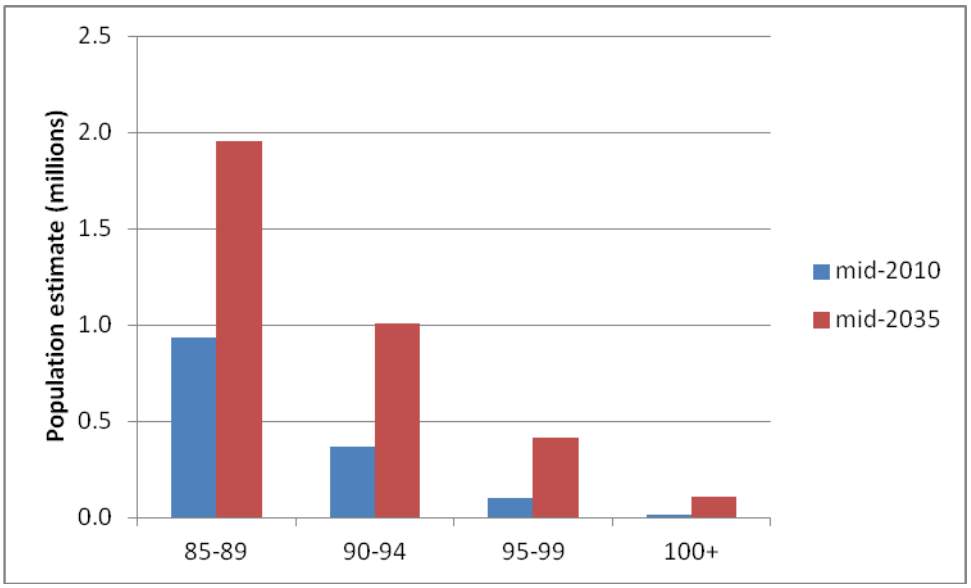


Figure 1.1 UK population estimates for ≥85 year olds in 2010 and 2035. Adapted from Office of National Statistics, 2011.

Health in the western society has improved resulting in this increase in the population of older adults, however reported personal health and satisfaction has declined. The discrepancies in objective and subjective status of health are likely due to the advances in medical care over the past 50 years (Barsky, 1988).The prevalence of disease and disability have increased with the increase in life expectancy; the majority of older adults are diagnosed with a chronic illness or disability in the later stages of life, living longer through the advances to 'modern medicine' but not living in better health (Crimmins, 2004). This is reflected in health-related quality of life questionnaires; with the advances in life extension, older adults are surviving but with discomfort and disability (Amarantos, Martinez and Dwyer, 2001). The concept of health is therefore

termed ‘multidimensional’ in which trends in mortality do not necessarily represent quality of health (Crimmins, 2004).

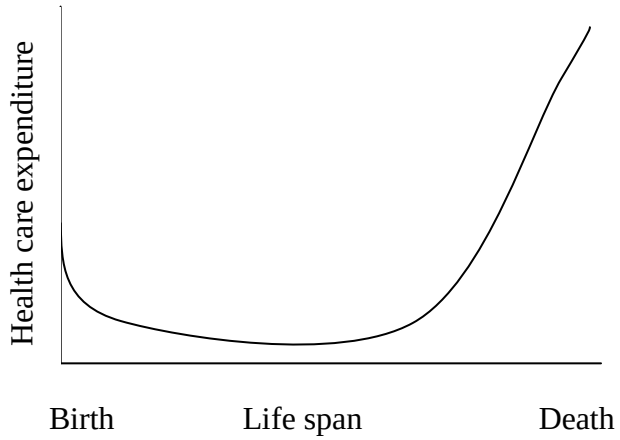


Figure 1.2 Health care expenditure in western society (adapted from Lynn and Adamson, 2003)

1.3 Nutritional changes and ageing

The nutritional requirements of an older person are different from those of younger adults. Energy requirements decrease, and the digestion, absorption, metabolism and excretion of nutrients change with advancing age. The observed reduction in food intake in this age group must therefore be associated with an adequate intake of other nutrients in order to maintain health; food eaten should be energy dense to allow for the smaller (more preferred) portion size. During periods of illness malabsorption, alterations in metabolism, excessive losses, and an increase in energy expenditure can occur. This increases a person’s requirements of energy and other nutrients, and must be recognised in order to prevent weight loss and to ensure efficient recovery (British Nutrition Foundation, 2004).

1.4 Anorexia of ageing

The ‘anorexia of ageing’ was first described by Morley and Silver (1988) as the patho-physiological decline in food intake and appetite associated with the ageing process. Poor nutritional status due to a decline in energy intake has been implicated in the development and progression of a number of diseases commonly associated with old age including osteoporosis, cancer, diabetes and cardiovascular diseases. An

understanding of the mechanisms contributing to the anorexia of ageing may help in the development of nutritional strategies aiming to improve quality of life for older adults (MacIntosh, Morley and Chapman, 2000). In today's Western societies, where obesity is a major issue, the decline in body weight may seem as desirable; as age increases, the mean body weight of older individuals has been shown to remain within or decrease into the recommended weight range (Steen, 1988). However, as documented by the prospective Cardiovascular Health Study (Newman *et al.*, 2001) weight loss by older adults can have adverse outcomes. Of the 4714 home-dwelling older adults (>65 years) with no diagnosis of cancer, approximately 17% lost ≥5% of their initial body weight in the 3 years post study entry. Those that lost weight showed a significant increase in total and risk-adjusted mortality over the following 4 years when compared to those at a stable weight. The increase in mortality rates in the weight loss group occurred whether or not weight loss was intentional and regardless of the individuals starting weight. It was concluded that even a modest decline in weight can act as an independent marker for mortality risk in older adults. There was no increase in mortality rates of those who gained weight over the 3 years.

Nutrition status of older adults is therefore a controversial issue, giving rise to the 'obesity paradox'; while obesity in the general population is associated with an increased risk of mortality, this is not necessarily the case for the older population where obesity may have a protective effect. Possible beneficial effects contributing to the association between obesity and improved survival in older adults include; the prevention and delay of cognitive decline, protection from loss of bone mineral density and osteoporosis, a reduction in oxidative stress and inflammation, and energy reserves preventing malnutrition (Oreopoulos et al., 2009). Although a high BMI is related to increased risk of cardiovascular morbidity and physical disability, it does not increase the risk of mortality in older adults. For obese older adults it is more important to focus on the prevention of functional decline and muscle loss by encouraging physical activity including resistance training than to focus of weight reduction through nutritional changes (Oreopoulos et al., 2009).

Weight change in older adults is variable but lean individuals appear to be at a greater risk of losing weight (Rumpel, Harris and Madans, 1993). Weight loss in this older population is disproportionately of lean body tissue (sarcopenia) which often causes

adverse effects and is associated with an increased risk of falls and protein-energy malnutrition (PEM) (Chapman, 2004). In turn, PEM , which is the result of an imbalance between nutritional intakes and the body's requirements (Raynaud-Simmons, Revel-Delhom, Hebuterne, 2011), has been known to cause impaired muscle function, decreased bone mass leading to osteoporosis, immune dysfunction, reduced cognitive function, delayed healing of wounds and recovery from surgery, and increased mortality. PEM is an independent predictor of mortality in older adults, and is not dependant of the social situation of the individual, whether they dwell in the community, in care homes or are hospital patients (Chapman, 2004).

In humans the age-related decline in energy intake was observed in the Baltimore longitudinal study (1990) in which 105 free-living males aged between 20 and 99 years took part in a 30 year follow-up. Over this time period, participants showed an average decline in energy intake of up to 25%. Similarly, the cross-sectional National Health and Nutrition Examination Survey (NHANES III) (1995) reported that, on average, there is a decrease in energy intake between the ages of 20 and 80 years of 1321 kcal/day in men and 629 kcal/day for women. There are some criticisms to be made over nutritional data collection in this study; data was collected from 24hour recall in which intakes often go under reported, particularly in women, overweight and weight conscious persons (Schoeller, 1990; Bingham, 1987). To address issues of underreporting, the ratio of energy intake to estimated basal metabolic rate (BMR) was calculated, despite this, the results still suggest some degree of underreporting. In comparison to the National Food Consumption data collected by the USDA (Wright and Hyattsville, 1992), NHANES III data showed higher nutritional intakes but this may be attributable to differences in the collection of data, interview environment, quality control procedures, nutrient calculations and survey response rates. Despite these differences, authors of NHANES III conclude that the data collected was more accurate to actual intakes through the use of the energy intake to BMR ratios. To further strengthen the results, it is suggested that food consumption data is collected alongside participants weights for more accurate data interpretation.

The reduction in resting metabolic rate and energy expenditure are physiologic processes associated with healthy ageing that cause a decrease in food intake and may predispose vulnerable individuals to detrimental anorectic effects; particularly for those

affected by psychological, physical or social changes that are commonly related to ageing (MacIntosh, Morley and Chapman, 2000). Although older adults are vulnerable to poor well-being, there are modifiable lifestyle factors that help to enhance successful ageing, for example, physical activity. Consistent with activity theory (Lemon, Begtson, Peterson 1972), a 6 year longitudinal study by Menec (2003) found that physical activity was positively related to happiness and reduced mortality. Functional decline was found to relate to low levels of participation in social and productive activities. Activity theory suggest that social activity provides opportunities for the maintenance of positive self-concept in addition to the physical benefits relating to better function an greater longevity (Lemon et al., 1972), whilst productive activities give the means for an individual to feel a sense of usefulness and competence (Herzog and House, 1991). Solidarity activities have also been shown to have potential benefits in ageing individuals in terms of enhanced psychological well-being, by providing a sense of engagement with life (Menec, 2003).

1.4.1 Causes of the anorexia of ageing

There is no one factor that is responsible for the anorexia of ageing, instead a number of factors (social, physical, and psychological) interact in the control of eating which are themselves influenced by the ageing process; it is these age related changes which in turn affect feeding behaviour and nutritional intake.

Social factors

Social isolation can result in a 30% decline in energy intake of meals eaten alone compared to eating in a group (de Castro and de Castro, 1989); over time this decline can cause marked increases in weight loss. Loss of social contact is particularly relevant in the older population because of bereavement and functional disabilities, contributing to low energy intake (Markson, 1997). It has also been shown that the frequency of social eating within a restaurant context is positively associated with body fatness; older adults suffering with social isolation, and possibly poverty, eat out less frequently (McCrory et al., 1999).

Social isolation, depression and functional disabilities can impact on an individual's ability to shop for food and cook; consequently, many older adults have low dietary variety which predicts a reduction in energy intake and body weight (Hays and Roberts,

2006). The examination of the association between low dietary variety, low BMI and inadequate nutrient intakes was conducted by Roberts et al. (2005) on a cohort of community-dwelling older adults. Although results showed that older adults (≥61 years) consumed a greater total variety of foods compared to younger adults (21-60 years), older adults with a low BMI of <22kg/m^2 consumed a lower variety of energy dense foods compared with older adults with higher BMI's (>22kg/m^2). These vulnerable adults are at particular nutritional risk due to the consumption of a low variety of micronutrient-dense foods. Only 65.4% consumed the RDA for protein, and none met the EAR for all 14 micronutrients.

Physical factors

Age-associated physiological dysregulation impacts on nutritional intake in the older adult population (figure 1.3; Hays and Roberts, 2006). The normal response in energy expenditure as a result of periods of overfeeding and underfeeding is reduced, and subsequent regulation of food intake is impaired in older individuals compared to younger individuals. Young men exhibit adaptations to increase resting metabolic rate after a period of overfeeding, and decrease after underfeeding; these adaptations are not observed in older men (Saltzman and Roberts, 1996). Although during periods of over- and under-feeding weight change in both young and older adults is similar, after overfeeding young men tend to lose all excess weight, whereas older men only lose 29% of excess weight. After underfeeding, young men regain all lost weight, while older men gain 64% of the lost weight (Roberts et al., 1994). Furthermore, following underfeeding, young men significantly increased their energy intake while older men did not significantly increase their energy intake, which actually remained lower relative to their previous weight maintenance requirement (Roberts et al., 1994). Even after a period of 6 months in which subjects were allowed to consume food freely, the older male group did not fully regain weight loss after a period of underfeeding (Moriguti et al., 2000). This lack of regulation has also been observed in older males offered a yogurt pre-load; older males have an inability to compensate in terms of the energy intake of the subsequent meal (Rolls, Dimeo and Shide, 1995). These results suggest that older men have a substantial reduction in their ability to maintain energy balance after periods of nutritional disruption compared to younger men. It can be concluded therefore, that ageing is associated with an impaired ability to accurately regulate food intake, and it

could be suggested that long-term persistent weight change can impact on body weight especially when combined with social, medical and psychological changes related to ageing (Hays and Roberts, 2006).

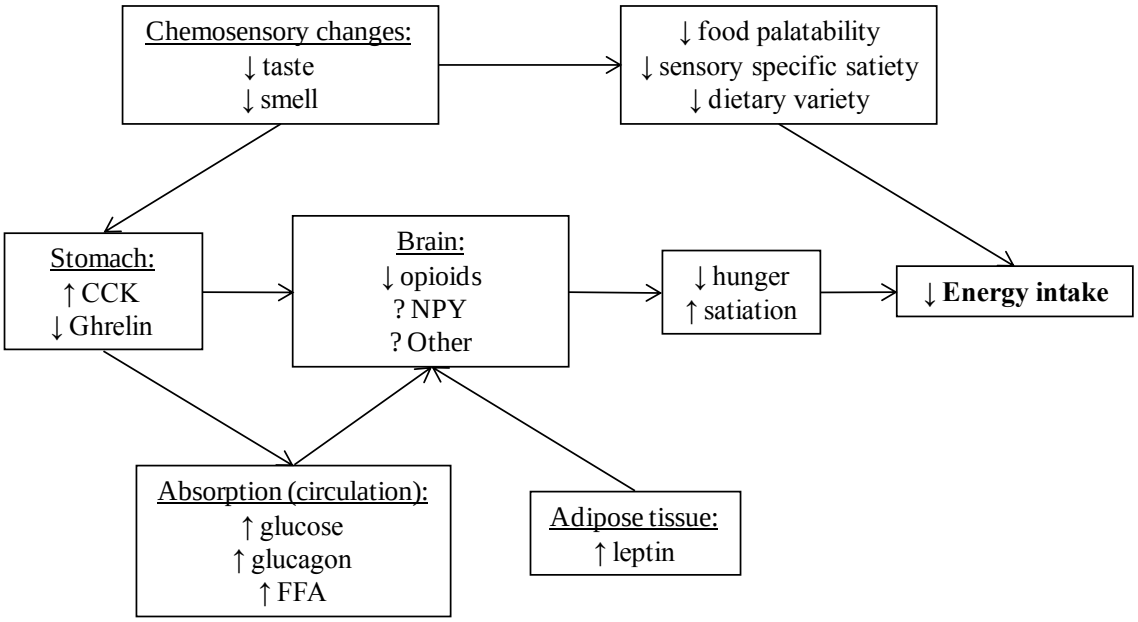


Figure 1.3 Biological changes contributing to the anorexia of ageing. Adapted from Hays and Roberts (2006).

Chemosensory changes (decrease in sense of taste and smell) may also account in part to the anorexia of ageing. Rolls and McDermott (1991) reported that older adults show a reduction in 'sensory specific satiety'; this is the term used to describe the decrease in pleasantness of a food as it is consumed. When younger adults are offered a yogurt snack, they report a subsequent decrease in the pleasantness of yogurt but not for other foods offered. This is not the case for older adults who equally rate their desire to eat the yogurt offered for a second time after having eaten the yogurt snack (Rolls and McDermott, 1991). The reduction in sensory specific satiety with ageing is potentially the consequence of a decline in sensory acuity for taste and smell (Weiffenbach, Baum, Burghauser, 1982; Schiffman, 1997; Hetherington, 1998; Ship, 1999).

Most previous research has been conducted on healthy older adult volunteers. Yet they exhibit less pronounced age-related decrements in function compared to older adults suffering from health problems; it is these individuals that are at higher risk of malnutrition (Hays and Roberts, 2006). A descriptive study of the prevalence of malnutrition in older adult care homes showed a significantly higher risk of malnutrition

in residential care (old age, failing in no other category) than in nursing care (24 hour nursing care required) (Norris, Shelton and Hetherington, 2011; chapter 3). Therefore, results concerning age-associated changes in appetite expression may be an under-estimation of the true extent of energy dysregulation in some sub-groups of older adult populations (Hays and Roberts, 2006).

During ageing gastric emptying slows, an effect that is associated with increased fullness and reduced food intake (Chapman, 2004). Healthy older subjects report less hunger before meals and more fullness after meals than younger adults, and post-prandial hunger has been inversely related to the rate of gastric emptying (Clarkson *et al.*, 1997).

Psychological factors

In addition to changes to biological systems, there are numerous psychological changes associated with weight loss in older adults including depression, bereavement, alcoholism, dementia/cognitive decline, fatigue, and late-life paranoia/mania (Hays and Roberts, 2006).

In young adults, the association between depression and weight change is variable. Atypical depression is linked with weight gain and melancholic depression with weight loss. Longitudinal studies have shown that obesity predicts depression (Roberts et al., 2003), that depression predicts obesity (Kivimaki et al., 2009), while in some cases no association between the two variables have been found (Patten et al., 2009; Gariepy et al., 2010). Depression is one of the most common diagnoses among older adults, and most commonly leads to involuntary weight loss in this group (Hays and Roberts, 2006), with approximately 90% of sufferers subject to weight loss (Morley, 1997). Kaplan and Tuchman (1986) theorised that "depression leads to a decrease in positive symbolism leading to a decrease in the enjoyment of pleasurable events such as eating" (cited in Morely, 1997, pg. 766). In older adults, refusal to eat may be seen as a suicidal gesture (Morley, 1997). In nursing home patients, psychiatric disorders such as depression account for 58% of involuntary weight loss cases (Huffman, 2002). In a cohort study of 1794 adults, Dipietro et al., (1992) found that depression was associated with weight loss in the over 55s and weight gain in the under 55's.

Dementia and Alzheimer's disease are both linked to weight loss. Weight loss has been found to precede dementia in a 20 year follow-up of community dwelling men and women before diagnosis as cognitively intact or demented. Those diagnosed as demented had a significantly lower weight from baseline, whereas there was no significant difference in weight in the cognitively intact participants. These results could not be explained by lifestyle, depression or other illness, and it was concluded that weight loss occurs prior to dementia not as a consequence of dementia. Specific mechanistic explanations are not offered by authors (Barrett-Conner et al., 1996). More recently, Knopman et al. (2007) found that weight loss preceded dementia diagnosis in women, although this was not the case in men. There was a linear trend of increased risk of dementia with decreasing weight over 10 years. The authors suggest that apathy, loss of initiative, loss of appetite and a decline in olfactory function predate dementia. On the other hand, in Alzheimer's disease, behavioural and psychological symptoms of dementia (BPSD) appear to be the most striking feature contributing to weight loss and malnutrition (along with other risk factors including acute disease, hospitalisation and changes in living environments) after diagnosis (Guerin et al., 2009). These findings support a French prospective study confirming a relationship between poor nutritional scores and poor Neuro Psychiatric Inventory scores (indicating the presence of psychopathology in patients with Alzheimer's disease and dementia) (Guerin et al., 2005). It is proposed that psychotic BPSD may cause malnutrition through two distinct mechanisms; the opposition to feeding frequently observed in advanced stage Alzheimer's leading to inadequate nutritional intakes, and agitation which is a common feature of Alzheimer's inducing an increase in energy expenditure and therefore increased energy demand (Guerin et al., 2009). The results of these studies assessing weight loss in dementia suggest that weight loss precedes diagnosis of dementia and continues throughout life with dementia.

Social changes have the potential to cause weight loss directly or indirectly with the potential to exacerbate existing physiological effects with ageing. Psychological and social changes may make an individual vulnerable to long-term weight loss as a function of altered metabolic signalling (Hays and Roberts, 2006).

1.5 Malnutrition

Definition

Malnutrition results from the depletion of body cell mass caused by a reduction in food intake or poor assimilation of energy and/or protein (Jensen et al., 2010). There is no agreed definition of malnutrition that exists in the literature leading to widespread confusion in the understanding of this term (Jensen et al., 2010). This can often lead to malnutrition going unrecognised and therefore left untreated.

Table 1.2 Aetiology-based terminology for malnutrition-status diagnosis in adults in the clinical practice (adapted from Jensen et al., 2010).

Disease State	Examples
Starvation-related malnutrition: *Pure chronic starvation without inflammation.*	Medical conditions e.g. anorexia nervosa.
Chronic disease-related malnutrition: *Chronic diseases or conditions that impose sustained inflammation (mild or moderate).*	Organ failure, pancreatic cancer, rheumatoid arthritis or sarcopenic obesity.
Acute disease or injury-related malnutrition: *Acute disease or injury states with marked inflammatory response.*	Major infection, burns, trauma or closed head injury.

In 2010, an International Guideline Consensus Committee proposed an aetiology-based definition for diagnosis of adult starvation and disease-related malnutrition (table 1.2) (Jensen et al., 2010). If there is no indication of inflammation, the loss of fat and fat-free mass is purely related to starvation caused by protein-energy deficiency (Yaxley and Miller, 2011), and can be treated even in advanced stages with nutritional intervention such as food fortification, encouragement to snack and ONS prescriptions. In the case that inflammation is present, and persists or is severe enough to cause a decrease in lean body mass (cachexia) affecting functional status, the diagnosis is considered to be ‘disease-related malnutrition’ (Zoico and Roubenoff, 2002). Disease-related malnutrition is partly caused by a decline in nutrient intake but is also linked to the

effect of the inflammatory response on metabolism. If inflammation is severe ('acute disease-related malnutrition'), nutritional support (enteral or parenteral nutrition) is primarily to aid vital organ system functions and to preserve immune responses while the underlying cause can be treated through medical therapy (Jensen et al., 2009). Nutritional interventions for the promotion of nutrient intake are therefore an integral part of malnutrition treatment. This is also the case for 'chronic disease-related malnutrition' in which inflammation is mild to moderate (Jensen et al., 2010).

1.5.1 Consequences of malnutrition

As a consequence of a number of conditions associated with low body weight and weight loss such as impaired immune function, delayed wound healing, poor recovery from illness and decreased functional status, malnutrition increases the risk of morbidity particularly for older adults. Due to high morbidity rates, malnourished patients have significantly longer hospital stays and time taken to treat underlying conditions is increased (Norman et al., 2008).

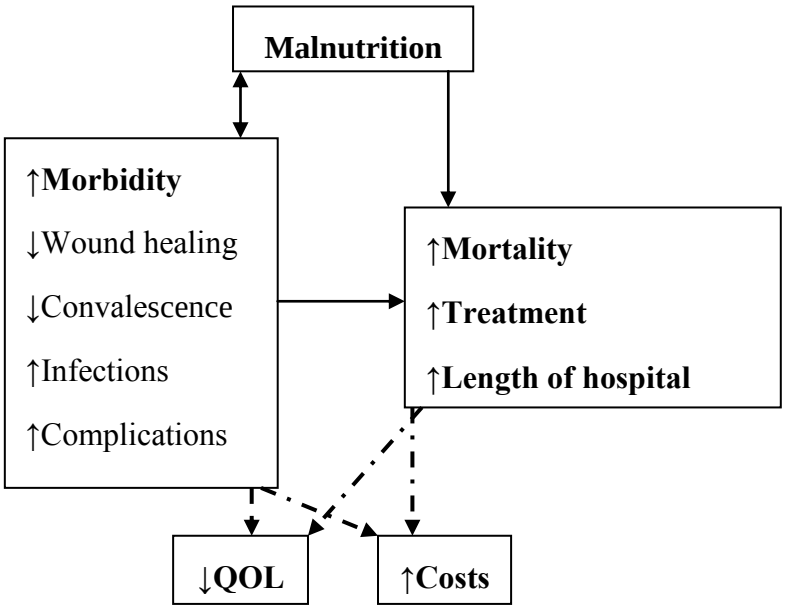


Figure 1.4 The prognostic impact of malnutrition. Adapted from Norman et al., 2008. *Note: QOL 'quality of life'*

There is also a close relationship between malnutrition and mortality in both acute and chronic illness. In older adult hospital patients, a low BMI of <20 kg/m^2 has been found to be an independent predictor of poor survival (Landi et al., 2000). The prognostic impact of malnutrition is described in figure 1.4 (Norman et al., 2008).

1.6 Evaluation of different screening tools

Malnutrition can be diagnosed through screening and/or assessment programmes which not only diagnose malnutrition (or risk of malnutrition) but incorporate a management strategy and follow-up into the treatment/care plan (figure 1.5) (Elia, Zellipour and Stratton, 2005).

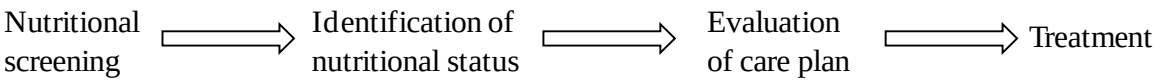


Figure 1.5 The malnutrition care pathway.

Prevalence of malnutrition in UK health care settings is known to be high, and the causes are various; to try to prevent malnutrition, the nutritional status of service users is screened and assessed routinely by HCPs and/or carers so that the appropriate action can be taken (Green and Watson, 2005).

A number of nutritional screening tools exist but no gold standard has yet been established. Typically screening tools are questionnaire based and examine known risk factors of malnutrition. A review by Green and Watson identified 71 published screening tools used for the detection of malnutrition (21 were specifically designated for use with older adults), findings show that screening tools employ a wide variety of nutritional risk factors from simple anthropometric measures to more complex aspects of eating behaviour. Although many are currently in use in clinical practice (table 1.4.2), not all have been subjected to validity, reliability and acceptability testing, and have not been evaluated for ease of use in the setting they are designed for.

1.6.1 Screening recommendations

The recommendations for screening across all types of care settings are highlighted in table 1.3. Specifically in care homes, both the Department of Health (2004) and ESPEN (2003) recommend that screening takes place on admission so that appropriate actions can be documented in the care plan. Screening is then repeated routinely e.g. monthly if there is little or no concern of malnutrition risk (Elia, Zellipour and Stratton, 2005). In addition to the recommendations, an ideal screening tool can be; (1) used in all health care settings preventing confusion (e.g. between hospitals and care homes) and ensuring continuity of actions set out in an individual's care plan, (2) used to detect both under-

and over-nutrition, (3) used to assess nutritional status in all types of patients regardless of disease states or frailty, and (4) flexible in terms of a care plan which can be tailored to the local care policy (Elia, Zellipour and Stratton, 2005).

Table 1.3 Screening recommendations for ALL care settings (adapted from Elia, Zellipour and Stratton, 2005).

Recommendation	Action
Screening test linked to care plan.	Ensure adequate infrastructure for implementing care plan.
Nutritional screening policy.	Results for individuals communicated between different care settings.
Use of a validated, reliable and practical tool.	Ensure it is quick, easy and acceptable to patients and health care workers.
Consideration of current, past and (likely) future weight changes.	Link weight changes to nutritional intake, appetite and disease severity.

These recommendations are in agreement with NICE (2006) guidelines on nutritional screening; however, NICE guidelines expand to give more specific details regarding the measurement of nutritional status, assessing patients to gain information about; intake history and normal food consumption, changes in intake, unintentional weight loss, eating difficulties, specific nutrient requirements, ability to metabolise nutrients, excessive nutrient losses, global assessments (physical measures). More details of the NICE guidance of nutritional status in adults can be found in NICE (2006).

1.6.2 Examples of nutritional screening tools

Table 1.4 Examples of commonly used nutritional screening tools used for older adults in a variety of settings

Screening tool	Author (year)	Population	Categories tested	Risk classification	Validity/reliability	Recommendations
Mini nutritional assessment (MNA)	Guigoz, Vellas, Garry (1996).	Older adults; outpatient clinics, hospitals, nursing homes.	18 items; 4x anthropometric, 6 x general assessment, 6 x dietary assessment, 2x self assessment.	Well nourished, borderline (at risk), malnourished.	Validity and reliability tested.	None stated.
Nursing nutrition screening assessment	Pattison *et al.* (1999)	Older adult hospitalised patients.	Medical and mental condition, weight, dietary intake, ability to eat.	Minimal risk, moderate risk, high risk.	Evidence of validity testing, not reliability.	Simple recommendations identified.
Malnutrition universal screening tool (MUST)	Elia (2003)	Adults; hospital, outpatient clinics, general practice, community, care homes.	5 steps; BMI, unplanned weight loss, acute disease effect, risk of malnutrition, management guidelines.	Low risk, medium risk, high risk.	Validity and reliability tested.	Recommendations for each category, management guidelines.
Seniors in the	Keller, Goy,	Community	14 items; weight	Low risk, high	Validity and	None stated.

community: risk evaluation for eating and nutrition (SCREEN II)	Kane (2005)	dwelling older adults.	change (planned/unplanned), appetite, factors affecting food intake.	risk.	reliability tested.	
Geriatric nutritional risk index (GNRI)	Bouillanne *et al.* (2005)	Older adult hospitalised patients.	Nutritional status; albumin, pre-albumin, BMI.	Death, alive with complications, alive without complications.	Validity and reliability tested.	None stated.
Simplified nutritional appetite questionnaire (SNAQ)	Wilson *et al.* (2005)	Older adults; LTC institutionalised, community dwelling.	4 items (derivative of 8-item CNAQ); appetite.	At risk of significant weight loss, not at risk.	Validity and reliability tested. Reliability comparable to CNAQ.	None stated.
Nutritional risk score (NRS)	Reilly et al., 1995	Hospital in-patients	Weight loss, BMI, appetite, ability to eat, stress factor	Risk category; low, moderate, high	Validated against 2 other assessment methods	None stated.

1.7 Treatment of malnutrition

According to the NICE (2006) guidelines, nutrition support should be considered and made available by HCP for people suffering from malnutrition or at risk of malnutrition. Nutrition support can be used to improve nutrition intake in those who can safely swallow, and can be stopped at the point when the patient has established an adequate oral intake from normal food. It is stated that HCPs should ensure oral nutrition support provides a balanced mixture of protein, energy, fibre, electrolytes, vitamins and minerals.

In most cases of malnutrition or risk of malnutrition, management and treatment can be successfully offered through a variety of oral dietary strategies such as food fortification, extra snacks, dietary counselling and ONS (NICE, 2006). The evidence for the use of nutritional interventions is examined in more detail in chapter 4.

1.8 Oral nutritional supplements (ONS)

There are a number of current practices available to improve nutritional intakes in malnourished older adults (table1.5). The success of nutritional strategies in the treatment of malnutrition depends both on the efficacy of the nutrients and compliance to the recommended intake or prescription (Nieuwenhuizen et al., 2010).

Table 1.5 Practices employed to improve nutritional intakes of older adults (Nieuwenhuizen et al., 2010).

Current practice	Effectiveness on energy and nutritional intake
Dietary advice	Lack of sufficient supporting clinical data.
Food first	Nutrient and energy intake often below recommended levels. Can results in elevated saturated fat intake.
Variety of diets	Evidence is insufficient but potential to stimulate energy intake and help to maintain nutritional balance.
Between meal snacks	Increase overall nutritional intake.
ONS	Significantly increases nutritional and energy intake and improves clinical outcomes.

ONS typically contain high amounts of energy and macronutrients; per 100ml there are approximately 150 kcal, consisting of 18.4g carbohydrate (49% of total energy), 6.0g protein (16% of total energy) and 5.8g fat (35% of total energy) and may also include vitamins, minerals and trace elements. They are available in a nutritionally complete form, containing the RDA of most micronutrients, and can be used to supplement a normal diet or as a sole source of nutrition in the case that the patient is unable to consume normal food (Stratton, 2000). They are suitable for older adults and patients with a variety of health and eating problems who are malnourished or at risk of malnutrition (Nieuwenhuizen et al., 2010). In clinical practice there are a variety of ONS product types in the form of milk and juice based drinks, bars, puddings and powders (to be mixed with with drinks) that are prescribed in both hospital and community settings (Stratton, 2000).

Table 1.6 ESPEN guidelines on enteral nutrition: geriatrics, summary of statements specific to ONS use. Adapted from Volkert et al. (2006).

Specific patient group	Treatment recommendations
Malnourished/at risk of malnutrition	ONS to increase energy, protein and micronutrient intake; maintain/improve nutritional status and improve survival.
Frail* older adults	ONS to maintain/improve nutritional status.
Post-hip fracture/orthopaedic surgery	ONS to reduce complications
Depression	Enteral nutrition (inc. ONS) to overcome phases of severe anorexia/lack of motivation to eat.
Demented patients	ONS may lead to improvements in nutritional status.
Early stage and moderate dementia	Consider ONS to ensure adequate energy and nutrient supply, and to prevent under-nutrition.
Pressure ulcers	High protein ONS reduces risk of development and improve healing of existing ulcers.

*Note *limited in ADL due to physical, mental, psychological and/or social impairments, as well as recurrent disease, multiple pathologies and limited independence.*

Like all treatment and prevention options, ONS must be prescribed appropriately in order to confer a beneficial effect. ESPEN guidelines on enteral nutrition, specially for use of ONS in older adults are summarised in table 1.6.

1.7.1 Effects of ONS

In both the hospital and community settings, compared to routine care, ONS have been shown to improve energy and nutrient intakes (figure 1.6), increase body weight and have beneficial effects on functional outcomes, and reduce mortality, complications and length of hospital stay (Stratton, Green and Elia, 2003).

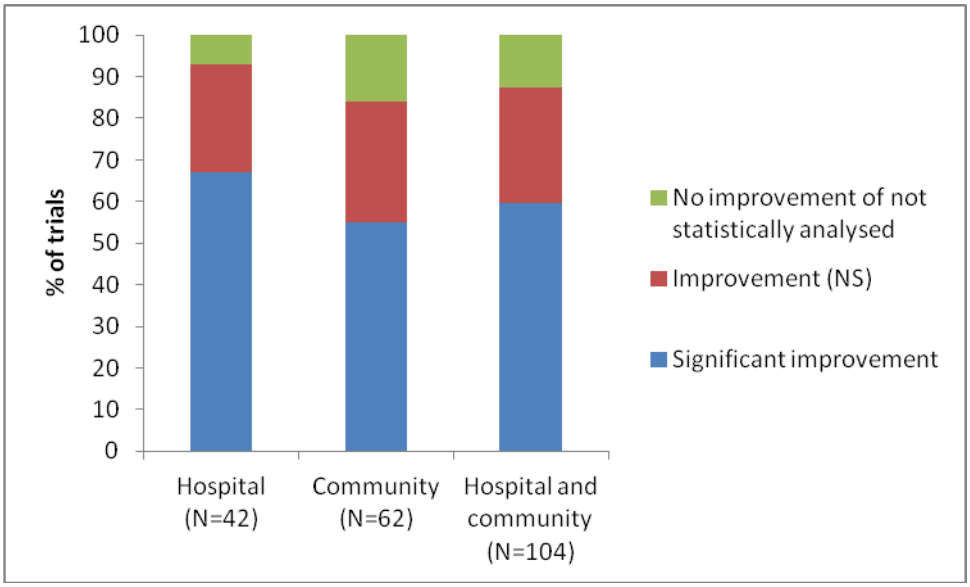


Figure 1.6 Summary of total energy intake from trials of ONS in hospitals, community and combination of settings (adapted from Stratton et al., 2003).

A meta analysis of 62 trials including 10,187 randomised participants concluded that ONS use results in small yet consistent weight gain in older adults finding that, for participants randomised to receive ONS, pooled % weight gain was 2.2% greater compared to control participants. Mortality rates were significantly reduced after ONS supplementation in already under-nourished participants (relative risk (RR) 0.79, 95% CI 0.64-0.97), and a reduction in risk of complications was observed in 24 trials, although it was concluded that this still needs to be confirmed in larger, multi-centre studies (Milne et al., 2009). In addition to this, a 3 month intervention comparing the use ONS with dietary counselling and dietary counselling alone in malnourished GI patients found that outcomes were improved in terms of functional status, QOL and

rehospitalisation in those receiving ONS. Patients were offered up to 3 200ml liquid ONS per day containing 150kcal and 10g protein per 100ml; on average patients consumed 2.5 ONS per day during the intervention period (Norman et al., 2008).

A Cochrane meta analysis by Baldwin and Weekes (2008) compared dietary advice alone and in combination with ONS. With combined nutritional intervention, weight change was significantly improved by 2.2kg (95% CI 1.16- 3.25), and an increase in MUAC, triceps skin fold thickness and handgrip strength was observed. The data used was sought irrespective of compliance to the interventions and so no conclusions can be drawn about the ideal level of compliance to achieve these beneficial results. The majority of the studies included had an intervention period of 3 months however there was no indication of the nature, intensity or content of the dietary intervention and so with this insufficient evidence the optimal length of a dietary intervention cannot be determined. Furthermore, whether the interventions used in the studies represent a realistic goal in clinical practice could be questioned; in reality, due to staffing levels, visits from the dietician to give dietary advice could be limited for both inpatients and outpatients, and the level of training and experience required of the dietician was not reported and so is unknown. For these reasons, it may be that ONS are more effective as a nutritional intervention, particularly in patients who are more independent and can manage their own prescriptions.

A comparison between ONS and isocaloric snacks assessed the effectiveness of the 2 nutritional interventions to increase energy and protein intakes in older adult, acutely ill anorexia patients. ONS was found to be the most effective method of supplying extra nutrition to patients by significantly increasing both energy and protein intakes in this group. The ONS group also had significantly greater intakes of total energy and protein from all food and ONS/snacks; mean difference of 314 kcal/day and 14.1g protein/day. Therefore, this study not only showed that ONS provide more energy and protein than isocaloric snacks; they also demonstrated a significant increase in total overall energy and protein intake throughout the day (Stratton, Bowyer and Elia, 2006).

The use of ONS in surgical patients has been widely researched; post-operatively, ONS has been shown to have a beneficial effect after GI surgery (Rana et al., 1992; Keele et al., 1997), orthopaedic surgery (Lawson et al., 2003), GI and vascular surgery in those who are already malnourished (Beattie et al., 2000), and surgery related to a femur

fracture (Delmi et al., 1990). Patients who have existing malnutrition prior to surgery and more likely to experience post-operative morbidity and mortality, and have longer hospital stays, increasing the cost of treatment and care (Dempsy, Mullen and Buzby, 1988; Giner et al., 1996). To reduce post-operative complications and costs, peri-operative nutritional support can be offered to improve clinical outcome of a patient; a RCT by Smedley et al (2002) found that, when ONS is initiated before hospital admission for GI tract surgery, weight loss was significantly lowered and incidence of minor complications are reduced post-operatively.

Stratton and Elia (1999a) conducted a systematic review of 84 trials to evaluate existing evidence on the effects of ONS in the community prescribed to diverse patient groups. Key findings suggest that ONS infer improvements in body weight and function, and total energy intake, and are associated with clinical and functional benefits that vary depending on the underlying chronic condition of the patient. The greatest difference in weight change between supplemented and un-supplemented groups was seen in those with COPD. The benefits of ONS appear more frequently in individuals with a BMI $<20kg/m^2$ (at risk of malnutrition) than those with a BMI $>20kg/m^2$.

A limitation highlighted by this systematic review related to the appropriate prescriptions of ONS to those who are vulnerable to malnutrition. However, there is a degree of difficulty in identifying small patient subgroups who are losing weight despite having a BMI $>20kg/m^2$ (Stratton, 2000). Weight loss in these individuals can still be detrimental, particularly if caused by an undiagnosed condition, and may easily go unrecognised leading to the progression of disease-related malnutrition.

1.7.2 Economic considerations for the use of ONS

The increasing number of people living into old age is putting an economic strain on healthcare services (figure 1.2) exacerbated by conditions such as malnutrition which can be treated. Nutrition strategies improve or maintain nutritional status and improve clinical outcomes (Russell, 2007). In support of clinical guidelines on nutritional interventions in adults, BAPEN prepared a health economic report based on the use of ONS in both hospitals and the community (Elia et al., 2006). It is important to note that, whereas standard cost evaluations are concerned with increasing efficiency by obtaining more benefits for the same cost or by establishing the same benefits by decreasing the

costs, health economics also includes an evaluation of quality of care, equity and fairness (Russell, 2007).

The estimated annual expenditure on managing medium/high risk disease-related malnutrition in 2003 was ~£7.3 billion (~€10.5 billion), over half of this (£5 billion) was spent on older adults (>65 years). The treatment of malnourished hospital patients was ~£3.8 billion, and £2.6 billion was spent on treating those in long-term care. It is likely that this figure is an underestimation of the true cost of malnutrition as it does not reflect the costs of home visits by health workers, GP or outpatient clinic visits or the costs of private healthcare. Due to this substantial cost, it is important to gauge cost: benefit ratio for the appropriate use of healthcare resources. These estimations, whilst important, do not reflect the costs and/or cost savings associated with nutritional therapy as a treatment for malnutrition (Russell, 2007). In the UK in 1992 it was estimated that there could be an annual saving of £266 million if 10% of hospital patients were to receive nutritional support primarily attributable to a reduction in length of hospital stay by 5 days (Lennard-Jones, 1992).

More recently, to assess the economic implications of ONS use in hospitals and the community, a cost analysis was undertaken using available data from published studies (Elia et al., 2005; appendix 1.1).

In the hospital setting, pooled results indicated that the use of ONS in patients at medium or high risk of malnutrition gave a mean net cost saving of £849 per patient based on bed-day costs and £298 per patient based on the cost of complications (Russell, 2007). There is still a lack of cost evaluation studies in the community, but analysis performed on the small number of existing studies does suggest that the use of ONS is cost effective; although it may be that the hospital sector derives this financial benefit due to the cost of interventions in the community (Russell, 2007). For the purpose of this thesis, estimated costs of nutritional interventions were calculated in chapters 4 and 6.

1.7.3 Compliance to ONS prescriptions

In order to gain both clinical and cost effective benefits from ONS prescriptions good compliance must be achieved. However, according to a recent systematic review by Hubbard et al. (2012), compliance can be as low as 37% (Gosney et al., 2003). From

this review, it appears that compliance is very varied across interventions and care settings (see chapter 6 for more details).

ONS are prescribed to individuals in terms of type, frequency and volume. In order for ONS to be effective in the treatment of malnutrition, the information given on the prescription must be adhered too. In many cases in hospitals and care homes, the individual prescribed ONS is not in control of their prescriptions; ONS are administered by nurses and care staff. It is therefore essential that the staff employed to do this take responsibility of the ONS prescriptions and administer ONS appropriately. This however is not always the case; a study by Simmons and Patel (2006) observing ONS use across 2 nursing care homes found that only 7% of participants received ONS consistent with their prescription with respect to the frequency of administration. It appears that there are a number of factors that can affect compliance to ONS; these factors are evaluated in a systematic review in section 1.9.

1.7.4 Implications for future research into ONS

It has been suggested that future research into the use of ONS should focus on:

- Comparisons of efficacy and effectiveness of different forms of nutritional based therapy for example, ONS, behavioural therapy, dietary counselling and combinations, to improve dietary intake, body weight and body function.
- Preferences of ONS in terms of type, palatability, size, timings and frequency of consumption that optimise short and long term effects on appetite, food intake, and positively affect clinically-relevant outcome measures such as nutritional status, physical function and psychological function (Stratton, 2000).

1.9 Systematic Review: Factors affecting compliance to oral nutritional supplements

1.9.1 Introduction

The ‘anorexia of ageing’ refers to the physiological decline in food intake observed in older adult populations, largely due to a decline in physical activity throughout the lifespan (Wilson and Morely, 2003). Poor nutritional intakes can lead to malnutrition resulting in pathological weight loss which is associated with the development of disease (Raynaud-Simon, 2009).

In 2007, 2008 and 2010, BAPEN carried out a UK (and Ireland in 2010) nutritional screening survey in hospitals, care homes and mental health units. On all 3 occasions, it was found that malnutrition affects >1 in 3 adults admitted to care homes (Russell and Elia, 2011). When malnutrition is identified ONS can be prescribed with the possibility of increasing or insuring adequate nutritional intake. Compared with routine care, ONS have been shown through a comprehensive review of systematic reviews to increase total energy and nutrient intakes, reduce mortality, lead to fewer complications and improve body function and weight (Stratton and Elia, 2007). A recent Cochrane review by Milne et al. (2009) concluded that ONS do produce a small yet consistent weight gain in older adults, and effectively reduce mortality in the already undernourished. Additional research is still required from large scale, multi-centre trials to confirm the beneficial effects of ONS on complications, functional status and hospital length of stay.

Despite the wide use of ONS in both the hospital and community settings, compliance towards the prescribed volumes of ONS is often unsatisfactory preventing both clinical and cost effectiveness (Elia and Russell, 2009). Past informal reviews of compliance to ONS have reported varied compliance rates; this variation could be due to the difference in study design, methods of measuring compliance, what is considered compliant, healthcare setting and participant group (Hubbard et al., 2012). This is also highlighted in a recent systematic review (Hubbard et al., 2012) of compliance across hospitals and community; community groups included out patients, community hospitals, rehabilitation hospitals, nursing care homes, residential care homes, GP surgeries, hospital discharge patients and free-living individuals. It was shown that the overall

compliance rate was satisfactory at 78%; however this rate ranged widely from 37-100%, suggesting that compliance could be dependent on the setting of ONS use (hospital compliance rate was 67%, community rate was 81%). Nine of the studies reviewed by Hubbard et al. (2012) were specifically conducted in care homes; the mean compliance rate between these studies was lower than the mean that encompasses all 'community' settings at 68.8% (54-91%).

There are many factors that could impact on the acceptance to ONS prescriptions; these could be either product or person specific. It is important that these reasons are identified and taken into consideration when prescribing ONS to older adults in order to increase compliance and to infer the relevant clinical and economical benefits. The aim of this systematic review was to identify and evaluate factors that affect compliance to ONS.

1.9.2 Method

Design: Studies relevant to the research aim were identified using electronic databases; The Cochrane Library and PubMed. The search terms used were: nutrition*, oral*, supplement*, older adult*, elderly*, compliance*, intake*. The reference sections of studies identified electronically were checked along with the reference section of the recently published review by Hubbard et al. (2012).

Eligible studies could be abstracts or full papers providing they met the pre-determined inclusion criteria. Only studies that report/identify barriers that affect compliance were included in the review.

Inclusion criteria: All study types; older adults (≥60 years); all disease states; all studies using multi-nutrient, high energy, high protein ONS (powder, liquid or readymade); nutritionally complete or incomplete ONS; ONS prescribed to supplement the diet or as sole source of nutrition; all study designs (intervention, RCT's, interviews, audits etc.); all studies that report factors affecting compliance to ONS.

Exclusion criteria: Participants <60 years; low energy, low protein ONS; micronutrient only ONS; parenteral nutrition; tube feeding; no mention of factors affecting compliance.

1.9.3 Results

Table 1.7 presents the studies identified and included in the systematic review; a summary of theses reviewed papers is presented, including compliance rates identified by the studies and the suggested barriers that may affect compliance to ONS.

1.9.4 Summary of main findings

Overall, 25 research papers were identified according to the inclusion and exclusion criteria. All these papers reported/identified factors that could affect compliance to ONS. Of these papers, 23 reported actual compliance rate, however the criteria for measuring compliance and for deciding what is considered compliant varies between studies. Reported compliance in these papers ranged from 20.9% to 95%.

The main identified factors that affect compliance to ONS are; the dependency on staff (Carver and Dobson, 1995; Ross 1999; Vlaming et al., 2001; Wouters-Wesseling et al., 2002; McCormick et al., 2007), the timings in which ONS are administered (Delmi et al., 1990; Keele et al., 1997; Wouters-Wessling et al., 2002; Lad et al., 2005, McCormick et al., 2007), and a dislike to flavour and other sensory properties of ONS (Ross, 1999; Bruce et al., 2003, Wouters-Wessling et al., 2003; the FOOD trial, 2005; Lad et al., 2005). Other identified factors affecting compliance included; monotony of supplements (Lad et al., 2005; Gray-Donald et al., 1995; Lauque et al., 2000; Krondl et al., 1997); medical issues/condition of the patient (Potter et al., 2001; Roberts et al., 2003, the FOOD trial, 2005); motivation and encouragement towards taking ONS (Larssin et al., 1990; McWhirter et al., 1996; Wouters-Wessling et al., 2002; Payette et al., 2002; Lauque et al., 2000); lack of knowledge about benefits of ONS and reasons for prescriptions (Miller et al., 2005; Gazzotti et al., 2003); and inappropriate prescriptions of ONS (Gosney, 2003).

Table 1.7 Summary of findings from reviewed papers

Authors	Participants (N, mean age)	Setting	Intervention	Compliance	Comments
Bruce *et al.*, 2003	N=109	Female hip fracture, hospital.	28 days. 235ml ONS/day (352kcals) vs. control.	Mean no. of cans consumed was 20.6, 74% compliance.	N=8 consumed <10 cans due to dislike for taste. Limited effectiveness despite strategies to ↑ compliance.
Carver & Dobson, 1995	N=46. Male: 69 years. Female: 80 years.	Senile dementia, hospital.	12 weeks. 2x200ml/day vs. control.	95% consumed all ONS offered. 5% consumed ~85% ONS offered.	N=2 withdrew- reluctant to take ONS despite encouragement. Compliance dependant on nursing staff.
Collins *et al*., 2005	N=38. 80.1 years.	Home nursed.	4 weeks. 237ml 1kcal/ml ONS vs. 2kcal/ml ONS.	1kcal ONS: 90.7%. 2kcal ONS: 95%.	N=7 did not consume all prescribed ONS. Product and volume well tolerated.
Delmi *et al.*, 1990	N=59. 82 years.	Neck fracture, hospital.	32 days. 250ml/day (254 kcals) vs. control.		Given at 8pm so did not interfere with meals. Well tolerated, completely ingested, no reported side effects.
Gazzotti *et*	N=80.	Hospital and community.	2x200ml ONS/day	81.4% compliance.	Compliance measure as 0, ¼, ½,

al., 2003	80.1 years				¾. 1 ONS consumed. Explicitly stated to participants that ONS prescribed to prevent deterioration.
Gosney, 2003		Geriatric hospital wards.	Observational study; ONS wastage monitored for 24 hours.	63% wastage (37% compliance).	70% ONS prescriptions given to patients with BMI ≥20. 56% did not like ONS, 19% dislike texture, 38% dislike sweetness, 19% felt sick/bloated after consumption.
Gray-Donald *et al.,* 1995	N=46 78 years	Frail elderly, at risk of malnutrition, community.	12 weeks 2x235ml ONS/day + dietician vs. just dietician.	68% compliance in compliant subgroup (mean 11.8 cans/week). Total compliance: 9.8 cans/week.	36% refused to participate due to lack of willingness to take ONS. Choice of ONS given in an attempt to ↑ compliance. Compliance measured weekly by counting ONS and dietary interview.
Keele *et al.,* 1997	N=100.	Post-operative GI patients.	7 days. ONS vs. control. Ad lib.	Mean: 305.3 kcal from ONS/day.	Encouraged to consume in small, frequent amounts between meals. N=4 refused to take ONS.

			supplementation (200ml/300kcal ONS, various flavours).		
Krondl *et al.*, 1999	N=71. 70 years.	Community, healthy older adults.	16 weeks. 6x235ml/week (1410kcal/week) vs. control.	Mean intake 202ml/day. 85% compliance.	N=1 averaged at 3 cans/week. Vanilla flavour preferred. Consistency, colour and sweetness highly rated. Monthly visits. Variety of flavours available.
Lad *et al.*, 2005	N=40, current users of ONS 78 years. 24 doctors. 13 dieticians. 33 nurses.	Hospital.	Compliance, factors affecting compliance (views and attitudes).	43% consume >80% ONS prescribed.	Factors affecting compliance: taste, flavour, texture, predictability, personal preference, lifestyle. HCPs: wide range of views regarding criteria for prescriptions.
Larsson *et al.*, 1990	N=501	Geriatric hospital patients.	400kcal ONS/day vs. control.		N= 39/197 withdrew due to refusal to take ONS. Served morning and afternoon.

Lauque *et al.*, 2000	N=78	Nursing home.	60 days. Risk of malnutrition categories. 300-500kcals offered daily.	No actual compliance value: ~82.5% compliance.	Choice and variety offered. Encouragement by researchers. Slight ↓ in consumption after day 50 and on weekends. Compliance measure as 0, ¼, ½, ¾. 1 ONS consumed.
Lauque et al., 2004	N=91. 79 years.	Alzheimer's, geriatric wards, day care centres.	3 months. 300-500kcal/day.	60-95% compliance.	3 products to choose from. Compliance measure as 0, ¼, ½, ¾. 1 ONS consumed. Acceptability of ONS was satisfactory.
Lawson *et al.*, 2000	N= 84. 72 years.	Hospital, post-operative orthopaedic patients.	Duration of hospital stay. 2x240ml juice based drink (300kcal) or 2x200ml milk based drink (300kcal)	20.9% compliance. N=17 did not comply at any level, N=33 discontinued supplements at some point during stay, N=34 continued for duration of stay.	Medical charts/medicine rounds. Lowest level of compliance in patients with BMI <25kg/m^2. Reasons for poor compliance: Nausea, dislike for taste/consistency, poor appetite, postoperative malaise, presentation of ONS by nursing staff, opinion of neighbouring

					patients, perceived health benefits.
McCormick *et al.,* 2007	N=37	Acute and long stay geriatric hospital patients.	6 month review; improvement identified- distinct ONS administration round, signs above beds.	Males: 85.7%. Females: 74%. Acute stay: 89.5%. Long stay: 74.2%. Improvement from 74.2% to 93% post 6 months.	Timing of ONS dispension and ↑ staff vigilance to positively affect compliance.
McWhirter *et al.,* 1996	N=86.	Hospital, malnourished.	ONS prescribed to meet nutritional needs.	74% compliance.	2 withdrawn due to refusal to take ONS.
Miller *et al.,* 2005	N=49 ≥70 years.	Nutritionally 'at risk' lower limb fracture. Acute/residential care setting.	42 days. Vol. ONS prescribed to meet 45% individual energy requirements. Supervised vs. self-administered.	67% median compliance. N=30 (61%) took >60% prescribed vol. 70-84 years, 78% compliance. ≥85 years, 45%	N=2 took no ONS. No difference between supervised and self-administered. 'Refusers' sig. older than 'non-refusers'. N=35 ONS for at least 35 days. N=26 failed to consume ONS on at least 1 day.

				compliance.	N=14 ‘refusers’, took no ONS for ≥5 days.
Payette *et al.*, 2002.	N=83 80 years.	Frail, undernourished/losing weight, community home care.	16 weeks. 2x235ml/day.	55% considered compliant (↑ total energy intake by ≥250kcal/day).	Active encouragement to eat.
Potter *et al.*, 2001	N=381. 83 years.	Hospital.	3x 120ml ONS/day (540kcal).	50% consumed 430-540kcal/day. 25% consumed at least 270kcal/day.	ONS prescriptions on medical charts. Reasons for non-compliance were mainly medical rather than low acceptance.
Roberts *et al.*, 2003	N=186	Hospital.	ONS vs. control. 3x120ml ONS/day.	50% consumed ≥80% ONS. 75% consumed 50-79% ONS. 33% refused ONS at times.	Medicine charts, administered at medication rounds; nurses indicate this ↑ compliance. Reasons for non-compliance were mainly medical e.g. vomiting, no oral intake.
Ross 1999		Hospital.	12 day audit.	80-85% compliance to carton ONS. Fresh milk based	Prescribed ONS offered 100% of the time. Ward house-keeper solely responsible.

				ONS: 20% consumed 'all/nearly all'. Total compliance rate of 43%. 32% refusal rate.	86% prescribed 3 ONS/day, 14% prescribed 1 ONS/day. Reasons affecting compliance: too thick, too sweet, beakers/glasses too small to hold full ONS.
The FOOD trial, 2005	N=4023 (2016 allocated ONS). 71 years.	Stroke patients, hospital.	34 days. 360ml/day vs. control.	76% compliance. 4% received no ONS.	Reasons for non-compliance: 43% error in distribution, 19% refused, 8% worsening clinical condition. 28% discontinued ONS before trial termination- dislike of taste, unwanted weight gain, nausea.
Vlaming *et al.*, 2001	N=846 42-76 years.	At risk of malnutrition/malnourished, Hospital.	2x200ml ONS/day	63% took ≥50% of prescribed ONS.	Need for research dietician or nutritionist in order to replicate compliance in routine practice.
Wengstrom *et al.*, 2009	N=32	Hip fracture patients, hospital and community.	6 months. 400ml ONS/day in hospital; individual prescriptions (400-	73% (26-100%) compliance.	Intake documented daily by participant/relative/carer. Dietician visits at 1, 3 and 6 months.

			600ml ONS/day) at home.		N=1 discontinued due to stomach discomfort self-attributed to ONS.
Wouters-Wesseling *et al.*, 2002	N=35 >60 years.	Psycho-geriatric nursing home.	12 weeks. 2x125ml (135kcal)/day.	91% compliance.	Given between meals. Help and encouragement by nursing staff to drink ONS.
Wouters-Wesseling *et al.*, 2003	N=68 82 years.	Care home, sheltered housing.	6 months. 2x125ml/day	85% compliance.	11 participants withdrew due to dislike of ONS/lack of tolerance for ONS. 20% reported difficulty in taking 2x125ml/day.

1.9.5 Discussion

Dependency on staff/HCPs

An intervention carried out by Carver and Dobson (1995) supplemented dementia patients with ONS; nursing staff were asked to record the volume of supplement consumed by participants daily but did not give any extra encouragement or assistance with meals and drinks other than routine care during the intervention period. Mean weight increased by 3.5kg during the 12 week period in the supplemented group who had a mean compliance rate of 85%. The effectiveness of ONS depended on compliance by nursing staff to deliver the correct prescriptions to the patient.

A 12 day audit to evaluate the economic value of nutritional supplements on a hospital ward noted that the ward house keeper was solely responsible for the administration of prescribed ONS. Despite the engagement of a staff member, the refusal rate was quite high at 32% and total compliance rate was low at 43% (Ross, 1999).

Timings of administration

The timings of ONS administration might affect compliance (McCormick et al., 2007). ONS are energy and protein dense leaving the consumer satiated after intake; this can interfere with intake from actual food and therefore ONS become less effective at increasing nutritional intakes. There is debate over the optimal time to administer ONS; whether they should be given as a snack between meals or whether they should be given during meal times. This issue also relates to the volume of ONS; it has been reported that users of ONS can find it difficult to consume even the smaller ONS products (125 ml) (Wouters-Wesseling et al., 2003); it can take a long time for the consumer to finish the whole product prolonging the feeling of satiation. Delmi et al., (1990) found that supplements were ‘well tolerated’ when given at 8pm as they didn’t interfere with meals (although no actual rate of compliance to ONS was reported). Post-operative GI patients were given ONS between meals and told to sip in small, frequent amounts. Supplementation of 300 kcal drinks was ad-libitum; participants were offered a variety of flavours. The mean daily intake from ONS was 305 kcals suggesting that very few patients choose to take >1 ONS per day (Keele et al., 1997). Wouters-Wesseling et al. (2003) found a high compliance rate of 91% when offering psycho-geriatric nursing

home residents ONS between meals. It is not clear whether it was the timing of ONS administration or the engagement of the nursing staff to help and encourage ONS intake that can account for a good rate of compliance.

The time at which ONS is administered seems to be related how ONS are regarded (as a food or as a medicine) and where the prescription is recorded. If regarded as a food, prescriptions are recorded as a general note in the care plan with no specified time of administration. However, if recorded on the medicine chart, ONS are given during the medicine rounds. Potter et al., (2001) recorded ONS on medical charts and found that 50% of participants consumed between 80-100% of ONS prescribed, and 25% had at least half the prescribed amount. Roberts et al., (2003) also recorded prescriptions on medical charts and administered ONS during medical rounds; in this study nurses indicted that this method increases compliance, however only 50% of participants were taking ≥80% of their prescription daily and 33% refused ONS at times. Lawson et al., (2000) asked nurses and domiciliary staff to record how much of the prescribed ONS was consumed; compliance was poor, measured at 20.9% even though ONS were prescribed on medical charts and delivered with medication.

Monotony

Lack of choice and variety, causing monotony of ONS in terms of product flavour and product form was also identified as a barrier affecting consumption (Lad et al., 2005). In a study by Krondl et al., (1997) participants were offered a choice of ONS as part of the intervention; compliance was reported to be quite high at 85%. Gray-Donald et al., (1995) and Lauque et al., (2000) actively gave participants a choice of ONS in an attempt to increase compliance. Despite this, Gray-Donald et al., recorded a refusal rate of 36% to take ONS among participants, and those categorised as a 'compliant sub-group' only achieved a compliance rate of 68%. No definite rate of compliance was reported by Lauque et al., however it is stated that consumption of ONS decreased after 50 days and on weekends suggesting that monotony affects intake over long periods and that consumption may decline when eating habits change over the weekend days.

Sensory properties

The sensory properties of ONS are important to ensure good compliance to prescriptions; however research has shown that current users do not necessarily enjoy

taking ONS, particularly over long periods of time. Ross (1999) and Lad et al. (2005) collected patient's views of the products they were prescribed; common reasons identified to affect compliance were a dislike of the taste and texture of the products. Gosney (2003) found that 56% of patients did not like ONS despite the availability of 10 different sweet and savoury flavours to choose from. Due to the low palatability of ONS, on this particular ward 50% of prescribed ONS were being wasted and 72% of patients were given ONS in a flavour they disliked.

Disruptions to ONS prescriptions caused by high refusal rates have been attributed to the sensory properties of ONS; Bruce et al., (2003) reported that a dislike for taste caused 8 participants to consumed <35% of their prescription. Wouters-Wesseling et al., (2003) reported that 16% of participants withdrew from the research giving reasons of taste aversion. The FOOD trial (2005) found that 28% of participants choose to discontinue their supplementation due a dislike for the taste and texture of the products used.

Issues of taste, texture and temperature have been addressed in some hospitals by diluting ONS to increase palatability. However, the dilution of a product decreases the energy density per 100ml, therefore satiation is more likely to occur before the necessary calories are consumed (Gosney, 2003). In hospitals, there are cases where an unfinished ONS carton is not removed from the bedside before a fresh ONS is administered; the ONS may decline in palatability due to sitting in a warm hospital environment for a number of hours. At administration of ONS, it may be of some benefit to date and time each carton to ensure that ONS are not left open in the environment for longer than is recommended, particularly by health and safety and food hygiene (Gosney, 2003). ONS can be served at varying temperatures; this should be taken into consideration so that individuals can receive their preference. An increase in encouragement from nursing staff for the individual to complete their ONS while it is at a palatable temperature may also help to increase compliance.

Opinions of palatability of ONS appear to vary on an individual basis; during the assessment of palatability of ONS against 5 other high energy foods, taste of ONS was rated as highly as the other foods, suggesting that taste alone cannot be held accountable for poor palatability (Harper et al, 2001). Ratings of small samples of ONS do not necessarily give an accurate impression of ONS palatability. A future research direction

would be to assess palatability in over long term prescriptions for issues of monotony in product flavour and product type based on bulk prescription orders. This would give an indication of whether ratings of ONS would remain highly rated in greater volumes over a longer period of time. By offering variety packs of ONS that fit individual preferences monotony could be alleviated thereby increasing compliance.

The presentation of ONS when dispensed may also influence compliance. Gosney (2003) reported that when older adult hospital patients are faced with the option of a novel, unfamiliar ONS drink or a frequently available, familiar cup of tea, they choose the latter. Gosney (2003) also suggests that the patients may not like drinking through the straws provided with the ONS, and may have problems with spillage when trying to hold the ONS; these issues could impact on compliance by discouraging the patient to take ONS. In this context assistance could improve compliance if made available to patients who require it in order to take their ONS; the handling and consumption of ONS could be made easier simply by pouring the ONS into a cup with handles.

Motivation and encouragement

Compliance rates can be affected by a general lack of willingness of participants to take ONS; Gray-Donald et al. (1995) and Larsson et al. (1990) reported refusal rates of 36% and 20% respectively. Refusal to take ONS is particularly concerning in interventions supplementing those currently suffering from malnutrition, for example, 2 patients withdrew from the McWhirter et al. (1996) study, and therefore only received standard nutritional care with no benefits of extra nutrition. Refusal and lack of willingness to take ONS could be overcome with encouragement from HCPs; in a study offering help and encouragement, a high compliance rate of 91% was found (Wouters-Wesseling et al., 2002). However, this is not always the case when encouragement is offered; Payette et al. (2002) observed only a moderate compliance level of 55%; those considered compliant had an increase in energy intake by only 250kcal/day. Although the calorie content of the ONS was not stated, this energy intake is likely to account for less than half of what was offered. Lauque et al. (2000) also offered participants encouragement to take their ONS prescriptions; this was relatively successful, producing a compliance rate of ~82.5%. However, in this intervention it was the researchers that offered encouragement; this must be transferred to routine clinical practice carried out by nursing staff in order to continue a high compliance rate.

Lack of knowledge

A lack of knowledge regarding ONS for use in the treatment and prevention of malnutrition could be a factor affecting compliance particularly in the older adult population. Memory loss, dementia and Alzheimer's disease are highly prevalent diagnoses among this vulnerable group in which high malnutrition is observed. These conditions can affect the patient's knowledge of why they are prescribed supplements; without knowing the beneficial effects of ONS, perceived-efficacy may be low and participants may be more reluctant to comply with their prescriptions. A compliance rate of 81.4% was observed when participants were explicitly informed of the reasons for ONS prescriptions to prevent health deterioration (Gazzotti et al., 2003).

Medical issues

Non-compliance to ONS prescriptions has been attributed to medical reasons on a number of occasions; Potter et al. (2000) found that medical issues impacted more on compliance rates than low product acceptance. Roberts et al. (2003) reported that medical problems such as vomiting and conditions which affect oral intakes (for example nil by mouth, dysphagia, throat cancers) were reasons for non-compliance, and the FOOD trial found that 8% of non-compliance was attributed to the worsening clinical condition of the subjects.

Prescriptions

Inappropriate prescriptions of ONS were identified by Gosney (2003). Of the patients who were categorised as underweight (i.e. with a BMI<20 kg/m^2) only 30% were prescribed ONS. Seventy percent of ONS prescriptions were for patients with BMI's $\geq$20 kg/m^2. This lack of coherence with ONS prescriptions could be explained by the wide range of views of different health care professionals. According to Lad et al. (2005), when asking HCP about their criteria to prescribe ONS, 67% (63% of doctors, 46% of dieticians and 79% of nurses) said poor appetite. Weight loss was part of the criteria for 38% of HCP; surprisingly this was a factor for only 29% of doctors asked. Poor nutritional status/malnutrition was only mentioned by 31% of HCP as a reason to prescribe ONS, 13% of doctors and 8% of nurses compared to 85% of dieticians. There appears to be a discrepancy between HCP disciplines as to why ONS should be prescribed; this could disrupt patient care particularly with regards to referrals between

HCPs and the movement/discharge of patients between hospital wards, care homes and the community in terms of the continuation of appropriate ONS prescriptions.

Wastage of ONS appears to impact highly on the economic cost of malnutrition. Nolan (1999) and Ross (1999) found mean wastage to be 24-45% and ~39% respectively. Over a 24 hour period Gosney (2003) reported a wastage of 63% of ONS, totalling at a cost of ~£50.12/day (of £79.56) which was extrapolated to £18,294/annum (across 4 wards). This high volume of wastage could partly be explained by the inappropriate prescriptions described above. Brosnan et al. (2001) reported that there were no documented reasons for ONS prescriptions for 34% of patients, 60% of patients were not weighed at hospital admission, and for those who were prescribed ONS, documentation of use was recorded in an unsystematic manner.

1.9.6 Conclusion

The results of this systematic review suggest that factors affecting compliance not only depend on the individual prescribed ONS (e.g. their likes/dislikes, appetite and medical diagnosis), but also on external factors such as the staffing levels of institutions and the prescriptions written, whether these are monotonous in terms of ONS flavour and product form. When some of these factors are taken into account compliance can be increased. Whether this increase in compliance is due to the intervention imposed or just generally due to an increase in awareness of nutritional supplementation is unknown.

There appears to be no single method to improve compliance but a combination of factors needs to be addressed. These factors include the sensory properties of the ONS product, the place in which ONS are administered, the carer responsible for the administration of the ONS, and the preferences of the individual prescribed the ONS.

1.10 Aims and Objectives

Aims

The principal aim of this research was to evaluate psychological methods to improve compliance to ONS prescriptions of older adults living in the care home setting. This was done through a 4 week intervention comparing 'choice and variety' of ONS with 'motivation and education' towards the prescriptions. Prior to this intervention, 3 other studies were conducted. The first aimed to assess the prevalence of malnutrition in care homes in the West Yorkshire area at 2 time points. The second study aimed to compare the use of ONS and food fortification to increase nutritional intakes at a lunch time meal. The third aimed was to identify barriers that affect compliance to ONS according to care home residents taking current ONS prescriptions and to care home staff involved in the administration of ONS prescriptions.

Objectives

In order to achieve the aims proposed for this thesis, specific objectives were set for each phase of the research.

Phase 1: Nutrition screening of older adults living in care homes in Leeds and West Yorkshire.

- ✓ To assess the overall prevalence of malnutrition of older adults living in care homes at 2 discrete time points separated by 6 months.
- ✓ To compare risk of malnutrition in this geographical location to risk of malnutrition in the whole of the UK.
- ✓ To track those residents who participated at both T1 and T2 over a 12 month period for change in malnutrition risk, weight change and BMI.

Phase 2: The effect of ONS vs. food fortification on nutritional intakes at lunch time.

- ✓ To evaluate the effect of fortification on the nutritional intakes of care home residents during their lunch time meals.

- ✓ To compare the nutritional intakes when a meal is given with no manipulation (plain meal, control); given with food fortification using everyday energy dense foods; given with ONS on the side of the meal (overt supplementation); and given with ONS incorporated into the meal (covert supplementation).

Phase 3: Identifying factors that affect compliance to ONS.

- ✓ To identify psychological barriers affecting compliance to ONS prescriptions for those currently taking ONS.
- ✓ To collect care home resident and staff opinions about ONS.

Phase 4: Methods to improve compliance to ONS.

- ✓ To evaluate the effects of 2 psychological methods to improve compliance to ONS by comparing the mean volume of ONS consumed over a 4 week intervention with the volume consumed over 1 control week (baseline compliance).
- ✓ To give 1 group of participants a choice of ONS daily by offering a menu card displaying a variety of product flavours and forms.
- ✓ To give 1 group of participants motivation and education about the benefits of ONS daily at administration of their prescriptions.

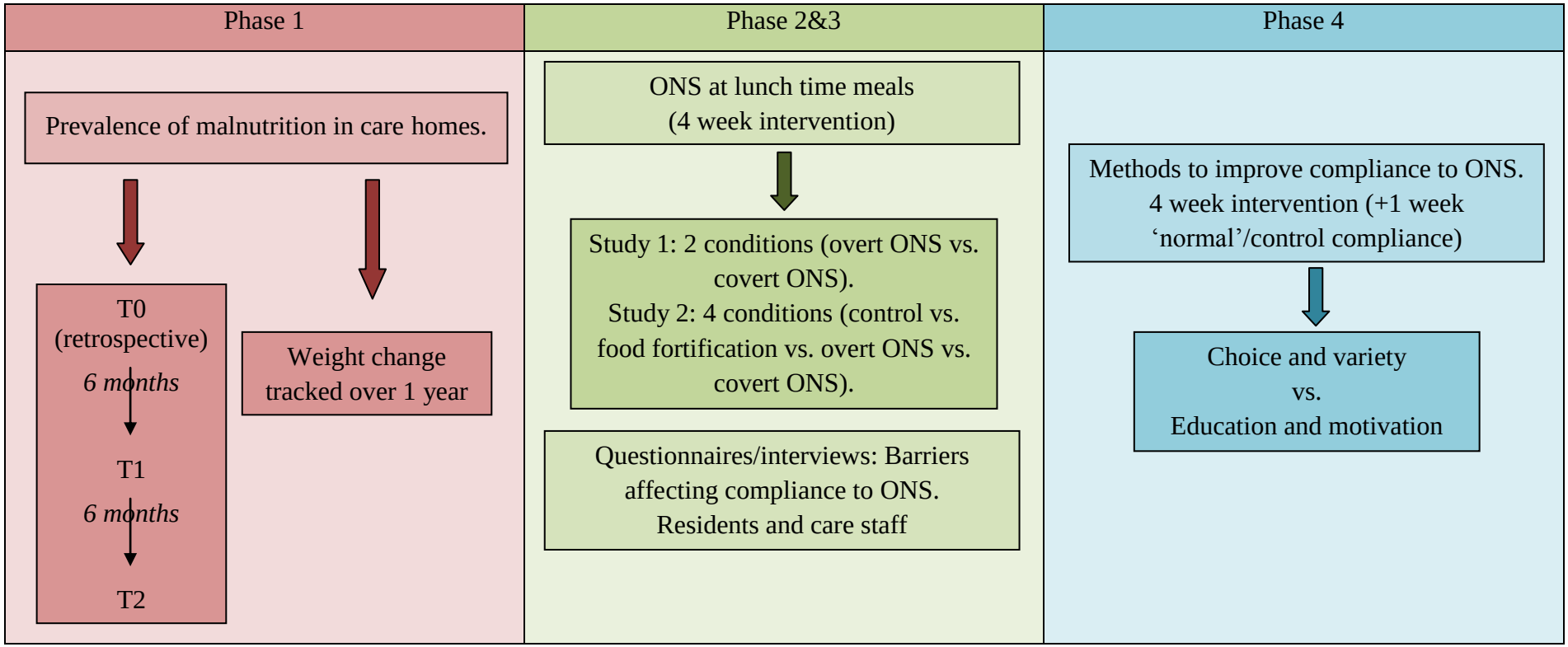


Figure 1.7 Summary of research, a 4 phase approach.

Chapter 2: Methodology

To address the aims of this thesis, the research was divided into 4 phases; phase 1 evaluated the prevalence of malnutrition in care homes at a single geographical location; phase 2 assessed ONS intakes when provided to care home residents during lunch time meals; phase 3 identified barriers that affect compliance to ONS by gathering the opinions of current users of ONS living in care homes and staff members working in care homes; finally, phase 4 addressed the barriers identified at phase 3 through the evaluation of methods to improve compliance to ONS.

The studies described in this thesis were all field experiments and therefore were conducted in the 'natural' setting of the care home. This chapter contains detailed descriptions of the materials used during all the phases of the research; subsequent chapters provide brief overviews of the methods and procedure used for each individual study.

All analysis presented in this thesis was carried out using PASW SPSS (v18, Chicago, USA). The chosen alpha value was $\alpha 0.05$.

2.1 Research Setting

Research set in the laboratory has the advantage of internal validity due to the controlled environment, however the unnatural setting lacks external validity, and findings may not relate to 'real world' situations. Participants are aware that they are being tested so their behaviour can be affected by 'demand characteristics' e.g. 'experimenter expectations' due to the presence of the researcher. Participants are told what to do and so engage in behaviours that they would not necessarily normally do, and so laboratory research lacks ecological validity (Blundell and Stubbs, 1997; Stubbs et al., 1998)

On the other hand, survey research, epidemiological and observational research is conducted in the field, specifically for external validity; the main advantages of field based research over laboratory research are; that observations can be made in a natural setting increasing external and ecological validity, the research is taken to the participants allowing for selected research groups to be targeted (in this case, care home residents), and participants can be observed during real situations and so the research has experimental realism (Stubbs et al., 1998; Heinman, 2002). There is however less

control over manipulations and less accuracy in outcome measurements. Intervention studies conducted in the field (e.g. in care homes) provide a good compromise between the unfamiliar and artificial laboratory setting, and the lack of manipulation and measurement control occurring in observational and epidemiological studies (Gatenby et al., 1995). Participants are given procedural instructions and typically adhere to the manipulation but are able to continue with their normal life so that the impact of the manipulation can be measured (Stubbs et al., 1998).

Due to the frailty of those enrolled in the studies, the research took place in the care homes as it was not feasible to transport participants to the institute at the university. Advantages of this approach included comfort, familiarity and available support to residents. The care home environment is an accurate reflection of the environment in which subjects spend their time and consume all nutritional intakes (Stubbs et al., 1997).

2.2 Selected groups

Care home residents (residential and nursing) and care home staff were recruited. In the UK, residential homes are those that provide general care to residents but with no registration to provide nursing care. Nursing homes cater for more dependent individuals by providing registered nursing care from registered nurses who are on site permanently.

The research was limited by the participants selected on the basis of the inclusion and exclusion criteria (see study chapters for specific research criteria's). The researcher only had access to care home residents depending on their ability to give consent and the willingness of the care home manager and family members to allow the research to take place in that care home. An example consent form used throughout each phase of the research can be found in appendix 2.1. During phase 1 (chapter 3) of the research, both residential and nursing care residents were asked to participate, however due to certain disease states, particularly in nursing homes, many residents were not of the capacity to understand the nutritional screening procedure and therefore were not included. For example, a common diagnosis among care home residents is dementia; at an advanced stage dementia limits participation due to the need for written and informed consent but also for participant involvement to complete questionnaires and rating scales. In research phases 2, 3 and 4 (chapters 4, 5 and 6), it was essential for the

participants to be able to communicate their opinions about their appetite and their use of ONS. It is likely however, that those older adults living with chronic diseases affecting their ability to participate are most at risk of malnutrition.

2.3 Prevalence of malnutrition

In order to study the use of ONS in care homes, the prevalence of malnutrition in the area was first measured. This was done by assessing risk of malnutrition at 2 time points (T1 and T2) separated by 6 months, plus retrospective data collection from 6 months prior to T1 (T0). Those who participated at T1 and T2 could be assessed over 12 months for malnutrition risk, weight change and BMI changes.

2.3.1 Malnutrition Universal Screening Tool 'MUST'

As no standard tool exists for the measurement of malnutrition risk (Meijers et al., 2010) in the care home setting, it was decided that MUST (Elia, 2003) would be used across each care home that participated, and at each stage of the research. This increased the validity of the research by alleviating the discrepancies between different nutritional screening tools. MUST was also used in UK national screening surveys in 2007, 2008 and 2010 (Russell and Elia, 2008, 2009, 2011); by using MUST in this research, comparisons could be made between prevalence of malnutrition in care homes at this single geographical location and the prevalence of malnutrition across the UK.

MUST is a simple, valid and reliable tool that categories patients into either low, medium or high risk of malnutrition. It is suitable across different care settings and is practical for use by a range of healthcare staff. The tool can be applied to all types of adult patient groups including those with eating disorders, critical illness and mental health problems, all of which can be seen in residential and nursing care homes. MUST was developed for the clinical detection of malnutrition (both under- and over-nutrition), and the management of nutritionally responsive conditions that can manifest as a consequence of physiological and psychological issues (Elia, 2003). The main drawback of MUST is the low specificity; this is due to the automatic classification of acutely ill patients as high nutritional risk, there is no graduation of disease effect (Kyle et al., 2006). MUST also appears to over-estimate high nutritional risk and under-estimate medium nutritional risk (Kyle et al., 2006). In care homes however, MUST is convenient as is not time consuming, does not require nutritional training so can be used

by all levels of care staff, and can be incorporated into the monthly routine of essential weight measurements of residents.

Although a number of nutritional screening methods are in existence, only 3; MUST, MNA and NRS (table 1.4.2), have been recommended by ESPEN (Kondrup et al., 2002) because of their ease of use and inclusion of questions that can be applied to various settings (Barbosa-Sliver and Barros, 2006).

2.4 Nutritional intakes at lunch time meals

To increase nutritional intakes, ONS are commonly given alone, for example, as a snack, drink or extra item at mealtimes. Less commonly, ONS can be incorporated into foods to add extra nutrition to meals or drinks. Chapter 4 was divided into 2 studies; the main objective of the study 1 was to compare intakes of a meal with ONS given on the side (overt supplementation), with intakes of the same meal but with ONS incorporated into the sauce (covert supplementation). This then lead to the development of study 2 for which 2 extra conditions were added. The conditions in study 2 were; a plain meal with no manipulation (NM); a meal with food fortification (FF); a meal with ONS provided overtly (OS); and a meal with ONS incorporated into it covertly (CS) (table 4.4, section 4.4).

2.4.1 Interventions to increase nutritional intakes

Manipulating the energy density of foods has previously been shown to increase energy intakes of older adults. In hospitalised patients Olin et al. (1996) compared 6 week intakes of normal hospital food, such as casserole with vegetables, with the same volume of high energy food (casserole with vegetables + 10g oil and 20g cream). Exposures to high energy food lead to an increase in energy intake by 40%, resulting in a 3.4% body weight increase after only 3 weeks. There were no differences in the volume of food consumed between the conditions. It was concluded that it is the volume of food that limits voluntary intake rather than the energy density of food. Energy density (the amount of energy in a given weight of food) is an important environmental factor influencing energy intake from food (Kral and Rolls, 2004). When participants are given equal volumes of the same foods but with differing energy density, energy intake is increased with the increasing level of energy dense foods (Bell et al., 1998; Bell and Rolls, 2001; Rolls et al., 1999). These findings could also be used in the

treatment of malnourished older adults. People eat for volume rather than energy density, and so by increasing the energy density of foods provided, energy intakes could also be increased.

Barton et al. (2000) compared food intake between a normal hospital food menu and a lower volume but higher energy density version of the same menu given to hospitalised older adult patients. For this age group, the daily recommended value for energy intake is 30-35 kcal/kg, 1g/kg for protein intake (BAPEN report, 1999). Energy intakes were 25% higher in the higher energy dense menu group compared to the normal menu group. Protein intakes however remained below the recommended values in both groups. The study concluded that a combination of fortification and smaller portion sizes to increase energy and protein density may increase nutritional intakes of older adults in a hospital setting.

In a nursing home setting, energy intakes are higher with increasing energy densities of meals through the use of food fortification; energy intake was increased in the experimental group compared to pre-test intakes and compared to the control group who received normal nursing home meals (Ödlund Orin et al., 2003).

ONS have consistently been shown to increase nutritional intakes of older adults compared to routine care (Stratton and Elia, 2005). Specifically in care homes, when compliance to daily ONS prescriptions over 60 days is high, malnourished residents increase both energy and protein intakes, show increases in body weight and improvements in overall nutritional status (Lauque et al., 2000). In psycho-geriatric nursing home residents, ONS intake increased body weight and plasma protein levels as well as increasing micronutrient status (homocysteine, vitamin B_1, B_6, B_{12}, folate and vitamin D) (Wouters-Wesseling et al., 2002). The effect of ONS on pressure ulcer recovery in residential homes was investigated by Heyman et al. (2008); high protein ONS enriched with arginine, vitamin C, vitamin E and zinc significantly reduced the size of pressure ulcers when compared to standard care. Turic et al. (1998) compared the use of ONS and snacks for older adults in long term care at risk of malnutrition. Both groups experienced an increase in nutritional intakes during the intervention period, but this was significantly higher in the ONS group (difference of 319 kcal at week 3 and 343 kcal at week 6). Although total energy and protein intakes during the intervention did not exceed the RDA (see Turic et al., 1998 for RDA), ONS did not

replace intakes at meals therefore provided additional energy (590-614 kcals) and protein (28-31g) as well as additional micronutrients. Post-intervention, only participants receiving ONS exceeded the RDA for vitamin D, niacin, folate, vitamin B_6, calcium, magnesium and zinc.

There is a lack of consensus regarding the time at which ONS should be offered in relation to mealtimes. Studies have shown that provisions of ONS between meals do not result in a decrease in intake at meals (Johnson, Dooley, Gleick, 1993; Simmons and Schnelle, 2004). A study that gave ONS as preloads either 30 or 90 minutes before an *ad libitum* lunch time meal to hospitalised older females found that there was a lack of compensation in food intake following the ONS pre-load in both conditions. It was concluded that ONS can be given up to 30 minutes prior to a meal without subsequently affecting intake at the meal (Boudville and Bruce (2005). However, in a study that observed the timings at which ONS were delivered to residents (either between or with meals), the volume of ONS consumed and the amount of assistance given by staff to residents was greater for patients given ONS with meals as compared to ONS given between meals (Simmons and Patel, 2006). Higher compliance rates during meal time supplementation could be due to the increase in staffing levels at mealtimes and an increase in staff awareness of oral intake during specified eating episodes. Ryan et al. (2004) gave malnourished older adult hospital patients 1050 kJ (~250 kcal) ONS immediately after breakfast and compared this to a 'no ONS given' condition. By adding ONS to the diet immediately after a meal, voluntary subsequent dietary intakes were not affected, thereby giving a net increase in energy intake.

2.4.2 Overt and covert malnutrition

If a meal is manipulated covertly, for example, if extra nutrition is added to a meal by stealth without the subject knowing, meal intake and subjective ratings solely assess the physiological effects of nutrition. However, if the meal is subject to overt supplementation, i.e. the subject knows about/can see the manipulation, meal intakes can be used to assess the interactions between physiologic and cognitive factors as the subject responds to both cues (Rolls and Hammer, 1995). It is therefore not just the physiological and metabolic processes that are concerned with human appetite and eating behaviour, but also cognitive processes that play an important role in determining food intake (Shide and Rolls, 1995). Healthy women who received a yogurt preload

labelled ‘low fat’ consumed a higher amount of energy at a subsequent meal than they did when they were given a yogurt pre-load labelled ‘high fat’ despite the fact that the 2 yogurts actually did not differ in energy content. In this case, it appeared that labelling yogurts with information about fat content provides a cognitive cue that overrides physiological processes associated with the metabolism of the ingested food (Shide and Rolls, 1995).

It has previously been reported that older adult males do not adjust their food intakes after periods of over- and under- feeding; after a 21 day *ad libitum* eating period, young men lose the excess weight gained but older men do not, and after periods of food restriction, young men regain lost weight whereas older men do not (Roberts et al., 1994). This indicates impaired regulatory ability in older males, however in this particular study it was unclear as to whether this was associated with age related changes in hunger and satiety or the loss of ability to adjust to changes in energy and nutrient content of foods (Rolls, Dimeo, Shide, 1995). Short term energy regulation was compared in healthy young and healthy older adults; participants were given yogurt pre-loads of varying energy content (blinded to the participants) followed by an *ad-libitum* lunch. Older participants showed poorer compensation at 37%, consuming significantly more energy from the lunch after the energy dense pre-loads compared to younger adults whose compensation was approximately 80%. This suggests that if older adults consume a high energy first course, overall meal energy intake can be increased (Rolls, Dimeo and Shide, 1995).

2.5 Identifying factors affecting compliance to ONS

To identify the reasons for poor compliance to ONS in older adults a questionnaire and interview based study was designed. In many cases the residents taking ONS prescriptions were not of the capacity to answer questions about their supplementation and so the study was adapted for care home staff involved in the administration of ONS who could give feedback about the supplements.

2.5.1 Questionnaires and interviews

Two questionnaires were developed specifically for this study; 1 was aimed at care home residents who were taking current prescriptions of ONS, the other was aimed at members of care home staff who were involved in the administration of ONS to

residents (appendix 2.4 and 2.5). The opinions of care home staff were particularly important in nursing homes where there are a number of residents prescribed ONS but the majority have too severe dementia to communicate their opinions about the ONS.

There are limitations of using a novel questionnaire due to the lack of validation to test whether the questionnaire does in fact assess the aims for which it was developed. In this study, the questionnaires were developed from a Nutritional Taste Questionnaire (NST- 14) (Jenkinson et al. 2009). The questions designed for the NST- 14 assess ONS acceptability in terms of palatability; some of these were suitable for adaptation for the questionnaires developed for this research. The NST- 14 specifically addresses liking of ONS but does not attempt to address alternative factors that may affect compliance such as the time at which ONS are administered and the choice of products offered. The questionnaires used in this study were developed specifically for the purpose of this research and although assessed the acceptability of the sensory characteristics of ONS, went beyond this to identify other psychological and logistical barriers that may affect compliance.

2.5.2 Subjective Measures

Likert scales were used to measure resident's attitudes, knowledge and feelings about the ONS they are prescribed. Likert scales are multiple item lists ranging from, for example, 'extremely unpleasant', 'unpleasant', 'neither unpleasant nor pleasant', 'pleasant', 'extremely pleasant'; subjects are directed to select the option that best describes their own feelings towards the subjective measure in question. Alternative VAS can be used; these are usually presented as a 100mm line anchored at each end by the extremes of the dimension in question which can be marked by subjects to indicate their feelings towards that particular variable (Guyatt et al., 1987).

Likert scales have been shown to be less problematic to understand and more easily communicated than VAS. For chronic respiratory disease patients, VAS required training for the effective use in pain measurement, where as a 7-point Likert scale was self-explanatory and needed little or no training for use (Guyatt *et al*., 1987, Jaeschke, Singer and Guyatt, 1990). Guyatt *et al.* suggest that another advantage of Likert scales over VAS is in recognising a minimal clinically important difference in ratings; a change in 1 or more on a Likert scale is an easier concept to grasp intuitively, and is more easily identified by a clinician or HCP than a change of 10-20mm on a VAS

Since cognitive impairments (all stages of Alzheimer's and Dementia) and physical impairments (loss of mobility and arthritis) were common amongst the recruited residents, Likert scales were chosen to measure subjective ratings, and assistance could be given if required.

2.6 Methods to improve compliance to ONS

With reference to the themes gathered from the interview and questionnaires an intervention was developed. The intervention was devised to improve compliance exploiting two basic psychological processes; variety and reward. In 1 group of participants, variety was offered daily to allow for a choice to be made regarding ONS product and flavour, and to prevent monotony. For the second group, motivational techniques, rewards and education towards ONS were offered daily to shape the health behaviour. Compliance during intervention weeks could be compared to 'natural compliance' assessed during a control week prior to the intervention, and to the prescribed amount of ONS documented on prescriptions from participants GP.

2.6.1 Choice and variety

Variety is known to stimulate food intake in adults and children (Rolls et al., 1981; Rolls, Rowe and Rolls, 1982) and so offering diverse flavours and form might enhance compliance. A recent unpublished study offering a daily choice of ONS in terms of flavour and texture found a high compliance rate of almost 90%. The high compliance was attributed to the variety of ONS products offered allowing participants to choose the product they wanted at that particular point in time. Over the four week intervention, acceptance in terms of liking and wanting, measured by participant interview, did not decrease and so it was concluded that offering variety could give rise to long term acceptance and high compliance rates (Weenen et al., unpublished manuscript).

2.6.2 Motivation and education

In the motivation and education condition (ME) participants were offered encouragement to take their prescription through motivational techniques and were given more information about why they were prescribed ONS and the benefits of ONS in order to increase education. ME relied on the engagement of the carer as well as the participating resident.

Motivation provided was adapted from psychological theory on ‘implementation intentions’. The intention to perform a task has 2 components; (1) a prospective component in which an individual must remember ‘that’ something needs to be done, and (2) a retrospective component in which ‘what’ has to be done must be remembered (Einstein and McDaniel, 1990 and 1996). When both components are remembered, the intended task can be carried out. ‘Implementation intention’ refers to a strategic method to improve the likelihood of translating an intended action into a goal intention (Gollwitzer, 1999; Gollwitzer and Sheeran, 2006), and can be used to increase motivation and to accomplish goal directed behaviours (Zimmerman and Meier, 2010). Compliance to ONS relies heavily on both the carer remembering to administer the ONS and, more importantly the resident remembering to finish their ONS; it was therefore hypothesised that implementation intention could be used to aid memory and therefore increase compliance. A number of studies have used implementation intentions to effectively increase actions of health related behaviours such as engaging in physical activity (Milne, Orbell and Sheeran, 2002; Prestwich, Lawton and Connor, 2003), attending cervical screening (Sheeran and Orbell, 2000), and regular breast examinations (Orbell, Hodginks and Sheeran, 1997).

Chapter 3: Who is vulnerable to malnutrition risk in the care home setting?

3.1 Introduction

By evaluating the prevalence of malnutrition in care homes, the characteristics of those at risk of malnutrition can be identified. This information is important for the recognition of factors that may be affecting compliance to the treatments prescribed for malnutrition, such as ONS. In 2007, BAPEN carried out the first UK national screening survey across hospitals, care homes and mental health units using MUST. Of those screened in the hospital setting, 28% were malnourished, in care homes the prevalence was slightly higher at 30%, and in mental health units was 19%. In care homes, 20% of care home residents fell into the 'high risk' category, the remaining 10% falling into the 'medium risk' category. Prevalence of malnutrition was found to be higher in nursing care homes (35%) where residents are frailer, than residential care homes (22%). The key points raised by the survey identified the high prevalence of malnutrition on admission to both hospitals and care homes. It was stated that malnutrition affected almost 1 in 3 adults on admission to the healthcare system, the majority of which were at high risk. A suggestion as to why malnutrition is so prevalent concerns the varying policies and practices regarding nutritional screening between and within healthcare systems, causing malnutrition to be left unrecognised and untreated (Russell and Elia, 2008).

The nutritional screening survey was repeated in 2008; it was found that malnutrition remained similar in terms of UK prevalence, except in care homes where it increased to 42%. Prevalence of malnutrition in hospitals in the 2008 survey was 28%, and in mental health units, was 20%. In care homes, 30% of residents were at high risk of malnutrition and 11% were at medium risk of malnutrition. It is suggested that the increase in the prevalence of malnutrition in care homes was due to the different proportions of categories of care homes partaking in 2008; there was a higher proportion of exclusive nursing homes and care homes with nursing facilities in comparison to residential care homes. In nursing care, residents are more frail, more dependant and are more likely to be living with number of disease states, all of which increase the risk of malnutrition over that of residents living in residential care (Russell and Elia, 2009).

The third survey, conducted in 2010 expanded to cover nutritional screening in the UK and Northern Ireland (NI). In the hospital setting, 34% of patients were at risk of malnutrition; this was an increase from both previously conducted surveys. In care homes, 37% were at risk of malnutrition (23% at high risk and 15% at medium risk), and nursing care homes had a higher prevalence of malnutrition (45%) than residential care homes (30%). The overall prevalence of malnutrition had declined from the 2008 survey but remained higher than during the 2007 survey. In metal health units, prevalence remained similar to both previously conducted surveys at 18% (Russell and Elia, 2011).

The reports highlight that there is a continued variation in screening policies and practices and therefore malnutrition remains an issue in terms of detection, treatment and prevention. Malnutrition was identified to mainly originate in the community therefore consistent and integrated screening strategies should be implemented to treat malnutrition within and between all care settings, focussing on targeting malnutrition in the community (Russell and Elia, 2000; 2011). The screening surveys identified a lack of scale calibration in each care setting, and therefore healthcare was failing to meet Department of Health recommendations (DOH, 2008). At discharge from health care there was also a lack of follow-through with regards to nutritional planning and therefore nutritional care of patients was being hindered (Russell and Elia, 2009; 2011).

The high prevalence of malnutrition in care homes recorded by BAPEN in the UK came from 173 homes in 2007, 74 homes in 2008 and 148 homes in 2010 (Russell and Elia, 2008, 2009, 2011). This number of care homes is very small considering that, according to *carehome.co.uk* there are 17, 538 care homes in England alone. In the present research a total of 25 care homes in a single geographical location participated allowing for a high proportion of residents to be screened for malnutrition risk. Another limitation of the UK nutritional screening surveys is that, although screening took place at 3 time points over 4 years there was no specific follow-up of participants; although malnutrition risk is identified, there is no way to know if conditions were managed and treated, and whether the participants who took part in 2007 were also included in the screening in 2008 and 2010. An advantage of the present research is that, by screening participants from the same care homes at 2 time points, participants taking part at both time points could be tracked in terms of weight change and malnutrition risk over a 12

month period. From this conclusions can be drawn addressing the management of malnutrition from the guidelines set out in MUST.

3.2 Aims and objectives

The principal aim of this study was to assess the prevalence of malnutrition risk in older adult care homes in a single geographical location (West Yorkshire) and to compare this risk to previously published data of malnutrition risk across the whole UK (Russell and Elia, 2007, 2008 and 2010). Secondary aims included the identification of 'high malnutrition risk' areas within West Yorkshire, and to identify those most at risk of malnutrition. It was predicted that the more vulnerable, frail older adults living in nursing care would be at higher risk of malnutrition that those living in residential care.

The study was then repeated with the aim of identifying changes in risk of malnutrition that had occurred over 6 months after the original surveillance. Participants that were involved at both time-points could then be followed over a 12 month period; the specific hypothesis at follow-up was that information relayed to managers about risk of malnutrition would result in action taken to obviate risk. It was predicted that risk of malnutrition would decrease over time.

3.3 Method

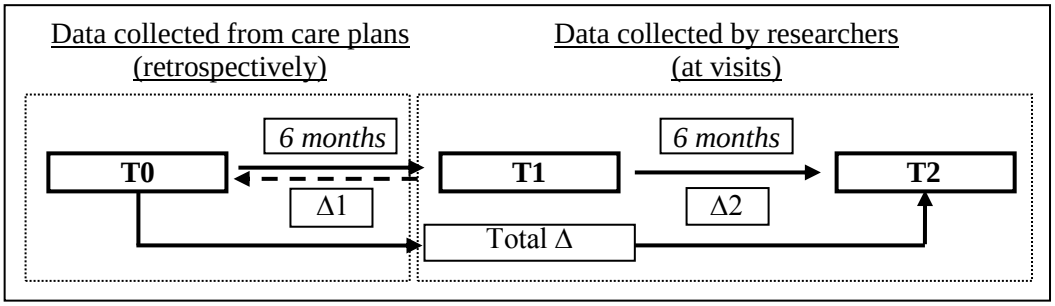


Figure 3.1 Method of data collection for nutritional screening.

3.3.1 Participants

Participant recruitment from both residential and nursing care homes spanned a large area of West Yorkshire. First approach was to contact care home managers by telephone call through which the purpose of the research was explained. If the care home manager

was willing for their care home to take part in the research, the researcher went to the care home to talk to potential participants.

At T1, a total 43 care homes in the West Yorkshire area were contacted about the research (figure 3.3). Twenty-five agreed to take part in the study; 18 residential care homes and 7 nursing homes. Reasons for not taking part included; uninterested in the research, too busy to take part or cared only for residents who were not of capacity to understand or give consent to the study (manager unwilling to consent on the resident's behalf). Across the 25 care homes, 513 (403 female) residents participated; 379 were living in residential care and 134 living in nursing care. Mean age of participants was 86 years (65-107 years) and mean length of stay in the care home was 32 months (1-219 months).

Six months later, at T2, a total of 348 residents participated across 19 care homes (figure 3.3); 6 care homes that previously took part in this research at T1 did not participate at T2. Reasons for not participating included; a change in manager (4 care homes); no longer interested in taking part (1); sickness within the care home (1). Participants were divided into care category; 261 participants were living across 14 residential care homes, and 87 participants were living across 5 nursing care homes. The mean age of participants was 86.7 years (65-109 years) and the mean length of stay at the care homes was 35 months (1-205 months).

There were 212 participants (171 female) who were screened for malnutrition risk at both T1 and T2 (figure 3.3) and so could be tracked for weight change over 12 months. Participants lived in 19 care homes across, 14 residential care homes (N=153) and 5 nursing care homes (N=59). Mean age of participants was 87 years (65-103 years) and the mean duration of stay at the care home at the time of the study was 40 months (8-205 months).

3.3.2 Ethical considerations

The study was approved by the Ethics Committee at the Institute of Psychological Sciences at the University of Leeds, reference no. 10096-06. The manager of each care home was asked to give oral consent to allow the researcher into the care home and identified suitable residents as potential participants. Participants who were of capacity to understand the study procedure were asked to give either written or verbal consent; verbal consent was witnessed by a member of care home staff who signed the consent

form on the participant's behalf. Particularly in nursing care homes, for those who lacked the capacity to understand the research procedure, care home managers and/or relatives of the participants were asked to act as representatives of the participant and to sign the consent form on their behalf. Participants were informed that they could withdraw from the research at any point without giving a reason.

3.3.3 Materials and procedure

Nutritional screening of care home residents was performed using the MUST which is a 5-step process (Elia, 2003). The effective use of MUST requires a number of measurements to be made in order to calculate a score; BMI (kg/m^2), unplanned weight loss and acute disease effect (appendix 3.1).

In step 1 a BMI score is calculated based on the individual's height (m) and weight (kg), to give a quick estimation of protein-energy status. Since height remains constant, BMI changes invariable reflect changes in weight (Elia and Lunn, 1997). Protein-energy status can be classified by BMI in adults; a BMI of <17 kg/m^2 indicates chronic PEM and a BMI of 17-20 kg/m^2 can indicate PEM in some individuals, although in others this can be 'normal'. This method of protein-energy status classification through the regular measurements of BMI (monthly measurements in the case of care home residents) is however limited in those with a low starting weight of <20 kg/m^2; in these cases, BMI fails to identify developing PEM (Shenkin et al., 1996). Height and weight are ideally recorded using a stadiometer (portable height measurement device) and calibrated clinical scales; conversion charts are provided so that metric measurements can be easily recorded. From these measurements, BMI can be calculated using the equation $BMI\ (kg/m^2) = weight\ (kg)/height\ (m^2)$, or can be read from the BMI chart provided. The measurement of height can often be difficult particularly for frail older adults who may have problems standing due to poor postural stability (Meizer, Benjuya and Kaplanski, 2004); in these cases alternative measures can be made. The length of the forearm (ulna), knee height or demispan can give accurate estimations of height. MUST provides charts for conversion of these measurements into an estimated height based on an individual's gender and age (<65 years/>65 years) (Todorovic, Russell and Elia, 2003). For the purpose of this thesis, all records of height were estimated through the measurement of ulna length and weights were either taken retrospectively from

documentation within the participant's care plan, or were measured by researchers using the scales provided at the care home.

BMI can be used as an indication of malnutrition risk by conversion into scores (table 3.1); those who score 2 or 1 according to their BMI are likely to have a poor protein-status and so are at risk of malnutrition. It is unlikely that those with a BMI of >20kg/m^2 have a poor protein status. Those with a BMI >25kg/m^2 are not at risk of under-nutrition, however in these overweight categories, other complications may arise associated with obesity (Todorovic *et al.*, 2003).

Table 3.1 BMI in relation to MUST scores and weight category (adapted from Todorovic et al., 2003).

BMI (Kg/m^2)	MUST Score	Weight category
<18.5	2	Underweight
18.5-20	1	Underweight
20-25	0	Desirable weight
25-30	0	Overweight
>30	0	Obese

Note: Score 2 indicates high risk malnutrition, score 1 indicates medium risk malnutrition.

Step 2 estimates unplanned weight loss that occurred over the previous 3-6 months. This is a more acute risk factor of malnutrition than BMI which may be unreliable in the presence of confounding factors such as oedema and ascites, and does not identify progressive unintentional weight loss when used as a single assessment (Campillo et al., 2002; Shenkin et al., 1996). Weights from the previous 3-6 months are obtained from participants care plans; current weight is deducted from the previous weight, and this is then converted into a percentage of the current weight to give the extent of unplanned weight loss (if any). If an individual has lost >10% of their body weight over the previous 3-6 months they score 2 according to MUST (high risk malnutrition). If an individual has lost between 5-10% of their body weight they score 1 and are at medium risk of malnutrition; they have more than normal intra-variation of weight increasing their risk of malnutrition. Any weight loss of <5% body weight is seen as normal intra-

individual variation and puts the individual at low risk of malnutrition (Todorovic *et al.*, 2003).

In step 3 is the assessment of an acute disease effect; a current acute patho-physiological or psychological condition that causes no nutritional intake or is likely to cause no nutritional intake for 5 days puts an individual at nutritional risk. If this is the case, they are given a MUST score of 2 (Todorovic *et al.*, 2003). Due to the severity of acute disease within this population, any person scoring on step 3 is likely to have been admitted to hospital and so no longer be in the care home.

Overall risk of malnutrition is calculated at step 4 by adding together the scores from steps 1-3 (figure 3.2).

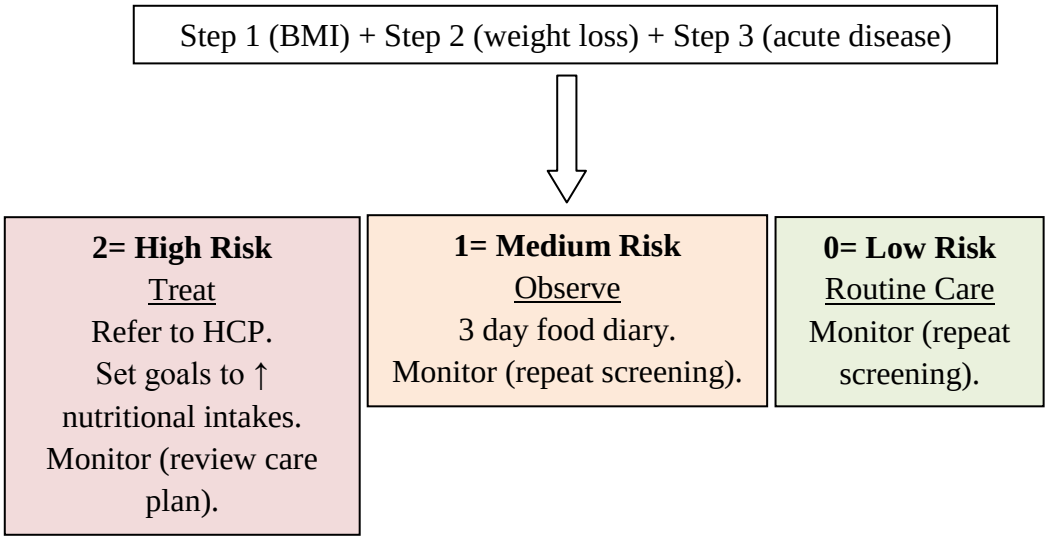


Figure 3.2 Step 4 and 5 of MUST; scores and risk of malnutrition with brief management guidelines (adapted from Todorovic *et al.*, 2003).

Step 5 involves provision of the management guidelines recommended for each risk category (figure 3.2, appendix 3.1). For those at low risk of malnutrition, routine clinical care is satisfactory; nutritional screening should be repeated weekly in hospitals, monthly in care homes and annually in the community for special groups such as the >75 years (NICE, 2006). Observations are recommended for those who are at medium risk of malnutrition; food and fluid intakes should be recorded over 3 days. From this, if intakes are considered adequate, routine screening should be continued (as with those at low risk). If nutritional intakes are not adequate and there is cause for clinical concern, goals should be set to improve nutritional intakes; this should be monitored closely as well as weight to assess any weight change. Immediate treatment is recommended for

those found to be at high risk of malnutrition. In all cases it is important that the underlying condition is firstly recognised and treated, and if a nutritional intervention is required then individuals should be referred to a dietician or other HCP. Malnutrition can be treated through the 'food first' approach and/or by ONS (see table 3.2). High risk individuals should be monitored closely and screened regularly, all information should be recorded and reviewed in the care plan (Todorovic *et al.*, 2003).

Table 3.2 Nutritional interventions to be considered for those at high risk of malnutrition (adapted from Nutrition Action Plan Delivery Board, 2009 and Todorovic et al., 2003).

Nutritional Interventions:	
Food (Food can be fortified to increase the energy of the meal, i.e. by adding extra milk/cheese to the meal).	• Provide help and advice on food and drink choices. • Make food appetising; consider the attractiveness of the meals for those on a liquid diet (due to swallowing difficulties). • Provide assistance with shopping/cooking and eating where required. Ensure meal times are sufficiently staffed. • Provide a pleasant eating environment and atmosphere, encourage carers, friends and family to visit and offer support during meal times.
Oral nutritional supplements	• ONS should be provided if it is not possible to meet nutritional requirements from food alone; ONS can provide an extra 250-600 kcal daily. • ONS should be combined with dietary advice and counselling.

Data collected at steps 1-4 during this study at both T1 and T2 were recorded on a screening *pro forma* (appendix 3.2); care home managers were sent a debriefing letter (appendix 3.3) with the results from their residents. If any residents were found to be at risk of malnutrition, recommendations were sent in the form of step 5: management guidelines.

Nutritional screening first took place at T1; weight change between T1 and T0 (6 months prior to the screening; data collected retrospectively from participants care plans) was assessed and care home managers were debriefed. Six months later, recruitment for the T2 screening survey began. All previous participating care homes were contacted and invited to take part in a follow-up study in which all measurements would be repeated. T2 screening was available to all residents who previously participated and who were still living at the care home; screening was also available to residents who did not previously participate but who consented at this point. At T2 weight change could be assessed between T2 and T1 in those who had participated at both time points, and could also be assessed between T2 and a weight from the previous 6 months in those who were new to the study. In summary, the procedure involved screening at both time points; weight change of those who had contributed to data collected at all 3 time-points could also be tracked and assessed over a 12 month period (figure 3.1).

3.3.4 Statistical analysis

MUST scores were used to calculate risk of malnutrition at both T1 and T2; these were then converted into percentage frequencies of low, medium and high risk. Risk of malnutrition was compared according to care category by dividing participants by their residential or nursing care status. Six month weight change was assessed by calculating the difference between weights recorded at T1 and T0, and T2 and T1. For those participating throughout the 3 time-points, a total yearly weight change could be calculated as the difference between the weights taken at T2 and T0 (figure 3.1). Relationships between risk of malnutrition between T1 and T2 were identified by Pearson's correlation coefficient and by Chi-square analysis. Correlational analysis was also applied to establish relationships between MUST and BMI scores, and between weight change and length of stay in the care home. Wilcoxon Signed rank test was used to identify any significant differences in categorical MUST scores between T1 and T2.

Weight, BMI, weight change and length of stay were assessed for differences at T1 and T2 using a repeated measures ANOVA. Using BMI, participants were divided into 4 weight status categories (specific to older adults); <18.5 kg/m^2, very low weight; 18.5-20 kg/m^2, low weight; 21- 29 kg/m^2, healthy weight; ≥30 kg/m^2, overweight. Changes within BMI categories could be assessed over time in those participating at T1 and T2. The length of stay (LOS) within the care home could be categorised; 0- 24 months, 25-48 months, and ≥49 months; weight change over time was then compared within each length of stay category. Bonferroni correction was applied post-hoc to identify differences in weight change between BMI categories and length of stay categories.

3.4 Results

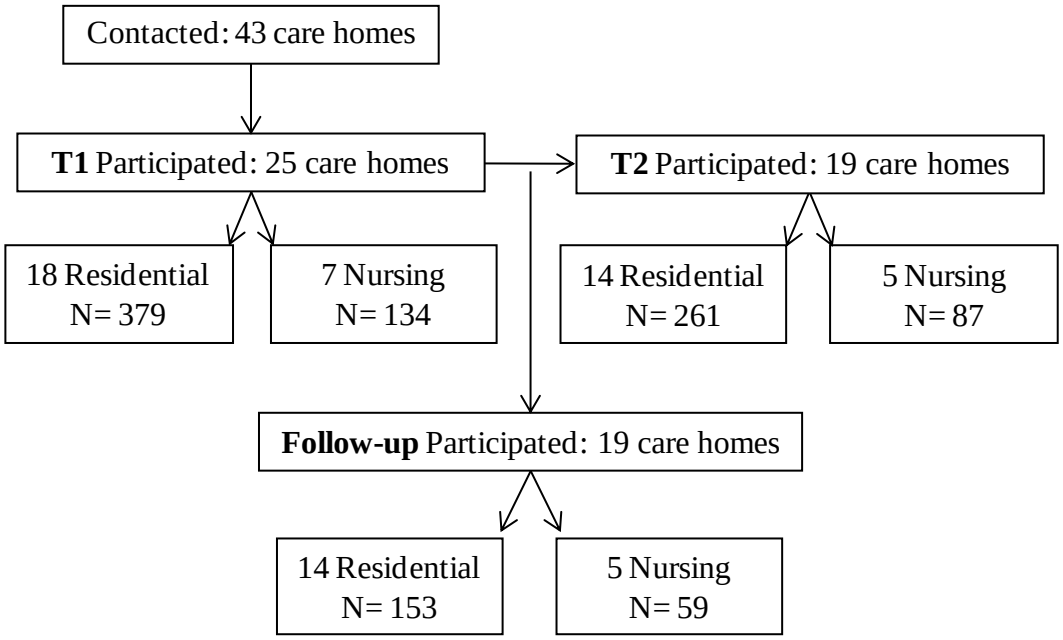


Figure 3.3 Consort diagram for each stage of the research

3.4.1 Nutritional Screening T1

Risk of malnutrition

Risk of malnutrition of all participants was calculated using MUST scores; 318 participants (62%) were at low risk of malnutrition, 95 (18.5%) were at medium risk and 100 (19.5%) were at high risk of malnutrition. This gave a total of 38% of care home residents at risk of malnutrition (medium + high). Figure 3.4 shows the

breakdown of malnutrition risk of participants between care categories; in residential care 251 (66.2%) were at low risk, 70 (18.5%) were at medium risk, and 58 (15.3%) were at high risk of malnutrition (total of 33.8% at risk of malnutrition). Significantly more residents were at risk of malnutrition in nursing care than in residential care (x^2= 11.603 (1), p<0.01); 67 (50%) were at low risk, 25 (18.7%) were at medium risk and 42 (31.3%) were at high risk, giving a total of 50% of nursing care residents at risk of malnutrition.

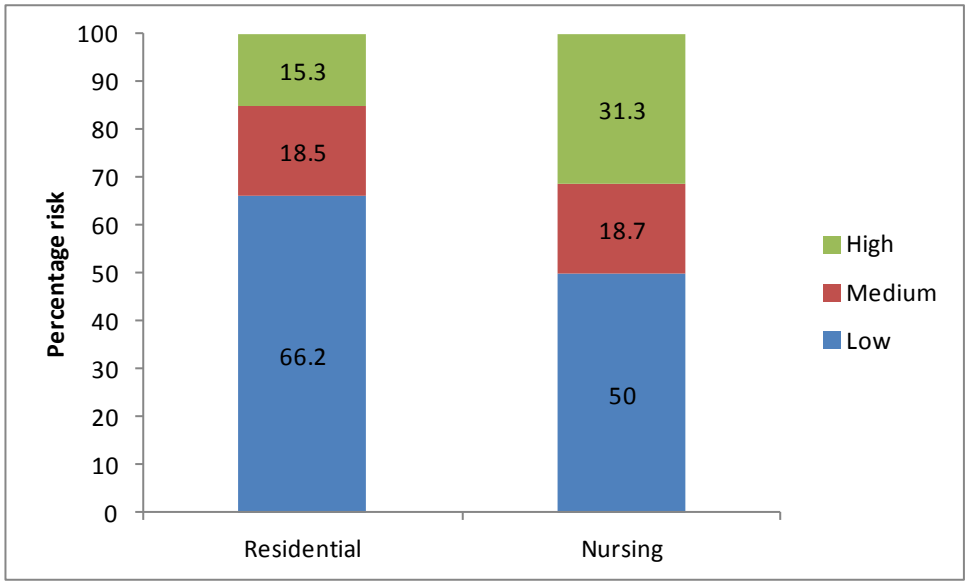


Figure 3.4 Percentage risk (high, medium or low risk) of malnutrition according to care category (residential and nursing) at T1.

Weight, weight change and BMI

Weights taken at T1 were compared to retrospective data of weights recorded in the care plans from the previous 6 months (T0). Overall, a repeated measures ANOVA showed that weight significantly decreased between the 2 time points with a mean difference of 0.7kg (F(1, 479)=10.812, p<0.01). When divided by care category, there was no significant difference in weight at T0 and T1 in residential care, however in nursing care weight significantly decreased from 60.4 kg at T0 to 58.9 kg at T1 (F(1, 127)= 18.492, p<0.01).

There were no significant differences in absolute weight at T0 or T1, or BMI between residential care and nursing care participants. Weight change however was significantly different between residential and nursing care residents (t(478)=2.487, p= 0.013).

Table 3.3 Mean (SD) weight at T1 and T0, mean weight change between T0 and T1 and mean BMI of all participants and divided into residential and nursing care categories.

	Residential	Nursing	Total
Weight T1 (kg)	61.1 (14.8)	58.3 (15.4)	60.9 (15.0)
Weight T0 (kg)	61.4 (14.4)	60.1 (15.4)	61.1 (14.6)
Weight change (kg)	-0.4 (4.6)*	-1.5 (4.0)	-0.7 (4.5)
BMI (kg/m^2)	25.0 (5.4)	22.7 (4.7)	24.3 (5.3)

*p<0.05, difference between residential and nursing care

Weight change was analysed according to BMI (figure 3.5); weight loss was greatest in those with the lowest BMI, the amount of weight loss decreased with each increasing BMI category.

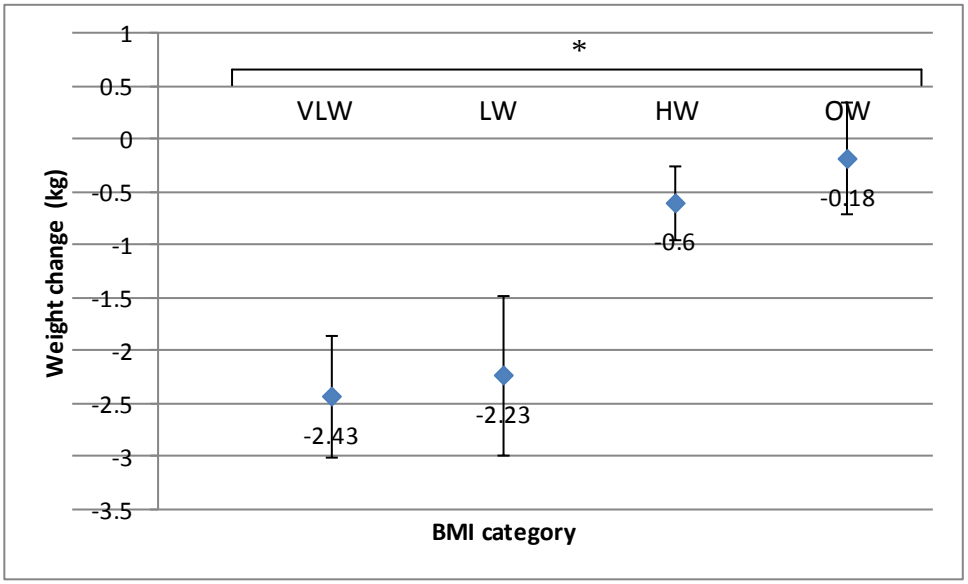


Figure 3.5 Weight change over 6 months (T0-T1) according to BMI category ('VLW'= very low weight, BMI <18.5kg/m^2; 'LW' = low weight, BMI 18.5-20kg/m^2; 'HW'= healthy weight, BMI 21-25kg/m^2; 'OW'= over weight, BMI >25kg/m^2).*p<0.05.

Overall there was a significant difference in weight change between BMI categories (F(3, 237)=3.456, p= 0.017), however post-hoc test revealed no specific difference between the BMI categories. When the BMI categories were pooled into 'BMI ≤20

kg/m^2' (N= 73) and 'BMI ≥21 kg/m^2' (N= 202), there was a significant difference in weight change (F(1, 272)= 9.953, p= 0.02); weight loss was significantly higher (-2.7 kg) in the lower BMI category than the higher BMI category (-0.4 kg). When the effect of BMI on weight change was assessed according to care category, there were no significant differences for either residential or nursing care.

Participants were also divided into length of stay (LOS) categories to assess the effect of months living in care on weight change. There was a significant difference between length of stay groups on weight change (F(2, 441)= 4.212, p= 0.015) (figure 3.6). Weight loss was greatest in those who had been living in care for between 25-48 months; post-hoc analysis revealed that this was significant when compared to 1-24 months (mean difference of -1.46kg, p= 0.014).

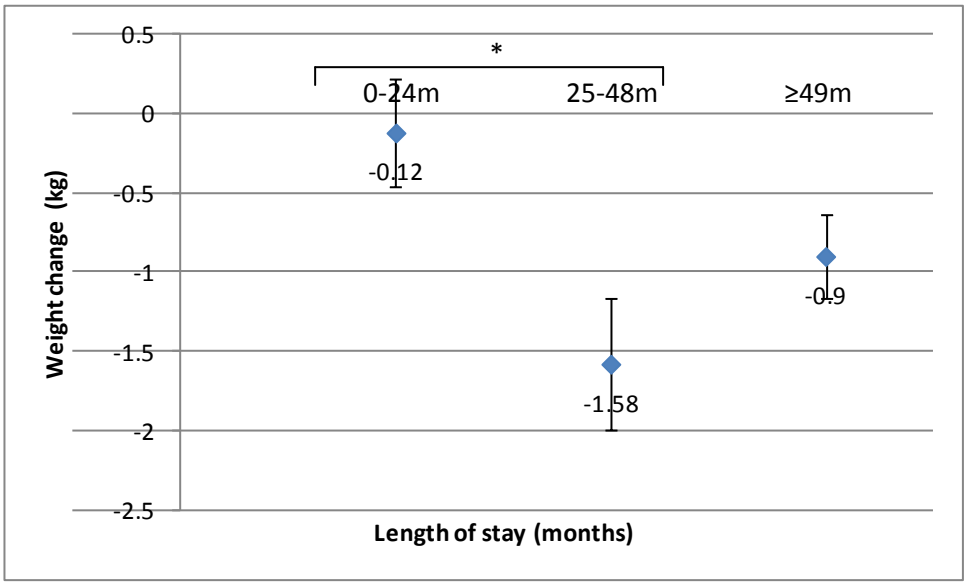


Figure 3.6 Weight change over 6 months (T0-T1) according to LOS in the care home (months since admission). *p<0.05 compared to 0-24 months.

Similarly, for residential care, LOS significantly affected weight change (F(2, 315)= 4.931, p= 0.008); weight change was significantly more negative in the 25-48 month group than the 0-24 month group (mean difference of 1.82 kg, p= 0.014). There were no significant effects of LOS on weight change in nursing care.

3.4.2 Nutritional Screening T2

Risk of malnutrition

Overall 57.6% of residents were at low risk of malnutrition, 20.9% of residents were at medium risk of malnutrition and 21.5% were at high risk of malnutrition (figure 3.7). When this data was collated, the percentage of residents at risk of malnutrition (medium + high) at T2 was 42.4%.

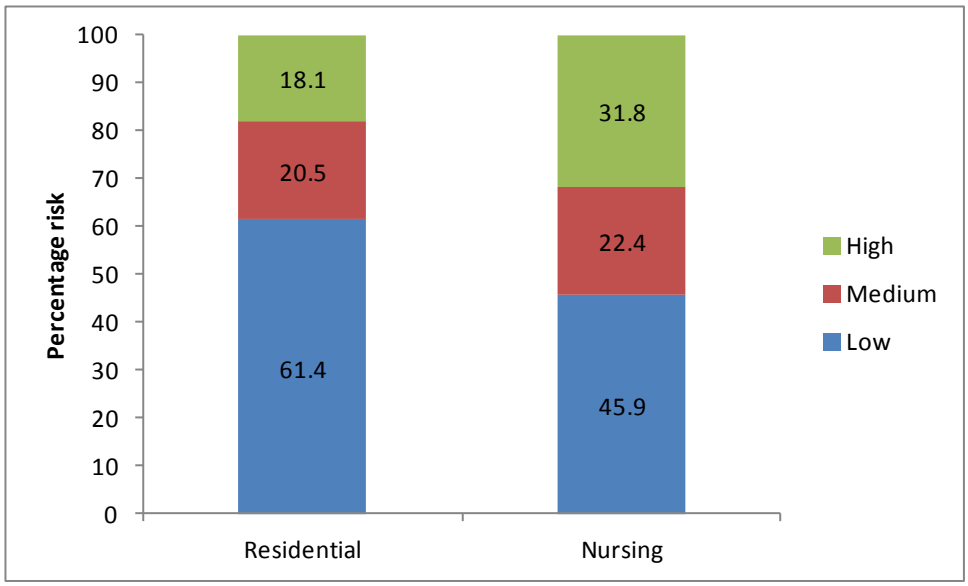


Figure 3.7 Percentage risk (high, medium or low) of malnutrition according to care category (residential and nursing) at T2.

The number of residents at risk of malnutrition was divided into residential and nursing care (table 3.2); according to Chi-square analysis there was a significantly greater risk of malnutrition in nursing care (54.2%) than residential care (38.6%) ($x^2(1)= 6.300$, $p= 0.012$).

Weight, weight change and BMI

The descriptive data for mean weights recorded at both T1 and T2 of these participants, weight change between the 2 discrete time points and BMI is shown in table 3.4. The mean weight of all participants at T2 was significantly lower than the mean weight taken previously at T1, mean difference of -0.4 kg ($F(1, 341)= 4.497$, $p=0.035$). When divided into care category, the mean weight at T2 was also significantly lower than T1 in nursing care, mean difference of -1.0 kg ($F(1, 83)=5.744$, $p=0.019$); there was no

significant difference in mean weights in residential care. When comparing residential care with nursing care there were no significant differences in weight at T2, weight at T1, weight change or BMI.

Table 3.4 Mean (SD) weight at T1 and T2, mean weight change between T1 and T2 and mean BMI of all participants and divided into residential and nursing care categories. *p<0.05; significantly different from T1.

	Residential	Nursing	Total
Weight T2 (kg)	60.2 (13.1)	61.0 (17.5)*	60.4 (14.3)*
Weight T1 (kg)	60.5 (13.1)	62.2 (17.4)	60.9 (14.3)
Weight change (kg)	-0.2 (3.4)	-1.0 (3.9)	-0.4 (3.6)
BMI (kg/m^2)	23.9 (4. 9)	23.5 (6.3)	23.8 (5.3)

Weight change was assessed according to BMI category; a significant main effect of BMI category was found (F(3, 341)= 2.985, p=0.031). Post-hoc analysis identified a significantly greater amount of weight loss in the VLW BMI category (-1.7 ±0.5 kg/m^2) than the healthy weight and overweight BMI category (-0.1 ±0.3 kg/m^2, p=0.037 and -0.11 ±0.3 kg/m^2, p=0.038 respectively) (figure 3.7).

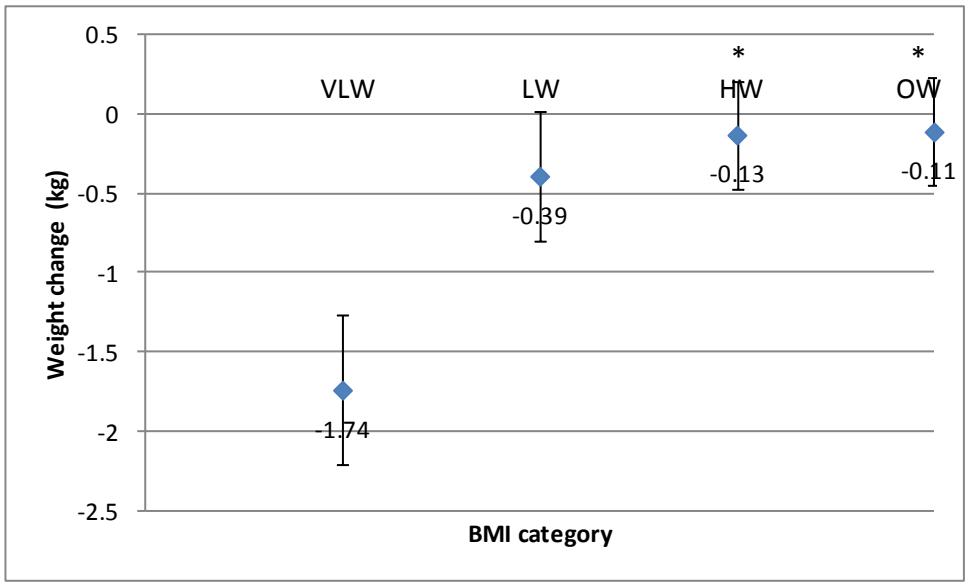


Figure 3.8 Weight change over 6 months (T1-T2) according to BMI category ('VLW'= very low weight, BMI <18.5kg/m^2; 'LW' = low weight, BMI 18.5-20kg/m^2; 'HW'= healthy weight, BMI 21-25kg/m^2; 'OW'= over weight, BMI >25kg/m^2. *p<0.05, significantly different from VLW category.

There was no significant effect of LOS in a care facility on weight, weight change or BMI for either residential or nursing care categories.

3.4.3 The follow-up

Risk of malnutrition

The risk of malnutrition at T1 was compared to risk of malnutrition at T2 (figure 3.9). Overall risk of malnutrition (medium + high) for all participants was 35.7% during T1 and 37.8% during T2. Risk of malnutrition was significantly correlated between T1 and T2 (r=0.7, p<0.01).

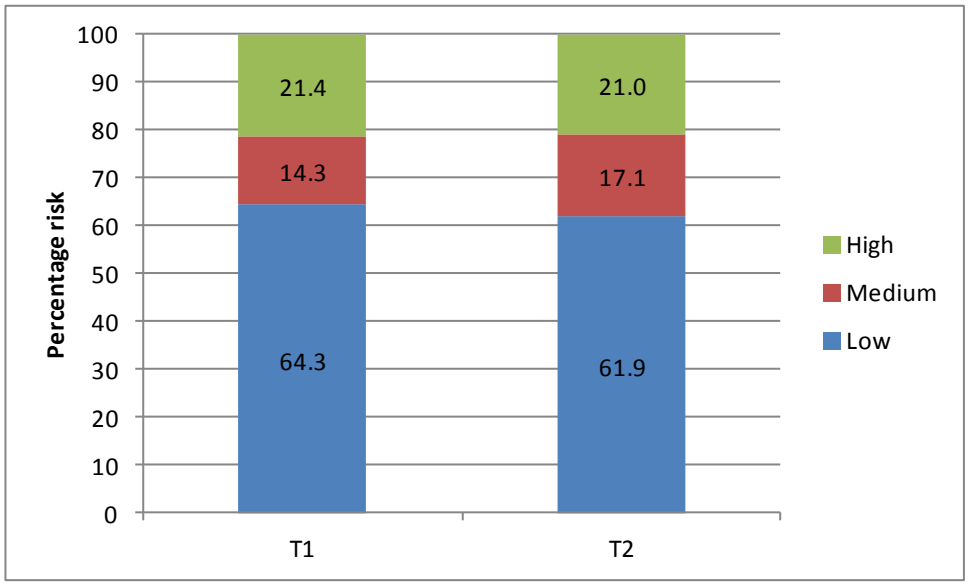


Figure 3.9 Percentage of MUST scores (low, medium and high risk of malnutrition) at T1 and T2 for all participants.

When participants were divided into residential and nursing care categories, the correlations remained significant (r=0.6, p<0.01; r=0.8, p<0.01 respectively). There were no significant differences of overall risk of malnutrition between T1 and T2.

According to care categories, 45 residential residents were at risk of malnutrition (medium + high) at T1. By T2 this number rose to 52 participants (x^2(1)= 66.166, p<0.01) (table 3.5). In nursing care, the number of participants at risk of malnutrition significantly declined from 30 at T1 to 28 at T2 (x^2(1)= 25.921, p<0.01).

Table 3.5 Movement (frequency) of all participants between MUST scores at T1 and T2.

		MUST score T1			
		0	**1**	**2**	**Total**
MUST score T2	**0**	111	12	7	**130**
	1	18	12	6	**36**
	2	6	6	32	**44**
	Total	**135**	**30**	**45**	**210**

Risk of malnutrition was significantly greater in nursing care (N=30 at risk, 50.8%) than residential care (N=45 at risk, 29.8%) at T1, $x^2(1)= 8.185$, $p<0.01$. No significant difference was found for risk of malnutrition in residential compared to nursing care at T2.

BMI

Overall a repeated measures ANOVA revealed that mean BMI did not significantly differ by time; T0 (24.99 kg/m^2), T1 (24.82 kg/m^2) and T2 (24.69 kg/m^2), nor were there any significant differences in BMI between residential care (T0; 25.07 kg/m^2, T1; 24.78 kg/m^2, T2; 24.12 kg/m^2) and nursing care (T0; 24.76 kg/m^2, T1; 23.09 kg/m^2, T2; 22.70 kg/m^2) at either time point.

BMI within the 'VLW' category significantly differed over time ($F(2, 20)= 3.776$, $p= 0.041$). BMI significantly declined between T0 (18.45 kg/m^2) and T1 (17.00 kg/m^2) ($p= 0.042$), however by T2, BMI had begun to increase (17.55 kg/m^2). There were no significant changes in BMI for all other BMI categories.

Weight change

There were no overall significant differences found between weight change at T1 (0.13 kg) and T2 (-0.54 kg), however there was a trend in increasing weight loss by T2 ($F(1, 205)= 3.384$, $p= 0.067$). In residential care, weight change significantly differed at T1 (0.33 kg) and T2 (-0.60 kg); more weight loss was observed by T2 ($F(1, 147)= 5.382$, $p= 0.022$). There were no significant differences in weight change between T1 and T2 in nursing care, nor were there any significant differences found in weight change

between residential and nursing home residents at either discrete time points or over a 12 month period.

Despite this, weight loss occurred at both T1 and T2; at T1, over 6 months 20.5% of participants had lost ≥5% of their body weight (MUST score 1) and 7.8% had lost ≥10% of their body weight (MUST score 2). At T2, 20.8% had lost ≥5% of their body weight and 6.2% had lost ≥10% of their body weight over the previous 6 months.

Weight change according to BMI

Once divided into BMI category, weight change between categories and over time was assessed. During the 6 months between T0 and T1, the 'VLW' BMI category had the greatest weight change (-3.7 kg ±1.0 kg; figure 3.10). However, by T2, weight in this category had stabilised and was beginning to increase with a mean weight change of 0.04 kg (±0.6 kg). The difference observed in weight change at T1 and T2 in the VLW category was significant ($F(1, 22)= 6.644$, $p= 0.006$). For those in the 'OW' BMI category weight change was also significantly different between T1 (1.71 kg ±1.0 kg) and T2 (-0.87 kg ±0.7 kg) ($F(1, 19)= 3.324$, $p= 0.027$); there was a net weight loss at T2.

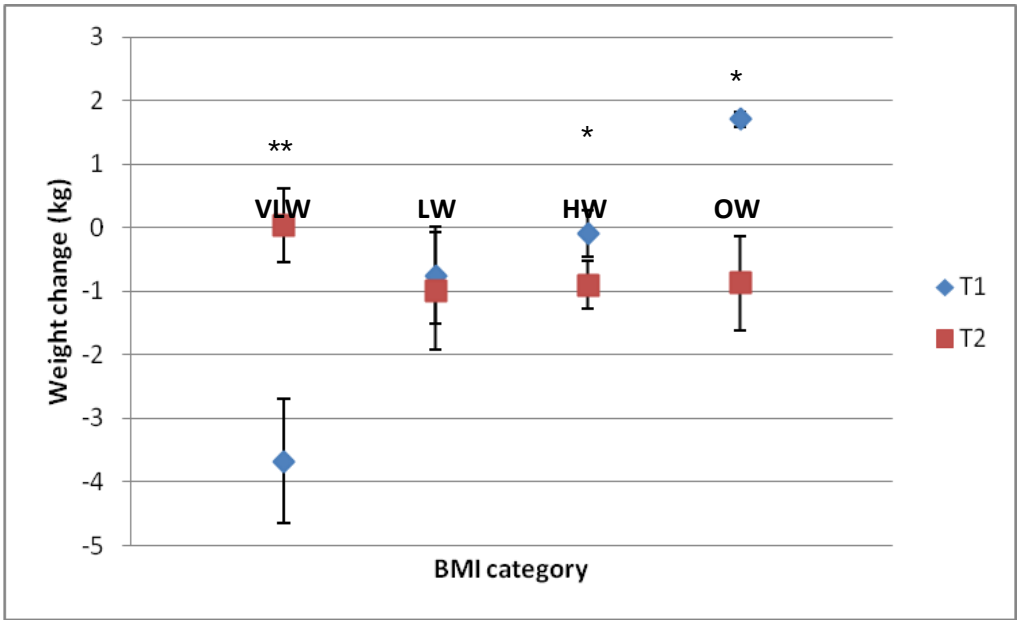


Figure 3.10 Weight change according to BMI category at T1 and T2. *p<0.05, significantly different from 'VLW' at T1. **p<0.05, significantly different between T1 and T2. 'VLW', N=24; 'LW', N= 26; 'HW', N=99; 'OW', N=20.

Repeated measure ANOVA showed that there was a main effect of BMI category in weight change between T1 and T2 ($F(3, 163)= 6.388$, $p<0.01$). Post-hoc tests revealed that this difference was between weight change in the 'VLW' category and in the 'HW' (mean difference of -3.58 kg ±0.7 kg), and between the 'VLW' and 'OW' category (mean difference of -5.39 kg ±0.9 kg, $p= 0.05$).

There were no significant differences in mean weight change over the total 12 month period between BMI categories (VLW, -3.70 kg; LW, -1.75 kg; HW, -1.01 kg; OW, 0.84 kg). However, when the mean weight change was pooled between a BMI of ≤20kg/m^2 and ≥21 kg/m^2, there was a significant difference in weight change over 12 months. Those with a BMI of ≤20kg/m^2 had a mean weight change of -2.7 kg over one year compared to -0.7 kg for those with a BMI of ≥21 kg/m^2 ($F(1, 165)= 3.941$, $p= 0.049$).

Residents in the VLW BMI category had the greatest percentage weight loss over 12 months compared to the other BMI categories; 61% of participants lost ≥5% body weight, and 39% lost ≥10% of their body weight. In contrast, the lowest weight loss was observed in the 'overweight' BMI category; 11% of these participants lost ≥5% bodyweight and 5% lost ≥10% of their bodyweight. There were no significant differences in percentage weight change over the total 12 month period between BMI categories (figure 3.11).

Weight change according to length of stay

There were no admission dates available for 5 participants. LOS had no significant effect on BMI at T1 or T2, nor was there an effect on weight change at T2 or over the total 12 months. However, at T1 there was a significant difference in 6 month weight change between LOS categories ($F(2)= 3.916$, $p= 0.021$). Participants in the ≥49 month category had an average weight change of -0.79 kg (±0.44 kg), whereas those in the 0-24 month category increased in weight on average by 1.06kg (±0.60 kg) ($p= 0.039$). This suggests that care home admission assists weight gain compared to residents who have been in care longer and whose conditions might be deteriorating.

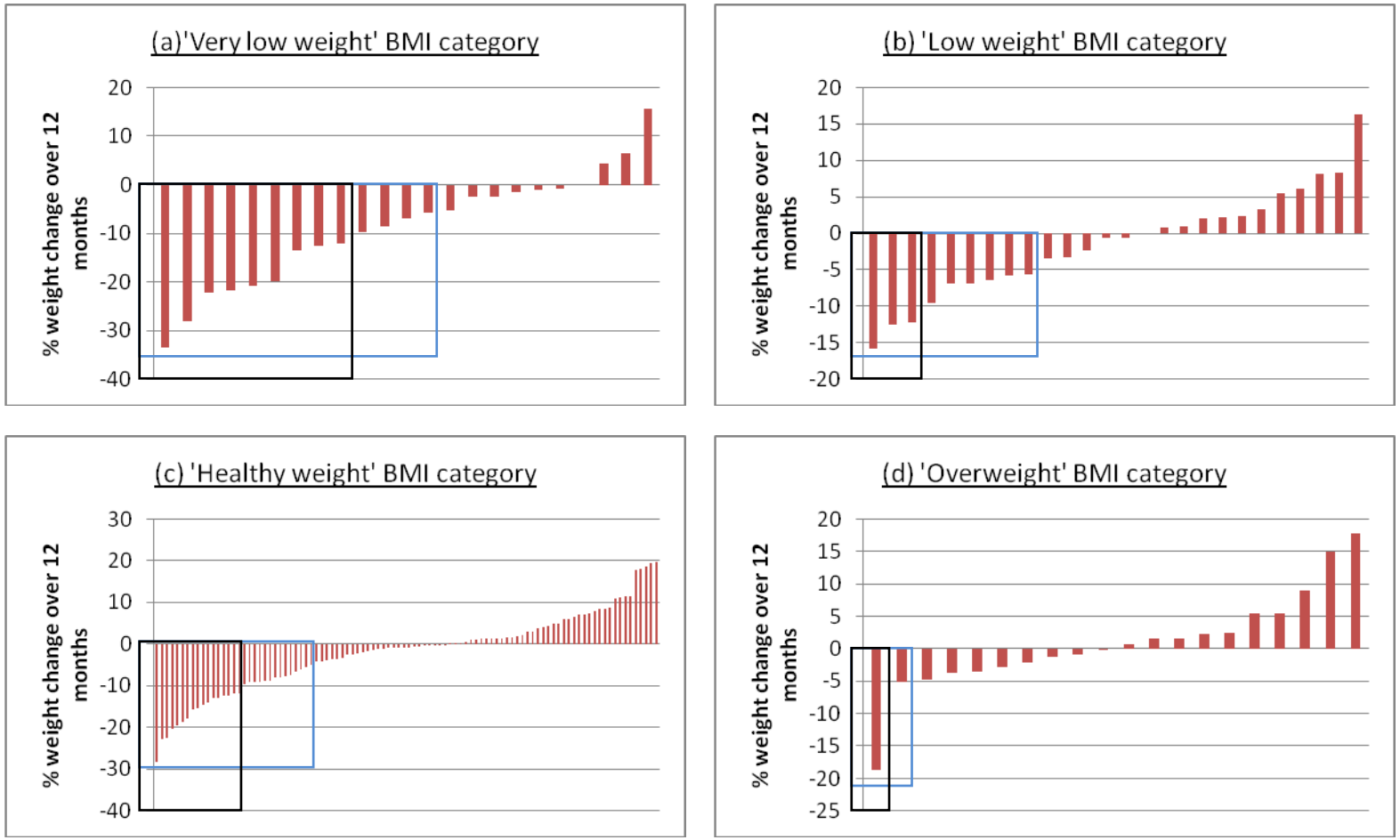


Figure 3.11 Weight change over 12 months for each BMI category. Boxed in blue are the participants who lost ≥5% of their body weight; boxed in black are participants who lost ≥10% of their body weight.

'At risk' areas

Once risk of malnutrition in each care home was calculated, care homes with the highest prevalence of malnutrition were plotted on a map of West Yorkshire; clusters of high risk of malnutrition areas are indicated by red circles in figure 3.12. These areas are local government/county council run, urban areas and so are expected to be of lower socioeconomic status as care homes are more likely to be funded by the council.

Figure 3.12 Map of West Yorkshire indicating the 2 areas of highest malnutrition prevalence in care homes. pink = rural district, blue = urban district, green = municipal district, orange = county borough.

3.5 Discussion

The aim of this research was primarily to assess the risk of malnutrition at 2 time-points in both residential and nursing care homes. Of those who participated at both T1 and T2 a follow-up could be conducted. It was hypothesised that, following advice given to care home managers regarding the amendment of care plans of those residents identified as 'at risk of malnutrition' at T1, overall risk of malnutrition would fall by T2 and would decline specifically in those participating in the follow-up.

Overall risk of malnutrition (medium + high) in care homes in West Yorkshire was calculated at 38% at T1 and 42% at T2. In those participating in the follow-up, risk of malnutrition was 36% at T1 to 38% at T2. There was no significant change in the prevalence of malnutrition risk between T1 and T2, and on this basis, the hypothesis was rejected. The follow-up study revealed significant correlations between MUST

scores at T1 and T2 suggesting an observed stability in risk of malnutrition. The results also suggest that for those residents within a healthy weight body weight is maintained.

The results of the present study suggest that BMI could be a predictor of weight loss in older adult care home residents. When weight loss was assessed according to BMI category, those in the lower BMI ('VLW') appear to be losing more weight, as was identified at T1. Once the weight of an older adult declines to the level of <20 kg/m^2, they may become more vulnerable and more susceptible to greater weight loss due to underlying illness and poor appetite which can both prevent these the older adult from reaching a stable, healthy weight. In addition to this, previous research has shown that older adults with a lower BMI consume less variety of energy dense foods, putting them at greater nutritional risk (Roberts et al., 2005), and that leaner older adults are at the greatest risk of weight loss (Rumpel, Harris and Madans, 1993). However, on identification by researchers, care home staff were made aware of these VLW residents after the initial screening and were debriefed with suggestions of ways to manage and treat malnutrition. This could explain the difference in weight change of these participants by T2; their weight appears to have stabilised and there is evidence of weight gain by this point.

Overall at T1, and at T1 in the follow-up, LOS in the care home significantly affected weight change. A length of stay of >25 months appeared to predict greater weight loss over a 6 month period, particularly in residential care. This suggests that the more time spent living dependently in a care facility, the greater the risk of an individual developing malnutrition.

Care homes with the highest risk of malnutrition were identified as being located in poorer, lower economically classed areas. Higher risk of malnutrition has previously been highlighted as associated with lower social class (Edington, Kon and Martyn, 1996); similarly Davies (1984) suggested that poverty was a primary source of malnutrition in older adults. Lower social class is a predictor of poor health status (Cheng et al., 2002); older adults in this economic situation rely on the state to fund their stay in care homes, increasing the risk of malnutrition.

Identification of malnutrition in care homes is largely dependent on the carers carrying out routine weight assessments and other care staff including nurses, who carry out

more detailed nutritional assessments. As is the case in hospitals, care home staff often have poor skills in recognising risk of malnutrition, or are limited due to time restrictions and work-loads to make a thorough nutritional assessment (McWhirter and Pennington, 1994).In a study identifying nurses attitudes and knowledge towards nutritional care, most indicted that their assessment of malnutrition was mainly focussed on more obvious physical signs such as weight loss, frailty and lethargy; most did not touch upon psychological factors that could be impacting on appetite such as depression and isolation (Kowanko, Simon and Wood, 1999).

One factor that may have contributed to the stability observed in MUST scores was the debrief given to care homes after screening at T1. Debriefs highlighted to managers the residents who were at risk of malnutrition and gave advice of precautionary actions to prevent any further weight loss in accordance with the management guidelines provided with MUST. Care homes revisited at T2 were asked if they had taken the debrief into account for the management of care plans; 4 care homes had passed the information onto a relevant HCP (GP, dietician, district nurse), 7 had identified those residents at risk and had introduced their own food intervention in an attempt to increase nutritional intakes (e.g. offered more snacks, fortified meals with high energy foods or observed nutritional intakes more closely). Of the remaining 8 care homes 5 were under new management and so it was not certain if any action taken was a result of the debrief, and 3 were unaware as to whether any was action taken.

The effect of debriefing care home managers is also highlighted when MUST scores are observed separately between residential and nursing care. In residential care, malnutrition risk significantly increased between T1 and T2; in contrast, in nursing care, malnutrition risk significantly declined between T1 and T2. An explanation for this could be that the increase in awareness and actions taken by nursing care home managers post-debrief that highlighted a high prevalence of malnutrition, promoted an active attempt to address the issue before the second nutritional screening survey. However, in residential care, a lower prevalence of malnutrition at T1 meant that there was less awareness of the risk of malnutrition, and therefore any developments of malnutrition in individuals could have gone unrecognised and therefore untreated.

Nevertheless, on all occasions there was a higher risk of malnutrition in nursing care than in residential care. These findings are in line with those of BAPEN from the UK

nutrition screening surveys of 2007, 2008 and 2010 (Russell and Elia, 2008; 2009; 2011); residents living in nursing care and needing 24 hour care are more vulnerable to malnutrition than those who live in residential care. Age related changes such a psychological and social changes as well as loss in physical and functional ability all impact to increase the risk of disease (Morley and Kraenzle, 1994); these changes are all observed more profoundly in nursing homes where residents have greater dependency issues. This higher level of dependency on care home staff within nursing home residents can have a major impact on an individual's health-related quality of life (HRQOL) (Amarantos, Martinez and Dwyer, 2001). HRQOL focuses on physical and mental health dimensional changes that can arise as a consequence of disease, ageing or alterations in functional status, and is closely related to an individual's emotional well-being. With a declining HRQOL, the ability to carry out ADLs (physical, psychological and social functioning required for independent living) also declines, and is commonly observed in nursing home residents (Amarantos, Martinez and Dwyer, 2001).

Many nutritional screening tools exist for the identification of malnutrition; in this case MUST was chosen as it has been extensively tested as a validated and reliable tool (Anthony, 2008; Elia, 2003), and allowed for a comparison between UK screening studies. As with any tool however, MUST is required to be implemented correctly in order to give the required results; it is therefore essential care staff have access to appropriate training. A useful method of training is the 'train-the-trainer' model which combines a formal day of teaching with an assessment. This has been shown to be an effective and realistic way of educating care staff in the correct use of MUST. By using this method, an increase in nutritional screening from 42% to 96% over 3 months was observed. During this time there was also an increase in the use of full-fat milk, snacking and the variety of food offered in care homes, all of which help to combat malnutrition (Lee and Scott, 2009). In care homes in the Wirral, a MUST training package was shown to be an effective method to monitor malnutrition risk, and provided sustainable improvement on nutritional care practices (Costa et al., 2010). At initiation of the present study, some of the care home managers had recently been advised to use MUST as the care homes nutritional screening method, however a number reported that appropriate training was not always provided. As a standard procedure, care homes record monthly weights in residents care plans but unless the

weights are reviewed from previous month, weight loss can go unnoticed and therefore appropriate action is not always taken.

The prevalence of malnutrition remains high in older adult care home residents, however once those at risk of malnutrition are identified, appropriate action takes place to maintain weight stability over 6 months. There is still as need to increase awareness of the nutritional needs of care home residents, particularly for those who are frailer and therefore more vulnerable to malnutrition. The identification of malnutrition needs to efficient so that methods to treat and prevent further weight loss can be implemented quickly and appropriately. Through a use of a follow up, care staff could be supported and trained to continue giving appropriate high standard nutritional care

Chapter 4: The use of food fortification and ONS to increase nutritional intakes. Is food first the best option?

4.1 Introduction

Once malnutrition (or risk of malnutrition) is identified, and providing the underlying cause (such as illness) is addressed, methods to increase nutritional intakes can be initiated; this can be done through food related strategies such as food fortification, or medically by ONS. Although evidence suggests that malnutrition in older adults can be treated by nutritional supplementation (Nutrition Action Plan Delivery Board, 2009) clinical practice promoted by dieticians (NHS Leeds, 2010) is to use 'food first' before resorting to supplementation. The efficacy of this strategy has not yet been established (NICE, 2006). Interventions using food fortification as a 'food first' approach have not demonstrated the same reduction in mortality observed with ONS in malnourished patients (NICE, 2006; section 1.7, table 1.5). NHS Leeds (2010) promote 'food first' as the initial choice of treatment, and use ONS as a final resort despite the evidence of the effectiveness of ONS; this is because of the poor compliance rates recorded for ONS prescriptions and the economic cost associated with this. To date there have been no direct comparisons of dietary treatments such as food fortification, snacking or dietary advice, alone or in combination with ONS in care homes (Stratton and Elia, 2007).In addition to this, there has been no research assessing compliance to ONS when it is treated as food fortification and incorporated into meals. A reason for this could be the difficulty in the measurements of nutritional intakes in care facilities.

Assessment of nutritional intake in care homes relies on staff to document the total percentage of food and fluid consumption at each meal. Simmons and Reuben (2000) reported that this had low levels of accuracy as staff significantly over-estimate food intake by around 22% relative to direct observation. This was calculated on the basis of a comparison between 3 nutritional assessment methods (care home staff chart documentation, researcher direct observation documentation, and researcher documentation according to photographs of residents meal trays before and after each meal). Moreover, care home staff failed to identify 53% of residents whose intakes were ≤75% at most mealtimes signifying a clinically relevant eating problem. Although both

direct observation documentation and photograph documentation gave the same results, the photography method was suggested as the more advantageous method as it does not require an observer to be present to record nutritional intakes.

Similarly, Reed et al. (2005) noted discrepancies between staff reported eating and drinking difficulties and the observed prevalence of difficulties recorded by researchers. Discrepancies may arise from the under-recognition of problems associated with oral intakes, such as resident dependency (unresponsive or non-alert residents, poor utensil use, and problems with postural movement) or the lack of attention to this level of detail from different care home staff in comparison to that captured at the single meal observation of the research. Overall, the study found that 54% of the cognitively impaired resident participants had low food and fluid intakes of ≤75% at mealtimes. The prevalence of low intakes was greater in nursing homes than in residential homes (50.4% and 61.8% respectively), however residential care homes were significantly less likely to be assessed for difficulties in eating and drinking than nursing homes, and also less likely to be treated and assisted either informally by care home staff or professionally through HCP input (Reed et al., 2005).

4.1.1 Current recommendations to improve nutritional intakes in older adults

Food Fortification

The food first approach is based around improving food and nutrient intake by increasing food frequency, increasing the consumption of energy and nutrient dense foods and fortifying foods to increase nutrient density. Small but frequent meals are encouraged incorporating energy and nutrient-rich foods such as lean meat, fish, eggs and full-fat dairy products. Frequent snacking of high energy foods and drinks is encouraged to provide additional calories. It has been recommended that food fortification be the first line of treatment for malnutrition in patients that are able to eat a normal diet but who are not meeting sufficient nutritional quantities (Thomas, 2001). Food fortification is advised to increase energy and nutrient value of foods without affecting the volume; butter, milk, cream, vegetables, honey, jam and sugar can be added to meals or snacks (Thomas and Bishop, 2007). Alternate to food fortification, commercially available energy or protein supplements can be added to the diet

delivering extra energy primarily through glucose polymers, lipid emulsions, protein supplements or combined protein and energy supplements (Stratton, 2005).

The effectiveness of food fortification on nutritional intakes addressed in the literature is variable; as described above, some studies have resulted in a successful increase in energy intake through food fortification but with no increase in protein intakes (Olin et al., 2996; Barton et al., 2000; Odlund Olin et al., 2003). Although food fortification is suggested as a low cost option to increase nutritional intakes, there is no evidence regarding the use of food fortification in patient recovery (Stratton, 2005). Furthermore, older adults suffering from malnutrition are often deficient in micronutrients (vitamins and trace elements) (Finch et al., 1998; Elia and Stratton, 2004); food fortification may increase energy but without concurrent improvement in micronutrient intakes (Stratton, 2005).

Oral nutritional supplements

The typical composition and use of ONS is described in detail in section 1.8. A review of reviews (Stratton and Elia, 2007) suggested that ONS are a good method of treating malnourished patients. According to the review, ONS have little effect on appetite or nutritional intake at meals, therefore the addition of ONS to the diet can increase total energy and nutrient intakes i.e. the increase in energy intake is additive to normal food intake.

Thus far there have been no studies comparing the use of food fortification with the use of ONS on intakes during mealtimes. Furthermore, no studies have combined the practiced method of food fortification with ONS to increase nutritional intakes; ONS can be incorporated into meals (e.g. into sauces), not only to increase energy and protein density but also to increase the micronutrient content of the meal. This may be more beneficial to older adults as typically, food fortification using food products tend to add only fats (butter, cream and cheese) and some carbohydrates in the form of honey or glucose polymers to increase the ED, but protein and micronutrient content stays the same. In the study by Barton et al. (2000), the ED of the daily foods offered were increased by 200 kcal, however total protein provisions dropped by 5g/day. This resulted in an increase in energy intake by 25% during the intervention period, but failure to increase protein intakes.

4.2 Aims and Objectives

Study 1 aimed to compare nutritional intakes when an ONS is given overtly, assessing physiologic and cognitive responses, with ONS given covertly (incorporated into a meal) assessing just the physiologic responses to the meal.

In study 2, there were 2 more conditions added to the intervention. In this study the aim was to assess and compare differences in nutritional intakes between a meal given with no manipulation (NM) as a control; with extra nutrition in the form of food fortification (FF); with ONS given overtly (OS); and with ONS given covertly (CS) (see table 4.1 for full description of conditions).

It was hypothesised that in study 1, meals given with covert ONS would yield higher nutritional intakes than meals given with overt ONS. Similarly, in study 2, it was hypothesised that intakes would be highest in the CS condition and FF condition, whereby extra nutrition is given by stealth, and lower in the OS condition in which the extra nutrition added a cognitive component to the meal. Nutritional intakes were expected to be lowest in the MN condition.

4.3 Study 1

4.3.1 Method

Participants

Letters were sent to the managers of residential care homes in Leeds detailing information about the research and inviting the care home to take part. Only residential care homes were selected for this stage of the research as it was essential that participants would be able to communicate their opinions to rate feelings of satiety and preferences towards food, and to answer questions about their appetite. It was originally decided to approach only residents identified as ‘at risk’ of malnutrition, however due to the frailty and capacity of these residents it was not possible to include them in the research. Many people who are at risk of malnutrition are also diagnosed with dementia or other co morbidities and so cannot communicate their opinions or understand the test procedure.

One week after letters of invitation were sent to care homes, the researcher contacted the care home managers via phone call; managers were asked if they had received the letter, if they had had time to read the letter, if they were interested in taking part, and if they thought there were any residents living at their care home who would be able to take part and who would enjoy inclusion in the study. If managers were not willing to participate they were thanked for their time. Main reasons for non-participation were; no residents would be able to take part (lacked capacity to complete the study); managers too busy to take part; in 2 cases the care homes were under new management and therefore going through a transition period; not interested in taking part.

In total 16 invitations were sent out, 5 care home managers were interested in the study and were visited by the researcher for an initial meeting. At this stage, 1 care home manager declined participation due to the length of the intervention. Four care homes took part and consent was gathered from 11 participants, 8 of which were female. Mean age of participants was 83 years (71-93 years), mean weight was 60.0 kg (±3.3 kg), and mean BMI was 22.8 kg/m^2 (±1.4 kg/m^2).

Ethical considerations

Prior to each study, full ethical approval was granted by the University of Leeds, Institute of Psychological Sciences ethics committee; ethics reference number 11-0118. Participants were asked to give either written or verbal consent; in the case that verbal consent was given it was witnessed by a member of care home staff who was then asked to sign a consent form on the participant's behalf. Participants were informed that they could withdraw from the research at any point without giving a reason.

Materials and measures

Risk of malnutrition and appetite assessment

On the first day of the 4 week study, the researcher took demographic details of date of birth and gender, and used MUST (section 3.3.3; appendix 3.1) to assess each participant's risk of malnutrition. Participant's self-perceived appetite and risk of weight loss was assessed through the administration of SNAQ (simplified nutrition appetite questionnaire) (appendix 4.1). There are a number of nutritional risk assessment tools used in hospitals, care homes and the community that are lengthy to complete and evaluate multiple interdependent nutritional domains, for example the MNA (Guigoz,

Vellas and Garry, 1994) and SCREEN (Keller, Hedley and Brownlee, 2000); table 1.4 in section 1.4.2 gives more details of these tools along with other commonly used tools. Most tools fail to assess appetite as a single construct to predict weight loss. Monitoring appetite in older adults through the use of the validated tools CNAQ (council on nutrition appetite questionnaire) and SNAQ identifies those at risk of significant weight loss (Wilson *et al.*, 2005). CNAQ is the original 8-item tool in which responses to questions are made using a 5-point Likert scale labelled A-E. Scores to the questionnaire are based on the sum of the responses to the 8-items; the lower the score (ranging from 8-40), the greater the deterioration in appetite. SNAQ consists of 4 of the original 8-items, scored in the same way but ranging from 4-20. The items and example responses are: 'My appetite is [average]'; 'When I eat [I feel full after eating over half a meal]'; 'Food tastes [good]'; 'Normally I eat [two meals a day]'. Those who score <28 with CNAQ or <14 with SNAQ are likely to have frank anorexia and be at risk of weight loss. Wilson et al. (2005) suggests that the short item tool (SNAQ) is comparable to CNAQ and is more effective in a clinical/health care setting. For older adults, routine use of SNAQ facilitates the early detection of anorexia. SNAQ scores were compared against the results from MUST so that loss of appetite could be identified in the context of malnutrition risk. In the present study, the researcher asked participants the questions related to SNAQ so as to ensure they could understand each question asked and gave answers in the correct manner.

Subjective ratings

Immediately before the participants received their test meals they were asked to fill out a 5-point Likert scale questionnaire; they were asked to rate how hungry they were, how full they were and how intense their desire to eat was at that moment. Once participants had received their meal and had taken the first bite they were asked to rate the taste and texture of the meal. After completion of the meal, questions of hunger, fullness and desire to eat were repeated (appendix 4.2).

ONS products

Two types of ONS were used in study 1 (table 4.1); Fortisip Bottle (neutral) was given in the overt condition, on the side of the meal, and Fortisip Savoury Multi Fibre (tomato) was incorporated into the tomato sauce of the meal in the covert condition. Both products are nutritionally complete, contain high energy, come ready to drink and are used medically to manage disease-related malnutrition.

Table 4.1 Macronutrient and energy composition of Fortisip Bottle and Fortisip Savoury Multi Fibre (per 100ml).

	Fortisip Bottle	Fortisip Savoury Multi-Fibre
Carbohydrate (g)	18.4	14.3
Protein (g)	6.0	7.5
Fat (g)	5.8	7.0
Energy (kcal)	150	150

Meal composition

Meals were developed so that ONS could be given in an overt and covert manner (table 4.2). Before the first test day, participants were asked to try a sample of the lasagne and rate it on a 5-point Likert-scale for taste, texture and desire to eat a full portion to ensure adequate acceptance of the foods before subsequent test days. The total macronutrient and energy content of the plain meal and the breakdown for the ONS (overt and covert) and food fortification conditions are shown in table 4.3.

Table 4.2 Meal ingredients list for lasagne.

Product and weight/volume	Carbohydrate (g)	Protein (g)	Fat (g)	Energy (kcal)
Beef mince (100g)	-	20.3	15.3	219
Dolmio bolognaise sauce (100ml)	7.3	1.5	1.3	50
Garlic (10g)	1.6	0.8	-	10.2
Dolmio lasagne white sauce (100ml)	6.9	0.5	7.5	98
Olive oil (10ml)	-	-	9.1	82
Medium cheddar (30g)	-	7.5	10.3	123
Lasagne sheets (50g)	31.3	6.4	1.6	165.5
Fortification (50g crème fraiche, 50g light soft cheese)	4.3	7.0	13.1	162.5

Table 4.3 Macronutrient and energy composition of lasagne (full meal) with no manipulation, with ONS and with food fortification (FF).

	Carbohydrate (g)	Protein (g)	Fat (g)	Energy (kcal)
Lasagne	47.1	37.0	45.1	747.7
with ONS (neutral)	65.5	43.0	50.9	897.7
With ONS (tomato)	61.4	44.4	52.1	897.7
with FF	51.4	44.0	58.2	910.2

Food intake

Food intakes were measured by weighing the complete meal before the participant received it and repeating this measurement once the participant had finished eating deriving the weight of food left over. From these measurements the weight of food eaten at the meal could be calculated and transformed into a percentage of the total meal offered. Macronutrient intakes were calculated from this percentage (table 4.3). By measuring the percentage consumed of the full meal (meal + ONS) offered in the covert

condition, the percentage of ONS consumed could be estimated. In the overt condition, 100ml of ONS was measured out and presented to the participant in a glass on the side of the meal. Left over ONS was measured and ONS intake calculated. ONS intake was added to the meal intake in this condition to give an overall intake.

Procedure

Study 1 was carried out over 4 weeks with 2 exposures repeated per condition. ONS were either given in a glass on the side of the meal as overt supplementation (OS) or ONS was incorporated into the sauce of the meal as covert supplementation (CS) (table 4.4). The order in which the conditions were presented was cluster randomised by care home as most participants ate together at the same dining table and so it was important that they received the same meal.

The researcher visited once a week on the same day for 4 weeks half an hour before lunch was served in the care home. Meals were prepared and weighed before the visit in the Human Appetite Research Unit at The University of Leeds; these were then transported to the care home to be heated in the kitchen on arrival. The test meal provided was a lasagne meal, details of which can be found in table 4.2 and table 4.3.

Participants were told that they could eat in their normal environment, whether that was in the dining room or in their bedroom. On the first test day participants were asked questions about their appetite using SNAQ, and had their MUST scores calculated. On each test day, before participants received their meal they were asked to fill out subjective measures for feelings of hunger, fullness and desire to eat; this was done using a 5-point Likert scale ranging from (for example) ‘Not hungry at all’ to ‘Extremely hungry’. Once the participants were given their meal they were told to eat as little or as much as they wished, or until they felt full. After the first bite of their meal, they were asked to rate the pleasantness of the taste and texture of the meal using a 5-point scale (‘Very unpleasant’ to ‘Very pleasant’). Participants were left to have their meal. Once participants had finished eating were asked to rate their feelings of hunger, fullness and desire to eat for a second time. Participants plates were cleared and any leftover food was taken away to be weighed so that overall intake could be calculated.

Statistical Analysis

Mean intakes of test meals at each of the 4 exposures (2 exposures for each condition) were calculated in terms of weight consumed, energy (kcal) intake and intake of carbohydrate (g), protein (g) and fat (g). Repeated measures ANOVA was used to check for differences between the 4 exposures, and Bonferonni post-hoc was applied to decipher where specific differences could be found between exposures.

Mean intakes of energy, carbohydrate, protein and fat were calculated for each condition (the mean of the 2 overt exposures and the mean of the 2 covert exposures). Paired-sample t-tests were used to find differences between the means of the 2 conditions.

Measured intakes of the full test meal (meal + ONS) were divided into energy and macronutrient contribution from the meal, and energy and macronutrient contribution from the ONS. For the covert condition, intakes were an estimation based on the percentage weight eaten; as ONS was incorporated into the sauce of the meal, the assumption was made that the same percentage ONS was eaten as the percentage of the meal. Repeated measures ANOVA was applied to test for differences in intakes of energy and macronutrients between conditions from the meal alone and from the supplement alone. This data was also transformed into percentage data.

Likert scale ratings were recorded in numerical form, an ANOVA was run to assess differences between pre- and post- test meal ratings of hunger, fullness and desire to eat. Pearson's correlation was also applied to check for associations between ratings and included ratings for taste and texture between exposures.

The cost of the plain lasagne meal was approximately £2.75 per portion. The cost of 1 (200ml) ONS is approximately £1.71 (NICE, 2006) in the community, and therefore £0.86 per 100ml. From these figures the cost of the meal and ONS leftover (wastage) after each exposure was calculated to assess differences in economical effectiveness of each condition.

4.3.2 Results

Risk of malnutrition and appetite assessment

According to SNAQ, 9 participants were at risk of malnutrition with a score ≤14; mean score on SNAQ was 11.8 ranging from 6-16. MUST scores highlighted only 5 participants at risk of malnutrition; 3 at high risk, 2 at medium risk and 6 at low risk. There were no significant correlations between SNAQ scores and meal intake, or ratings of hunger, fullness and desire to eat.

Mean intakes at each meal

Intakes were analysed using a repeated measures ANOVA for comparison between exposures; 4 in total, 2 for each condition. There was no significant difference in the mean weights of food eaten at each exposure or in mean energy intake at each exposure (figure 4.1).

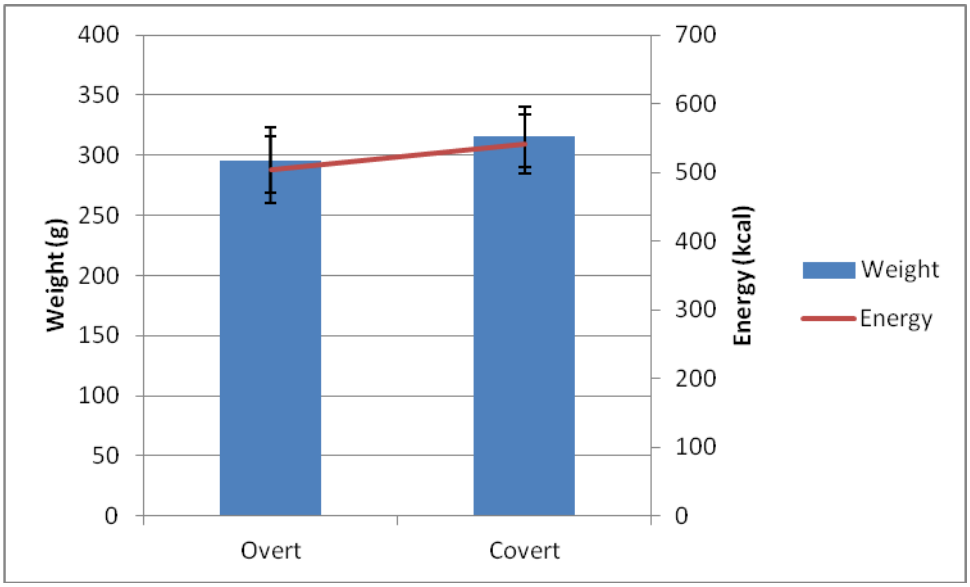


Figure 4.1 Pooled mean (SEM) of total intake (meal + ONS) from the 2 exposures of each condition (overt and covert). Intake measured as weight (g) consumed and energy (kcal) consumed.

A significant difference of protein intake was found between conditions ($F(3, 24)= 3.129$, $p= 0.044$); Bonferonni post-hoc revealed that this difference was between an overt exposure (26.2g) and a covert exposure (32.5g), intake of protein was significantly

greater in the covert condition than overt condition (p=0.046). There were no significant differences in carbohydrate or fat intakes between the 4 exposures.

The mean total intakes at each exposure were pooled for each condition; overt and covert (figure 4.2). There were no significant differences between the weight consumed in the overt condition (292.59g ±25.25g) compared to the covert condition (315.59g ±20.41g). The intake of protein was significantly higher in the covert condition compared to overt condition with a mean difference of 4.5g (±1.72g) (F(1, 10)= 4.633, p= 0.025). Similarly, fat intake was significantly higher in the covert than overt condition with a mean difference of 4.3g (±5.64g) (F(1, 10)= 3.534, p= 0.030). There were no significant differences in carbohydrate intake between the 2 conditions.

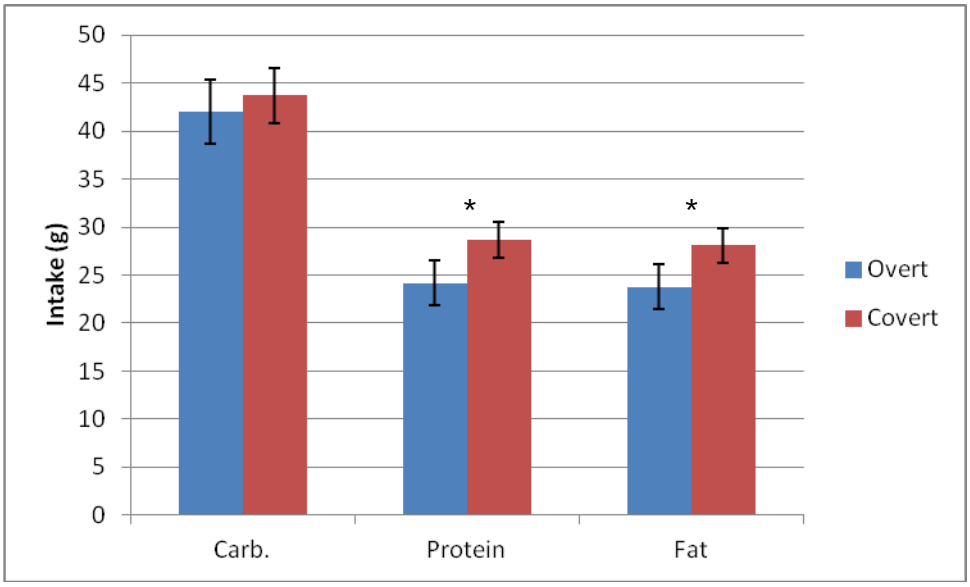


Figure 4.2 Pooled mean (SEM) of total intake of macronutrients (meal + ONS) from the 2 exposures of each condition (overt and covert). *p<0.05, difference between overt and covert conditions.

Mean intakes in each condition were calculated separately for meal consumption alone and ONS consumption alone. There were no significant differences in carbohydrate, protein or fat intakes from ONS between overt and covert conditions. There was a trend towards a difference in carbohydrate (mean difference of 6.1g, F(1, 10)= 2.032, p= 0.070), protein (mean difference of 4.2g, F(1, 10)= 2.023, p= 0.070) and fat (mean difference of 4.2g, F(1, 10)= 2.032, p= 0.070) intakes just from the meal; these trends suggest that there were higher intakes of all 3 macronutrients in the covert condition.

In the overt condition, mean percentage of the ONS consumed was 72.1% (±12.2%), and mean percentage of meal consumed was 51.0% (±6.8%). Mean percentage of the meal and ONS consumed in the covert condition was 61.9% (±4.0%). There were no significant differences of ONS consumed between conditions, however there was a trend in difference between the percentage of the meal consumed; intake of the meal was greater in the covert condition than overt condition ($F(1, 10)= 2.032$, $p= 0.070$).

Likert ratings

There were no significant differences between the 4 exposures in appetite ratings pre- and post- meal (statistics presented in appendix 4.3), nor were there any significant difference in mean ratings for the overt and covert conditions (figures 4.3 and 4.4).

Mean ratings of pre-hunger and pre-desire to eat were positively, significantly correlated (r=0.913, p<0.001). Pre-desire to eat and pre-fullness were negatively, significantly correlated (r=-0.775, p=0.005). Ratings for taste and texture were also significantly correlated (r=0.959, p<0.001).

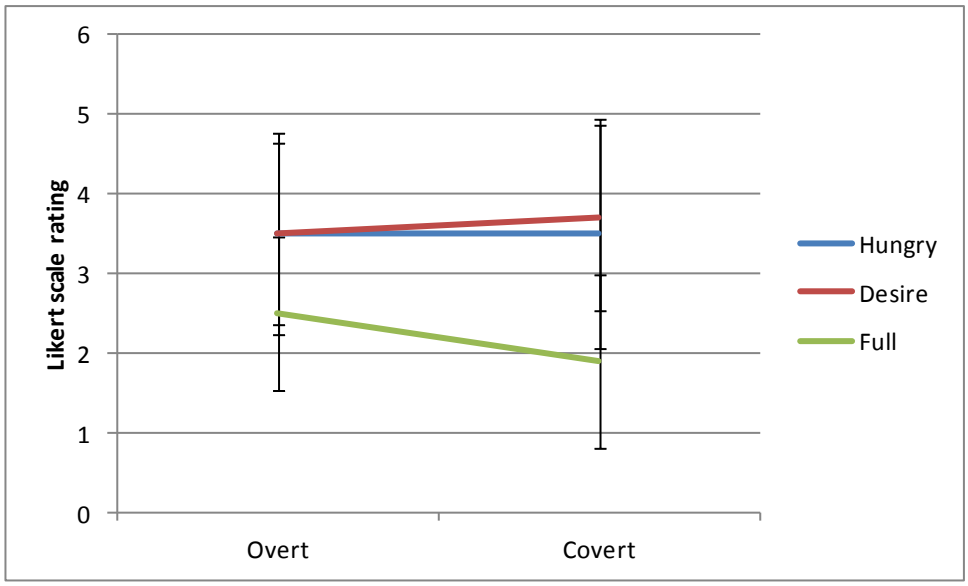


Figure 4.3 Pooled mean (SD) ratings of hunger, desire to eat and fullness pre- test meal (immediately before test meal was given) in the overt and covert condition.

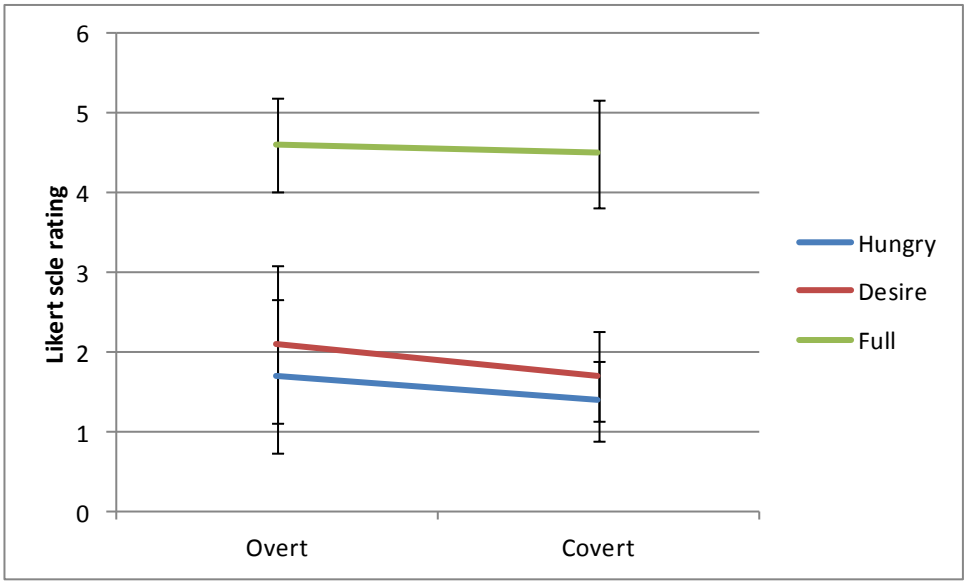


Figure 4.4 Pooled mean (SD) ratings of hunger, desire to eat and fullness post- test meal (immediately after test meal was removed) in the overt and covert condition.

There were no significant differences in mean ratings for taste or texture of the meals between the overt and covert conditions. In the overt condition, mean rating for taste was 4.1 and for texture was 4.3, and in the covert condition, mean taste rating was 4.0 and 4.5 for texture.

Wastage cost

Wastage costs were calculated for the meal and ONS based on the volume served compared to the volume consumed. The mean wastage cost of the meal alone in the overt condition was £1.35, and of the ONS alone was £0.24. In the covert condition, mean wastage cost of the meal alone was £1.04 and of the ONS alone was £0.33. There was no significant difference in meal alone wastage cost between conditions although there is a trend towards higher wastage in the overt condition ($t(10)=2.032$, $p=0.070$). There was no significant difference in wastage costs of the ONS alone between conditions. The total cost of wastage (meal + ONS) was calculated at £1.59 in the overt condition and £1.37 in the covert condition; there were no significant differences between conditions.

4.3.3 Summary of findings

The results of study 1 are summarised as follows:

- Intakes of protein and fat were greater in the covert condition than the overt condition.
- No significant differences in overall weight or energy of food consumed, and no overall difference in the volume of ONS consumed at each exposure.
- Percentage consumption suggests that more of the ONS is eaten, and less of the meal in the overt condition compared to the covert condition. A trend suggests that there were greater intakes of the meal in the covert condition than overt condition.
- No difference in ratings of hunger, fullness and desire to eat pre- and post- test meals between conditions; participants were at a similar state of hunger on each test day prior to receiving the test meal, and ate until satiation once the meal was given.
- Trend for a higher wastage cost of the meal given in the overt condition compared to covert condition, but wastage of the ONS was lower in the overt condition than in the covert condition, suggesting that ONS intake displaces meal intake to a small extent.

4.4 Study 2

4.4.1 Method

Participants

Recruitment of participants was done in the same way as with study 1. The care homes contacted in this instance were different from the care homes contacted for study 1. A total of 12 care homes received invitation letters, only 2 of which were interested in participating in the study. There were 7 participants consented onto study 2, all of which were female with a mean age of 88 years (72-99 years). Mean weight of participants was 56.5 kg (SD 14.9 kg) and mean BMI was 23.6 kg/m^2 (SD 4.3 kg/m^2).

Materials and Measures

As in study 1, on the first day of the 4 week intervention, the researcher recorded demographic details of the participants and calculated MUST scores in order to assess malnutrition risk. Participant's completed SNAQ with the assistance of the researcher for the assessment of appetite and risk of weight loss.

Immediately before the participants received their test meals they were asked to fill out the same 5-point Likert scale questionnaire used in study 1; participants rated how hungry they were, how full they were and how intense their desire to eat was at that moment. Participants rated the meal for taste and texture after the initial bite of their test meal. Ratings of hunger, fullness and desire to eat were repeated once participants had finished their meal (appendix 4.2).

Table 4.1 details the 4 conditions for the 4 test meal exposures during the intervention. Measurements of food intake were calculated in an identical manner to measurements made in study 1 but with 2 extra conditions added to study 2; a control condition with no manipulation of the test meal and a food fortification condition in which extra nutrition was added through food (cheese and crème fraiche) (see table 4.4). Contributions of energy and macronutrients from just the meal, just the ONS and just the food fortification were also calculated in this study.

Procedure

Study 2 was carried out over 4 weeks; in each week participants were exposed to a different condition. Each exposure occurred once for each condition. Table 4.4 gives the details of each condition. The order in which the conditions were presented to participants was cluster randomised by care home, for logistical reasons it was important that participants in the same care home received the same meal on each test day.

Research visits were made once a week for 4 weeks; test days were always on the same day of the week and at the same time. Meals were prepared and weighed before the visit in the Human Appetite Research Unit at The University of Leeds. The test meal provided was a lasagne meal, details of which can be found in table 4.2 and table 4.3. The researcher transported the pre-prepared meals to the care home and entered half an

hour before the lunch time meals were served. The meals were re-heated in the care home kitchen ready for service.

Table 4.4 Description of the 4 conditions of the intervention and an overall combined ONS group.

Condition	Description
NM	Plain meal; no manipulation
FF	Food fortification; extra cream/cheese incorporated into meal
OS	Overt ONS; ONS given on the side of plain meal
CS	Covert ONS; ONS incorporated into meal
OS+CS*	Combined data; mean of OS and CS

**Note: OS+CS was the combined data of OS and CS, not a condition received by the participants*

Pre-intervention measures of appetite (SNAQ) and risk of malnutrition (MUST) were calculated on the first test day. On each test day participants were instructed that they could eat in their normal environment, either in the dining room with other residents or alone in their bedroom. Before participants received each meal they were asked to fill out subjective measures for feelings of hunger, fullness and desire to eat; this was done using a 5-point Likert scale ranging from (for example) 'Not hungry at all' to 'Extremely hungry'. Once the participants were given their meal they were told to eat as little or as much as they wished, or until they felt full. After the first bite of their meal, they were asked to rate the pleasantness of the taste and texture of the meal using a 5-point scale ('Very unpleasant' to 'Very pleasant'). Participants were left to have their meal. Once participants had finished eating were asked to rate their feelings of hunger, fullness and desire to eat for a second time. Participants plates were cleared and any leftover food was taken away to be weighed so that overall intake could be calculated.

Statistical analysis

Mean intakes of test meals at each of the 4 exposures (1 exposure for each condition) were calculated in terms of weight (g) consumed, energy (kcal) intake and intake of carbohydrate (g), protein (g) and fat (g). As with study 1, repeated measures ANOVA was applied to check for differences between the 4 exposures, followed by Bonferonni post-hoc test to identify specific differences between conditions.

Measured intakes of the full test meal (meal + ONS) were divided into energy and macronutrient contribution from just the meal, and energy and macronutrient contribution from just the food fortification and ONS (extra nutrition). For the food fortification and covert condition, intakes were estimated based the percentage weight eaten; as the extra nutrition was incorporated into the sauce of the meal, the assumption was made that the same percentage of extra nutrition was eaten as the percentage of the meal. Repeated measures ANOVA was used to test for differences in intakes of energy and macronutrients between conditions from just the meal and from just the food fortification and ONS.

Data collected from the OS and CS conditions were combined and a mean of the two conditions calculated. This gave the overall effect of supplementation (OS+CS), which could then be compared to NM and FF for energy and macronutrient intakes of the complete meal with extra nutrition, and for the meal alone using repeated measures ANOVA, and could also be compared to FF for the contribution of the extra nutrition, again using a repeated measures ANOVA.

Likert-scale ratings were converted into numerical form, and ANOVA was run to assess differences between pre- and post- test meal ratings of hunger, fullness and desire to eat. Pearson's correlation was also applied to check for associations between ratings and included ratings for taste and texture between conditions.

As with study 1, the cost of the plain lasagne meal was approximately £2.75 per person per meal, and he cost of 1 ONS is approximately £1.71 (NICE, 2006) in the community, and therefore £0.86 per 100ml. The cost of adding extra nutrition through food fortification per person per meal was £0.41. From these figures the cost of the meal, FF and ONS leftover (wastage) after each exposure was calculated to assess differences in economical effectiveness of each condition.

4.4.2 Results

Risk of malnutrition and appetite assessment

Risk of malnutrition was assessed using MUST and SNAQ. According to MUST, 4 participants had a score of 0 indicating low risk of malnutrition; the remaining 3 participants had a score of 1 indicating medium risk of malnutrition. However, with

reference to SNAQ, 4 participants scored ≤14 indicating risk of malnutrition. SNAQ scores did not significantly correlate with intakes in any of the 4 conditions. However, SNAQ scores were significantly correlated with ratings of hunger and desire to eat in the NM condition (r= 0.837, p= 0.019; r= 0.769, p= 0.043).

Mean intakes of complete meal provided

Mean weight and energy intake of food consumed (meal + extra nutrition) is shown in figure 4.5. There was no significant difference in weight of food consumed between conditions; NM= 157.4g, FF= 174.9g, OS= 230.5g and CS= 165.3g. According to the mean energy intake of food consumed, intake was greatest in OS (521.0 kcal) and lowest in NM (318.6 kcal). There were no significant difference between energy consumed in each condition, although there was a trend for meal intake to be greatest in the OS condition (F(3,15)= 2.798, p= 0.076).

When OS and CS were combined (OS+CS), there was a significant difference in energy consumed between groups (F(2, 12)= 6.400, p=0.013). Significantly more energy was consumed in the ONS condition (453.0 kcal) compared to NM (294.1 kcal) (p=0.024).

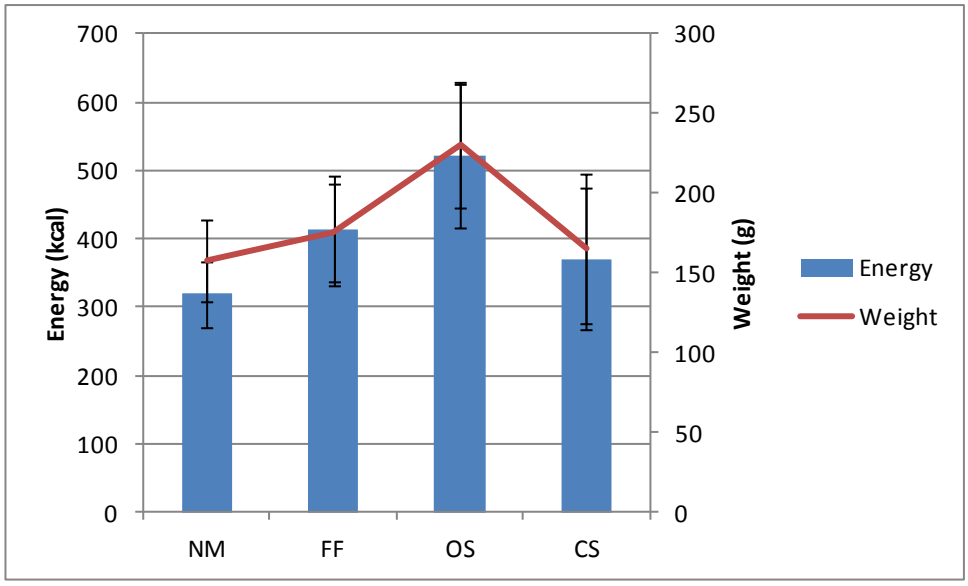


Figure 4.5 Mean (SEM) weight (g) and energy intake (kcal) of the food consumed in each condition. *NM= no manipulation; FF= food fortification; OS= overt supplementation; CS= covert supplementation.*

When divided into macronutrient content, there were no significant differences in fat or protein intake between conditions. There was however a significant difference in

carbohydrate consumption between conditions ($F(3, 15)= 4.222$, $p= 0.024$); there was a significantly higher intake of carbohydrate in OS (37.8g) compared to NM (18.6g) ($p= 0.035$) and FF(22.6g) ($p= 0.046$) (figure 4.6).

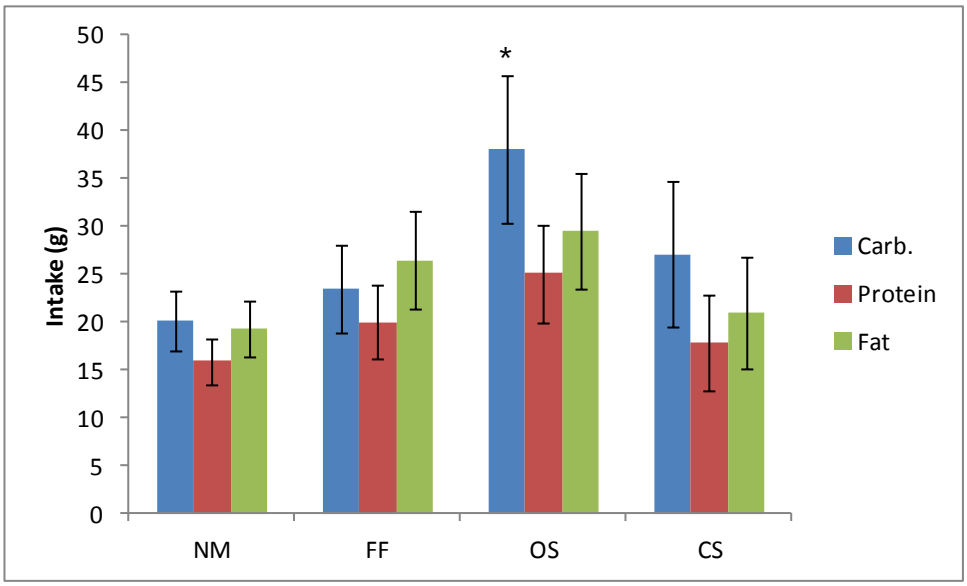


Figure 4. 6 Mean (SEM) macronutrient intake (g) during the meal in each condition. *Significantly different from NM and FF, $p<0.05$.

When compared against OS+CS, there was a significant difference in carbohydrate intakes ($F(2, 12)= 11.091$, $p= 0.002$); intake was significantly higher in OS+CS than NM ($p=0.011$) and FF ($p=0.015$). Protein and fat intakes also significantly differed between groups ($F(2, 12)= 5.635$, $p=0.019$ and $F(2, 12)= 5.643$, $p=0.019$ respectively); intake was significantly higher in OS+CS than NM for protein; $p=0.05$, and for fat; $p= 0.039$.

Mean energy intakes from meal provided seperated from extra nutrition provided

Mean intake of energy was calculated in terms of contributrition from the actual meal provided and the contribution from the extra nutrition provided (food fortification/ONS). There was a significant differences in energy intake between conditions from the meal alone ($F(3, 15)= 3.498$, $p= 0.046$), however there was no effect of condition.

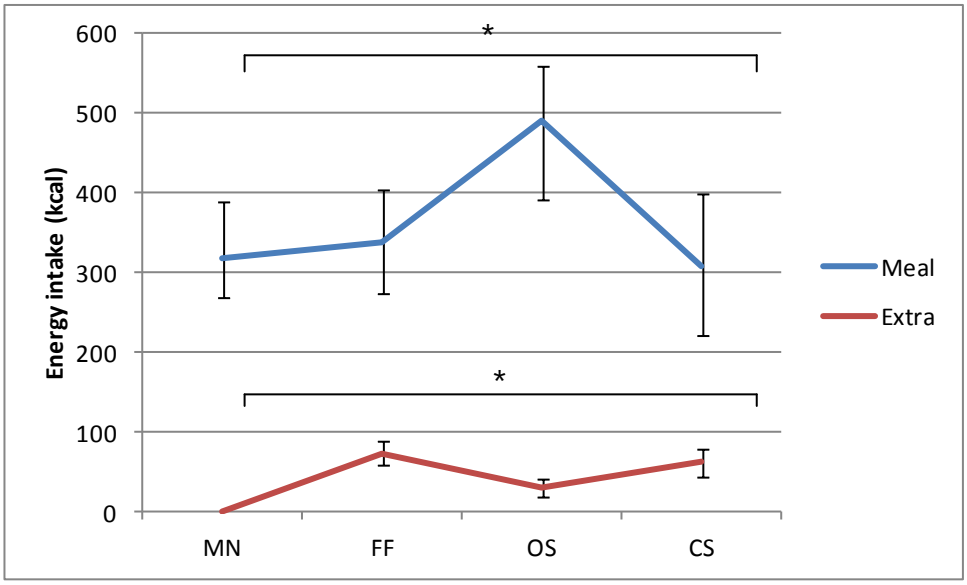


Figure 4. 7 Mean (SEM) energy intake (kcal) from just the meal (blue line) and just the extra nutrition (red line) from food fortification or ONS in each condition. *p<0.05.

There was also a significant difference in energy intake from extra nutrition alone between the 3 manipulated conditions (FF, OS and CS) (F(2, 10)= 4.609, p=0.038), but also no effect of condition (figure 4.7). There were no significant differences in intake between OS+CS when compared with NM and FF from the meal alone, or between OS+CS and FF from the extra nutrition alone.

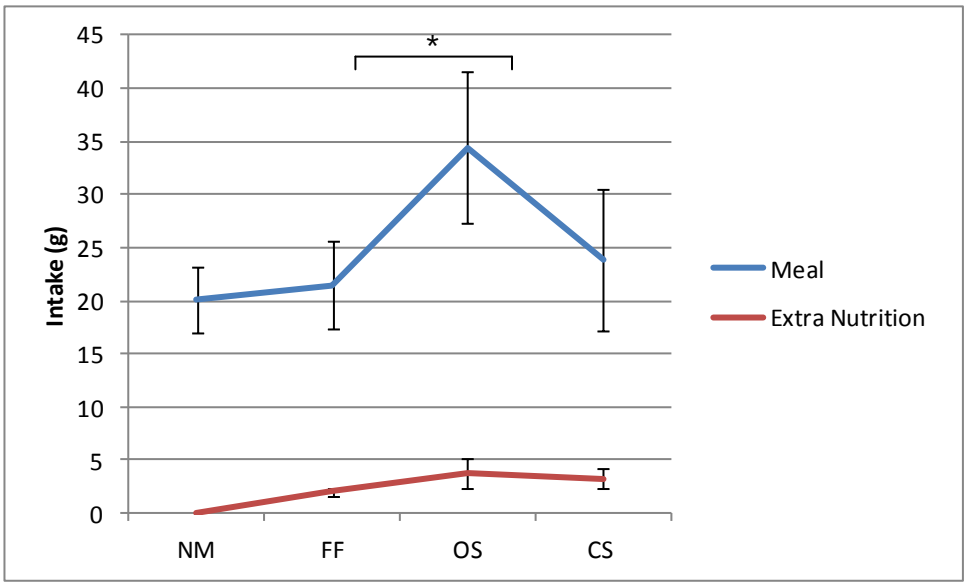


Figure 4.8 Mean (SEM) carbohydrate intake (g) from just the meal (blue line) and just the extra nutrition (red line) food fortification or ONS in each condition. *p<0.05.

Macronutrient contributritions of intake from the meal and from extra nutrition are shown in figures 4.8, 4.9 and 4.10. The carbohydrate contributition from just the meal significantly differed ($F(3,15)= 3.598$, $p= 0.039$), this difference was between FF (21.5g) and OS (34.4g). There was also a significant difference in carbohydrate contributition between NM, FF and OS+CS ($F(2, 12)= 8.102$, $p= 0.006$); significantly greater intakes were seen in OS+CS (29.1g) than NM (18.6g) and FF (20.7g) ($p= 0.022$ and $p= 0.021$) respectievly. From the extra nutrition provided, there were no differences in carbohydrate intake between the 3 conditions ($F(2, 10)= 1.136$, $p= 0.359$) (figure 4.8); however carbohydrate intake between OS+CS and FF did significantly differ ($F(1, 6)= 4.773$, $p=0.003$), intake was greater in OS+CS (4.0g) than in FF (1.9g).

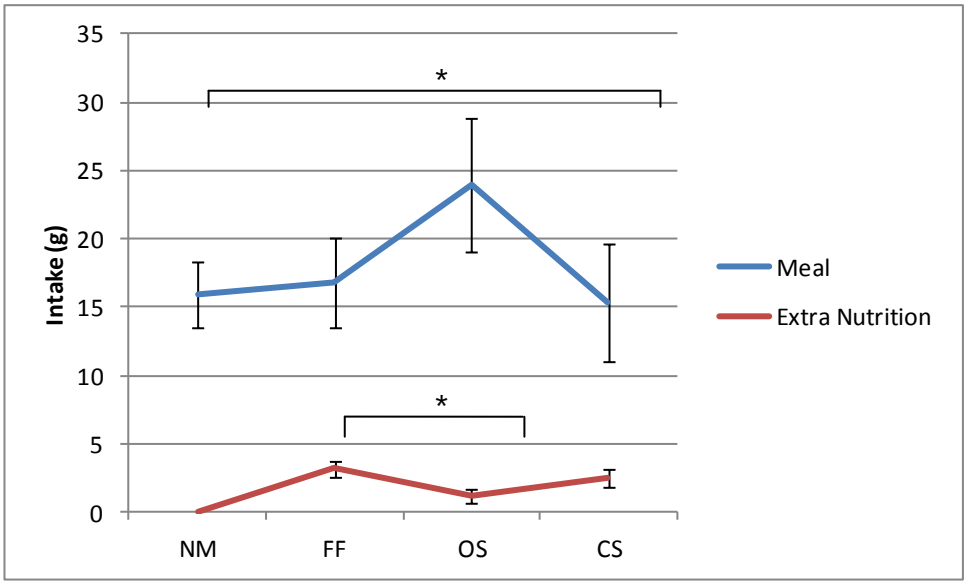


Figure 4.9 Mean (SEM) protein intake (g) from just the meal (blue line) and just the extra nutrition (red line) from food fortification or ONS in each condition. *p<0.05

Protein intake from just the meal significantly differed between conditions ($F(3,15)= 3.200$, $p= 0.05$), but Bonferroni post-hoc revealed no overall effect of condition. The contributrition of protein from extra nutrition was also significant between conditions ($F(2, 10)= 5.448$, $p= 0.025$), with the effect lying between FF (3.2g) and OS (1.2g) (figure 4.9). These differences disappeared when comparing OS+CS with NM and FF.

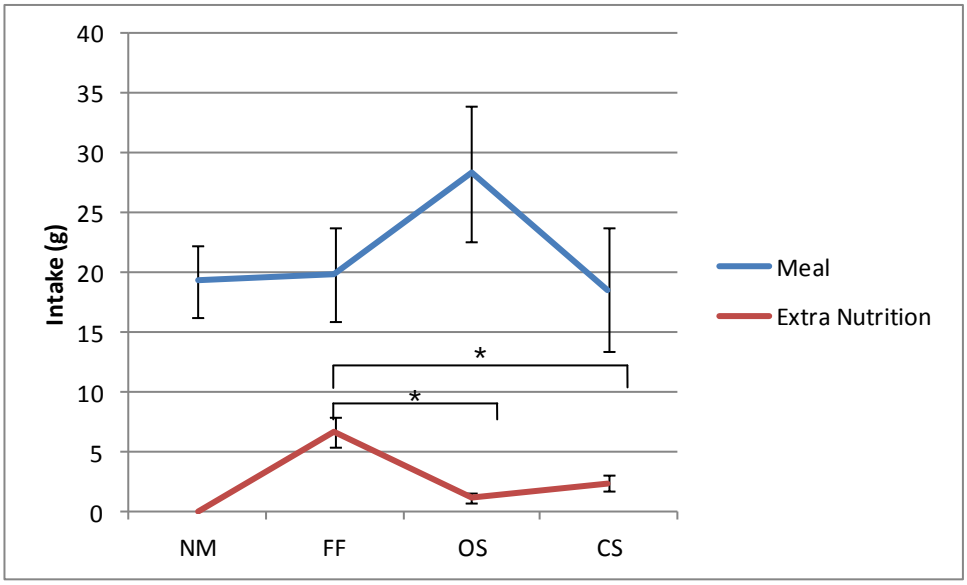


Figure 4.10 Mean (SEM) fat intake (g) from just the meal (blue line) and just the extra nutrition (red line) from food fortification or ONS in each condition. *p<0.05.

There were no signifcant differences in fat intake from the meal ($F(3, 15)= 1.930$, $p= 0.065$), although the results show a trend. There were also no significant difference when OS and CS conditions were combined. There was however a significant difference in fat intake from extra nutrition ($F(2, 10)= 17.582$, $p= 0.001$); fat intake was significantly higher in FF than OS ($p= 0.009$) and CS ($p= 0.003$) (figure 4.10). Similarly, there was a significant difference between FF (6.4g) and OS+CS (2.9g) for fat from just the extra nutrition (t(6)=4.654, p=0.003).

Likert ratings

Mean rating for the taste of the meals was 3.7 (SD 0.9), and mean rating for texture (mouth feel) was 3.6 (SD 0.6). There were no significant differences between ratings of taste or texture between conditions (figure 4.12). In FF and CS, taste and texure were significantly correlated ($r= 0.843$, $p= 0.035$ and $r= 0.963$, $p= 0.008$ respectively). There were no significant correlations between taste and texture ratings and energy intake.

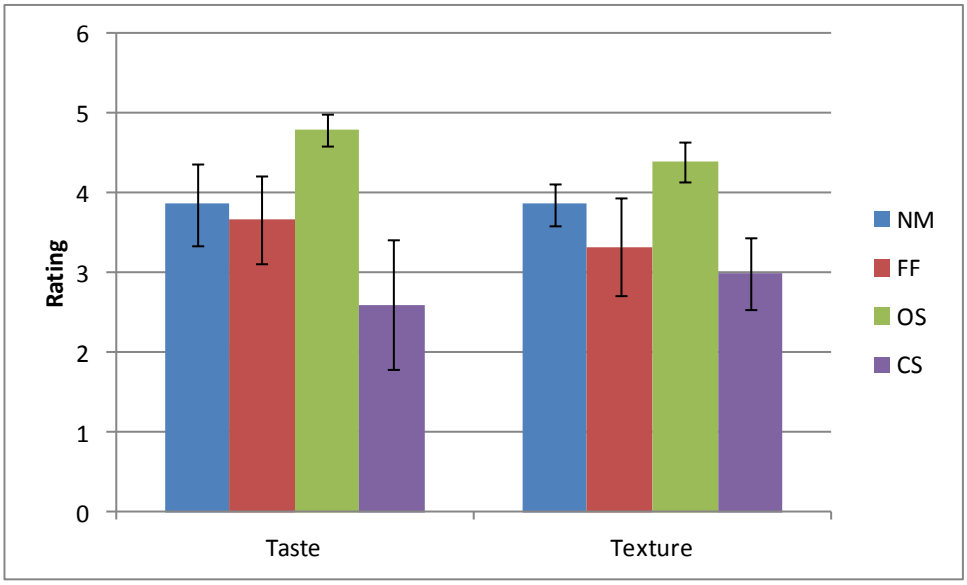


Figure 4.11 Mean ratings of taste and texture of meal provided in each condition

There were no significant differences of the ratings made pre- meal between each condition, nor were there any significant differences of post-meal ratings between conditions (appendix 4.4)

There we no significant correlations between ratings of hunger, desire to eat or fullness in NM or FF. In OS, a significant, strong positive correlation was found between pre-hunger and pre-desire to eat (r= 0.910, p= 0.004). Strong negative correlations were found between; pre-hunger and pre-fullness (r= -0.953, p= 0.001), pre-desire to eat and pre- fullness (r= -0.804, p= 0.029), and post-desire to eat and post-fullness (r= -0.959, p= 0.006). In CS, strong negative correlations were found between pre-desire to eat and p pre-fullness (r= -0.933, p= 0.006), and post- hungry and post- fullness (r= -0.953, p= 0.012).

Wastage costs

The wastage costs in each condition are reported in table 4.4; there was no significant difference in wastage cost across conditions (F(3, 15)= 1.704, p= 0.209). Costing was then broken down into contribution from the meal alone and contribution from extra nutrition alone. There was no significant difference in the wastage cost across conditions from the meal alone (F(3, 15)= 1.022, p= 0.411), however a significant difference was found from the wastage cost of extra nutrition (F(2, 10)= 16.826, p= 0.001); the extra nutrition wastage cost in FF was significantly lower than OS (p=0.001) and CS (p= 0.011).

Table 4.5 Cost (SEM) of wastage in each condition from the meal, extra nutrition and in total (£). *Significantly different from FF, $p<0.05$.

Condition	Meal	Extra Nutrition	Total (Meal + EN)
NM	1.58 (0.18)	-	1.67 (0.18)
FF	1.96 (0.21)	0.22 (0.04)	1.78 (0.24)
OS	0.94 (0.37)	0.69 (0.06)*	1.53 (0.36)

4.4.3 Summary of findings

The results of study 2 are summarised as follows:

- No significance difference in the overall weight of food consumed between the 4 conditions.
- Trend towards a difference in energy intake from the complete meals; greatest energy intake observed in OS.
- Carbohydrate intake was significantly higher in OS than NM.
- When OS+CS were combined, energy, carbohydrate, protein and fat intakes were significantly greater that NM.
- *Meal alone*; carbohydrate intake was significantly greater in the CS condition than FF, and was significantly greater in OS+CS than NM and FF.
- *Extra nutrition alone*; protein intake was significantly greater in FF than OS (removed in OS+CS); intakes of fat were also significantly greater in FF than OS, CS and NM. Energy and carbohydrate intakes were significantly lower in the FF condition compared to OS+CS.
- SNAQ scores were positively significantly correlated with hunger and desire to eat ratings in the overt condition; a higher SNAQ score indicates a lower risk of malnutrition due to a healthier appetite of the participant.
- No differences in the liking (taste and texture) of the food provided, pre- and post- meal hunger, fullness and desire to eat between conditions.

- Total cost of food wastage did not differ between conditions. There was a significantly lower wastage cost of extra nutrition in FF than OS and CS due to the higher initial cost of ONS compared to food fortification.

4.5 Discussion

It was hypothesised that extra nutrition delivered covertly would produce an increase in nutritional intakes during a lunch time meal, and that extra nutrition given by any method (overtly or covertly) during a meal would improve nutritional intakes above intakes of a meal given on its own.

There were no differences in weight and energy consumption between overt and covert conditions in study 1. There was however significantly greater intakes of protein and fat in the covert condition compared to overt, supporting the hypothesis. This suggests that hiding the supplement within the meal provides a benefit relative to offering the supplement on the side. Although the total volume of the food provided (meal and ONS) was the consistent between conditions, the physiological processes of nutrient metabolism were over-ridden by the awareness of an extra food item in the overt condition and so intake of the ONS was less. This is similar to the findings of Shide and Rolls (1995), that the labelling of fat content of pre-load yogurts affects subsequent intake rather than the actual fat content of the yogurt.

During cost analysis of study 1, it was found that the wastage of the total meal was lower in the covert condition than in the overt condition. For local policy, this suggests the promotion of incorporating ONS into meal as a method of increasing nutritional intake rather than giving ONS on the side of a meal.

Study 2 found no differences in the weight of food consumed between conditions. However, there was a trend towards a difference in energy intakes; the highest energy intake was observed when ONS was given overtly. This was likely to be due to the overall higher carbohydrate intake in the overt condition. From the meal alone, carbohydrate intakes were significantly higher in the overt condition compared to food fortification, and were also higher for the meal and extra nutrition alone when the 2 ONS conditions were combined. The extra nutrition in the food fortification condition had a higher initial fat and protein content compared to ONS; this allowed for a significantly greater intake of these macronutrients from extra nutrition alone in the

food fortification condition compared to the overt and covert condition. Covert supplementation by means of food fortification is a cheaper option than ONS; the contribution from extra nutrition in terms of wastage cost was significantly lower in food fortification condition compared to both ONS conditions.

Meals provided in each condition were well accepted by residents who continued to eat until full; there were no differences in the ratings of taste and texture of meals between conditions. There were also no differences in ratings of hunger, fullness and desire to eat pre- and post- test meal between conditions. Although only found in the NM condition of study 2, SNAQ scores correlated with ratings of hunger and desire to eat, suggesting that the lower the risk of malnutrition, the greater the residents appetite. Research focussing on the appetite of older adult care home residents can be done at mealtimes using SNAQ as an appetite assessment tool; residents can give more accurate opinions about their appetite at these times in anticipation of receiving food. The dining room setting is also a useful environment when studying appetite; participants can be unobtrusively observed from a distance in their natural eating environment and so are more likely to relax when compared to scenarios when the researcher must observe a resident in a one-on-one situation.

The results of study 2 were not consistent with the hypothesis predicting higher intakes overall in covertly manipulated conditions, however, intake of the extra nutrition alone was significantly higher in FF for protein and fat intakes, and both covert manipulations (FF and CS) had greater intakes than overt extra nutrition (OS). Intakes were also greater in manipulated conditions compared to the control meal (NM), justifying the use of extra nutrition at mealtimes. Energy and carbohydrate intakes were greatest when the overt and covert ONS condition were combined (OS+CS). Whether extra nutrition should come in the form of food fortification or ONS remains a topic for further investigation.

The results of the present two studies show some disagreement in intakes for overt and covert ONS use. In study one, as hypothesised; intakes were greatest in the covert condition, however, in study two intakes were greater in the overt ONS condition than covert condition. Previous research suggests that responses to just physiological cues based on the energy density of food are poor thereby promoting greater intakes (covert supplementation). In comparison, both physiological and cognitive cues are associated

with overt supplementation and therefore intake is more controlled (Rolls and Hammer, 1995). These discrepancies between studies may be explained when total intakes are divided into the contribution from the meal alone and the extra nutrition alone. In the covert condition, the contribution of energy from the extra nutrition was in calculated proportion to the contribution from the meal. However, in the overt ONS condition, exact measures of ONS and meal intakes could be taken. It was observed that the meal intakes were greater than the ONS intakes in the overt condition. The high energy intake in the overt condition was based on the intake from the meal alone with only a small contribution from the ONS; ratings made of the taste and texture of the food offered in this condition may have been made based on the meal rather than the ONS and therefore it may be that ONS is preferred when incorporated into a meal rather than given overtly. Alternatively, participants could have eaten their meal first until they felt full, and so when they turned to consume their ONS they may have found it too energy dense and so declined intake. To draw firm conclusions as to why this disagreement in results occurred and to add to this study, future research could include an observational element in which the order that the participant chooses to consume all nutrition offered could be assessed; whether they eat the meal first, the ONS first or whether they alternate between meal and ONS

Under normal energy regulation, the consumption of higher energy dense foods should lead to a reduction in calorie intake at the initiation of satiety signals (Kral and Rolls, 2004); this however was not the case in the present study. Intakes were higher in the energy manipulated conditions than the control condition despite the consistency in hunger and fullness ratings between conditions.

Offering lower volumes of food in terms of portion size, but with a high energy density could be an effective method to increase energy intake in older adults. Older adults are particularly affected by the volume of food offered, finding large volumes intimidating, perceiving them as ‘unmanageable’ (see chapter 5). The consumption of larger volumes of foods is limited due to gastric distension and satiety cues causing the cessation of eating. Therefore high volume, low energy dense diets fail to meet adequate nutritional intakes (Bell et al., 1998). In addition, other factors that contribute to low intakes of high volume foods with low energy density include; knowledge of a socially acceptable portion size (Rozin, 1996), and knowledge of an appropriate size of meal to cause satiety (Rolls and Hammer, 1995). The factors have psychological influences which

contribute to the termination of food intake before the consumption of an appropriate amount of energy to meet individual needs (Bell et al., 1998). Large portion sizes also have an effect on sensory specific satiety, and so intake is limited by the decline in the pleasantness of an eaten food (Rolls, Hetherington and Burley, 1988). In malnourished older adults, sensory specific satiety could be used to an advantage; at the termination of the consumption of the eaten food, a novel food could be offered to promote extra intake (Rolls, Hetherington and Burley, 1988). Small portions of high energy dense foods should be offered to older adults to promote adequate nutritional intakes.

An advantage of ONS use over food fortification in the treatment of malnutrition in older adults is that ONS are often nutritionally complete, not only providing provisions of macronutrients but also providing the RDA of micronutrients (Stratton, 2005). As older adults are often deficient in many micronutrients (vitamins and trace minerals), ONS have an extra benefit over food fortification which often only increases the energy, fat and/or protein content of food (Finch et al., 1998; Elia and Stratton, 2004). Treatment of vitamin and mineral deficiencies have been shown on a number of occasions to improve outcomes; a recent meta-analysis assessing the effect of vitamin D supplementation in older women concluded that vitamin D decreases rate of mortality particularly in those living in institutionalised, dependent care (Bjelakovic G et al., 2009). Other meta-analysis' provide some evidence to support the use of vitamin B and folic acid supplementation to improve cognitive function in healthy and demented older adults (Malouf and Evans, 2008; 2009). Heyman et al. (2008) gave older adult nursing home residents ONS enriched with arginine, vitamin C, vitamin E and zinc, reducing the size of pressure ulcers compared to standard oral care, and both Wouters-Wesseeling et al. (2002) and Turic et al. (1998) found increases in the micronutrient plasma status of participants during and post- ONS supplementation. One issue surrounding the use of ONS is the effects on overall nutritional intake; ONS should supplement the diet not replace intake from standard food. Wouters-Wesseling et al. (2003) did not observe a decline in energy intake from regular food in participants receiving ONS due to the lack of compensation after consumption; baseline intakes of these participants was inadequate and so extra nutrition from ONS was beneficial in terms of weight gain for the participants. Similarly, Boudville and Bruce (2005); Johnson, Dooley, Gleick (1993); and Simmons and Schnelle (2004) all found that ONS does not affect overall daily energy intake. The local policy of 'food first' recommends

food fortification of meals with no concern of the effects on snacking and subsequent intakes, and therefore it may be more appropriate to recommend ONS given at mealtimes, particularly in the acutely ill who may be deficient in a number of vitamins and minerals (Finch et al., 1998) and will benefit from increased micronutrient intakes.

The results of this study have demonstrated that by offering meals of a standard portion size but with a greater energy density through the provision of extra nutrition, either through food fortification or ONS, nutritional intakes can be increased. Although the use of food fortification has the advantage of being more cost effective, ONS are nutritionally complete and could be considered for the treatment of specific micro-nutrient deficiencies as well as malnutrition. In terms of ONS compliance, when supplements are given at meal times (either overtly or covertly), when an episode of eating is expected, compliance may be enhanced without displacing 'normal' meal intakes in some individuals, and therefore increasing overall nutritional intakes.

Chapter 5: A qualitative study identifying resident and carer perspectives of oral nutritional supplements

5.1 Introduction

The 'food first' approach is attractive since fortifying familiar foods might optimise nutrient intake in some individuals that dislike supplements or for whom ONS intake displaces food intake. Supplementation might work best when offered as a medicine rather than with food; and older adults who have low levels of health self efficacy might resist intake of ONS. The previous chapter revealed the complexity of offering ONS overtly and covertly, but there are other factors that affect ONS intake which in turn may also affect long term compliance. These factors are considered in more detail in section 1.9. It is not known what older adults feel about the supplements they have been given; few studies address the staff and residents directly on factors influencing poor compliance. As mentioned in chapter 3, the role of the carer is crucial when considering the treatment and prevention of malnutrition. What then do the carers themselves think about ONS and what do they identify as the main barriers to compliance, specifically in relation to the residents in their care?

There is widespread variability in reported compliance to ONS; Gosney (2003) found compliance to be poor at 37%. This study only observed compliance over 1 day and so the compliance rate cannot be extrapolated for the duration of normal prescriptions; it is unknown whether this observed compliance rate would alter over time. Over a 2 day period, Simmons and Patel (2006) reported nursing home staff delivery of ONS, the compliance rate to ONS, and the assistance given by staff to encourage ONS consumption. The compliance rate of this study was also reported as low although no percentage compliance is given. The main reasons for poor compliance rate generally focussed on issues around care home staff; the ONS provided to residents by staff were inconsistent to the prescriptions provided by the HCP, and there was little time spent by staff encouraging and promoting ONS consumption.

There are also studies that report a much higher level of compliance to ONS. Wouters-Wesseling et al. (2005) reported an 88% compliance rate to ONS among older adults living in care homes and sheltered housing. These authors aimed to enhance cognitive

function by improving nutritional status through the use of ONS. Although all participants had nutritional intakes that were less than the recommended amounts, the average BMI was within a healthy range (25.3 ± 2.4 kg/m^2) and so participants would not be categorised as malnourished or at risk of malnutrition. In addition to this, all participants had sufficient cognitive capacity to "not forget to consume the daily supplement" (Wouters-Wesseling, 2005, pg. 268). None of the participants of this study were prescribed ONS prior to the initiation of the intervention and so ONS were novel and therefore participants were more likely to be compliant as there were no issues of monotony that may be seen in current users of ONS. Although the intervention was over a longer period of time (6 months), the researchers actively aimed to maximise compliance by visiting participants every 2 weeks. In terms of assessing compliance to ONS, this study does not benefit from the observations in the 'natural' environment of subjects currently prescribed ONS as reported by Gosney (2003) and Simmons and Patel (2006). A 4 week intervention assessing compliance to an energy dense (>2 kcal/ml), low volume (125ml) ONS also found a high compliance rate of 97%. Participants were community dwelling at risk/malnourished older adults, prescribed ONS specifically for the purpose of the research. No information was given in this paper regarding methods employed by researchers to promote compliance e.g. regular visits by the researcher/dieticians, and therefore it is impossible to draw conclusions as to whether the high compliance rate was due to the promotion of ONS consumption or the lower volume of ONS delivered which were approximately 75ml less than standard 200ml ONS.

A clear interaction between the patient and the prescribing practitioner is likely to help enhance compliance (Kennelly et al., 2009); this is particularly true in settings outside of the hospital where HCP contact may be limited. A study conducted in the Republic of Ireland surveyed GP and community nurses finding that there is a lack of knowledge about ONS, poor assessment of nutritional status prior to ONS initiation, and a lack of patient monitoring once ONS is prescribed (Loane et al., 2004). One cause of poor compliance which has been identified is a lack of knowledge about ONS in both patients and HCP. An Irish study interviewing 78 patients prescribed ONS (N=50 community dwelling, N=28 private nursing home) by 10 GPs over a 3 month study period aimed to evaluate current ONS prescribing practices (Kennelly et al., 2009). Of the participants taking ONS approximately one third could not remember whether it was

the GP, dietician or nurse who had recommended nutritional treatment. Reasons identified for poor compliance included; volume of ONS too large; tired/bored of taking ONS; dislike for ONS flavour; desired ONS not available from the pharmacy. The assessment and advice given to patients by the HCP prior to ONS prescriptions was limited; only one quarter of patients had their weight measured, approximately the same number of patients had food related dietary advice given, only a fifth were allowed to choose what flavour ONS to have, and the same percentage were able to try the ONS before being given a prescription (Kennelly et al., 2009). These issues from the HCP could have an impact on the poor compliance rates reported; without dietary advice it is likely that patients will carry on not getting enough energy, protein and micronutrients from food and therefore ONS prescriptions will be over a longer period of time enhancing monotony. By not giving patients a choice in ONS flavour, patients are less engaged in their prescriptions and may not like the flavour they are given thereby affecting compliance.

5.2 Aims and objectives

Poor compliance to ONS is not well understood and the research assessing compliance to ONS particularly in care home residents is lacking. It appears that the variability in compliance rates is highly dependent on the individual prescribed ONS and the care setting in which the ONS are prescribed. Despite this, only a limited number of studies identify factors that affect compliance to ONS in the care home setting. Therefore, the principal aim of this questionnaire and interview based study was to identify and understand factors and barriers affecting compliance to ONS prescriptions specifically in care homes. Care home residents prescribed ONS were recruited to provide their personal views regarding the sensory properties of ONS, factors that do/would increase compliance of ONS and factors that affect compliance to their prescriptions. Care home staff who oversee nutritional supplementation were also interviewed as part of the study.

5.3 Method

5.3.1 Participants

At the initial stage of the research study, letters of invitation were drafted and sent to 94 care homes in the Leeds area. A week after the letters were sent the researcher contacted the care home managers via phone call to ask if; the letter had been received, the care home manager had had the time to read the letter, and whether the care home manager was interested in participating. If interested, the researcher made an appointment to go to the care home to meet the manager and to identify potential participants. Resident participants were recruited on the basis of the inclusion criteria; older adults (≥ 65 years), male or female, current users of ONS, willing and able to take part and understand the test procedure, able to form independent opinions, and able to give either written or verbal informed consent. Those excluded from the study were; users of tube feeds, diagnosed with severe dementia or Alzheimer's, those in which the researcher or any member of care home staff was uncertain about their willingness to participate, and those that could not give consent. In the case that all current users of ONS were unable to participate, the researcher recruited care home staff involved in the administration of ONS.

Fourteen care home managers were willing to allow the research to take place in their care home. Reasons for not participating included; no ONS currently prescribed in the care home; those taking ONS prescriptions had late stage dementia/Alzheimer's and so could not participate; manager unprepared to give any information about prescriptions; ONS was not used as a method to increase weight.

Thirteen residents currently prescribed ONS or who had had recent ONS prescriptions consented to be interviewed, all of whom housed in residential care and were of the capacity to understand the questions asked and to express personal attitudes, thoughts and feelings. Nine carers from nursing homes participated as no residents prescribed ONS in these homes were of capacity to answer questions.

5.3.2 Ethical considerations

The study was approved by the Ethics Committee at the Institute of Psychological Sciences at the University of Leeds, reference no. 09275-11. The manager of each care home was asked to give oral consent to allow the researcher into the care home. Suitable residents were identified by the care home manager and asked to give either written or verbal consent if they agreed to take part in the research. Participating staff members were also asked to give written consent. Each participant was informed that they could withdraw from the research at any point without giving a reason. All information collected was anonymised. Questionnaires were completed using unidentifiable participant numbers; these were also used to identify participants from their verbal answers recorded by Dictaphone (Sony TCM-150).

5.3.3 Materials and procedure

Two questionnaires were developed for this study, 1 specifically aimed at residents (appendix 5.1) and 1 specifically aimed at care home staff (appendix 5.2). Residents were specifically asked to give their own personal opinions in answer to questions. Staff were invited to comment on the behaviours displayed by nursing home residents on presentation of ONS. The questions aimed to gather information about; the number and volume of ONS prescribed per day, knowledge of why ONS are prescribed, compliance (self-reported), reasons for non-compliance, ratings of the sensory characteristics, flavours and product types offered to residents, timings at which ONS are administered, the presentation of ONS, temperature at which ONS are served and general likes/dislikes of ONS.

The questionnaires/interview

Some of the questions developed for the questionnaire were closed-ended questions in which all alternative answers were provided to the participant. Closed-ended questions provide aggregated data; the responses were predetermined by the researcher and so the richness of potential responses is low (Boynton and Greenhalgh, 2004). Responses made were either in the form of multiple choice or 5-point Likert scale ratings, ranging from, for example, ‘extremely unpleasant’ to ‘extremely pleasant’ (see section 2.5.2). Although the closed-ended questions provided limited information as participants could only select from the answers provided and were not specifically asked to elaborate on

their responses, the questions were simple for residents to understand and scores were easily interpreted (Heiman, 2002). Participants were asked to if they would like to comment further on the closed-ended questions (appendix 2.4 and 2.5). Any comments and answers were recorded anonymously with permission of the interviewee using a Dictaphone (Sony TCM-150 cassette recorder) for later transcription by the researcher. Open-ended questions introduced a qualitative element to the research. The qualitative inductive research method allowed for the identification of dominant themes (relevant to the research objectives) were later used for the development of the research intervention that evaluated methods to improve compliance to ONS (Thomas, 2006). For open-ended interview questions, interpretation and scoring of responses is less reliable and susceptible to experimenter bias, however content analysis was applied to specify certain responses (themes) which were counted and scored depending on the number of times they appeared in answer to the questions. By creating a questionnaire that combined open- and closed-questions the research had the advantage of providing both reliable answers from a narrow, pre-formed selection, in combination with answers that were wide-ranging, elaborated and opinionated (Heiman, 2002).

The questionnaires were read out by the interviewer and the responses recorded manually on the questionnaire sheet. This was mainly for the benefit of the resident whose eyesight or hand-eye coordination may have been impaired, and the majority of residents were unable to record answers for themselves due to loss of manual dexterity. This technique ensures that all questions were completed as instructed, that questions were understood, and that any clarification could be sought by the participant (Heinman, 2002).Closed questions were followed by an opportunity for participants to comment on their answers and give more details. Staff completed questionnaires for themselves in response to closed-answer questions, but also had their comments recorded from later transcription.

5.3.4 Analysis

Demographic data of residential participants weight 6 months prior to the research, current weight and weight change was collected. Differences between admission and current weight were assessed using a paired-sample t-test. Differences in these 3 measures were also compared between males and females using independent sample t-tests where ‘gender’ was the grouping variable.

Ratings made regarding the sensory properties were converted into numerical answers ranging from 1-5 (e.g. ‘very unpleasant’- 1 to ‘very pleasant’- 5). Pearson’s correlations were then applied to assess relationships between the mean ratings.

Recorded interview data was transcribed and divided into themes of factors contributing to poor compliance and factors contributing to good compliance.

5.4 Results and Discussion

5.4.1 Participant information

Of the 13 residents participating in the research 9 were female, and the mean age was 86 years (68-99 years). Eight participants were prescribed ONS prior to care home admission, the remaining 5 initiated ONS prescriptions once living in the care home. Where possible, data was collected about participant’s weight 6 months prior to the researchers visit, and their most recent weight to the time of the researchers visit (table 5.1). Mean weight of participants 6 months previously was 56.1 kg (±3.2 kg), and mean weight at the time of the research was 56.9 kg (±3.0 kg). Weight change was assessed for 8 of the participants; 3 participants showed an increase in weight over 6 months (mean +6.36kg) and 5 showed a decrease in weight (mean -2.48kg). Body weights were checked and there was no significant differences between the 6 month weight and the weight taken at the researchers visit ($t(7)=-0.424$, $p= 0.684$).

5.4.2 Prescriptions

Prescriptions of ONS varied between participants from 1 to 5 per day depending on the specific purpose for supplementation; to enhance nutritional intakes from normal food or as the sole source of nutrition. Seven participants (R1-5, 8 and 10) were prescribed 1 supplement per day due to low weights or weight loss to a degree of concern at the time of ONS initiation, 1 participant reported a prescription of 1-2 per day (R12), 1 participant reported a prescription of 1-3 per day (R7), and 1 participant reported to take a varying amount per day with no clear indication of the actual prescription (R6).

Table 5.1 Resident (R) participant's gender, weight at the researchers visit, weight from 6 months previously, current prescription of ONS per day and their self-report compliance.

Participant No.	Gender	Weight (kg)	6-m weight change (kg)	Prescription /day	Compliance
R1	F	47.1	-3.4	1	Half of the time
R2	F	55.5	+10.4	1	Always/nearly always
R3	M	71.5	+0.1	1	Always/nearly always
R4	F	49.8	-2.6	1	Most of the time
R5	F	44.9	-	1	Most of the time
R6	F	74.8	-	Varies	Less than half the time
R7	M	66.0	-1.3	1-3	Always/nearly always
R8	M	58.0	+8.6	1	Half of the time
R9	F	57.3	-0.4	5	Most of the time
R10	M	50.0	-4.7	1	Always/nearly always
R11	F	-	-	2	Always/nearly always
R12	F	-	-	1-2	Half of the time
R13	F	-	-	4	Always/nearly always

Higher volumes of ONS were prescribed to participants with underlying chronic illness; 1 participant (R13) had received recent throat surgery and so was unable to swallow solid foods and therefore took 4 ONS daily as a sole source of nutrition, and 1 participant had been diagnosed with Crohn's disease (R9) and so was prescribed 5 ONS daily in order to help manage the condition.

When asked about the time that they received their ONS, 9 participants reported getting them at different times each day, and 4 received them at the same time each day, either at medication rounds or meal times. All prescribed ONS were in the form of either juice or milk based drinks; these were either consumed directly from the bottle using the straw provided or poured into a glass. If the care homes stored the supplements in the fridge participants received them cold (N=5), or if stored in a store cupboard participants received them at room temperature (N=7). No participants had ever been offered a warm supplement in their care home, and only participant R2 was aware that some supplements can be heated.

5.4.3 Compliance

Compliance was measured through self-report by the participants using a 5-point Likert scale. Six participants reported taking their prescriptions 'always/nearly always', 3 reported taking their prescriptions 'most of the time', 3 said they finish their supplements 'half of the time,' and 1 reported taking their full prescription 'less than half the time' (table 5.1). Compliance from this group of residents was therefore quite high; almost 50% of participants reported to finish their ONS always/nearly always. In terms of percentage compliance, mean ratings translate to approximately 80-100%. This percentage is in line with the findings of Hubbard et al. (2012), that compliance across all care settings is approximately 78%, but is slightly higher than the mean compliance rate specifically recorded in care homes (69%).

Responses given were converted into numerical data in accordance with the Likert scale (1- 'hardly ever/never' to 5- 'always/nearly always'). These data could then be correlated against the sensory ratings of ONS below).

5.4.4 Ratings of ONS

Participants were asked to rate the sensory characteristics of ONS on a 5-point Likert scale for taste, texture, smell, enjoyment of consumption, and presentation of the packaging (adapted from Jenkinson et al., 2009). Mean ratings are shown in figure 5.1.

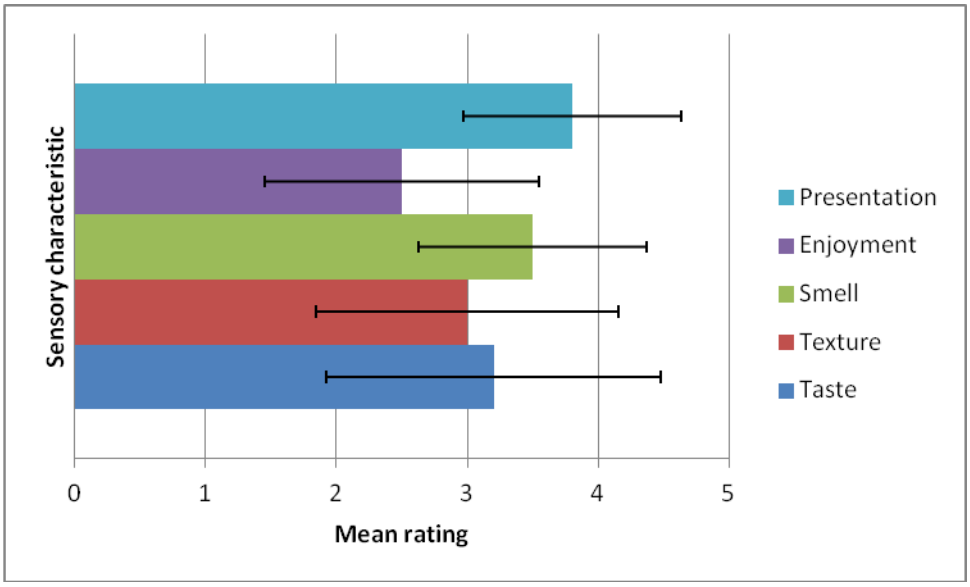


Figure 5.1 Mean (SD) ratings for sensory characteristics of ONS scored by resident participants.

Likert scale ratings provided a method to gather resident's opinions of the sensory characteristics and palatability of ONS that may be affecting intake. Ratings of the sensory characteristics of ONS varied between individuals. Overall the presentation of ONS product packaging was rated highest (3.8) and the enjoyment of consumption lowest (2.5). Significant correlations were found between; taste and texture (r=0.789, p<0.01), taste and enjoyment (r=0.810, p<0.01), enjoyment and texture (r=0.619, p=0.024), and presentation and smell (r=0.594, p=0.032). There were no positive correlations between the sensory ratings of ONS and the self-reported compliance ratings. When all 5 sensory ratings along with the ratings of compliance were analysed using a one-way ANOVA, significant differences were found (F(5, 60)= 5.128, p= 0.001). Enjoyment was rated significantly lower than smell (p= 0.011). This is possibly related to the artificial flavourings used in ONS products to give them an intense, appetising odour. Previous research has used flavour enhancement to increase the smell and taste intensity of food to promote greater meal intakes in nursing home residents. Mathey et al. (2001) significantly increased participants smell perception of a meal using flavour enhancement resulting in a mean increase in meal intake of 133 kJ over a 16 week period. The intense smell does not necessarily translate to other sensory properties related to the enjoyment of consuming ONS. This is also true with the ratings of ONS presentation which were significantly higher than enjoyment of consumption (p=0.001); ratings of presentation measure how visually appeasing the product is, but do

not take into account taste/texture or odour characteristics. Lower ratings of enjoyment did not seem to affect compliance; reported compliance was significantly higher than ratings of enjoyment (p=0.003). This is an example of self-efficacy; despite the lack of product enjoyment, participants comply to their prescriptions because they believe that ONS will have a health benefit.

The sensory properties of ONS have previously been identified as important to compliance; Gosney (2003) reported a moderate compliance rate of 63%, with 19% of participants reporting a dislike for the texture and 38% a dislike for the sweetness. Lad et al. (2005) also reported that taste, flavour and texture affect compliance leading to a low compliance rate of just 43%. Other contributing factors affecting compliance suggested by Lad et al. (2005) included personal preferences and lifestyle.

5.4.5 Themes indicating factors affecting compliance to ONS

Responses to the semi-structured interviews gave key insights to the factors linked to compliance. The responses were analysed via transcription and coded into themes that represent factors promoting good compliance, and factors that contribute to poor compliance to ONS. These themes are displayed through mind-maps; factors that appeared to enhance compliance to ONS were divided into 4 main themes; ‘beneficial effects of ONS’, ‘encouragement’, ‘personal control’ and ‘knowledge’ (figure 5.2). Factors that appeared to affect negatively compliance to ONS were divided into ‘lack of knowledge’, ‘normal diet preferred’, ‘mood’ and ‘lack of variety’ (figure 5.3). Tables 5.2 and 5.3 show examples of responses by residents and carers to the questions asked by the researcher from which these themes were extracted.

Figure 5.2 Mind-map of identified factors that aid good compliance to ONS.

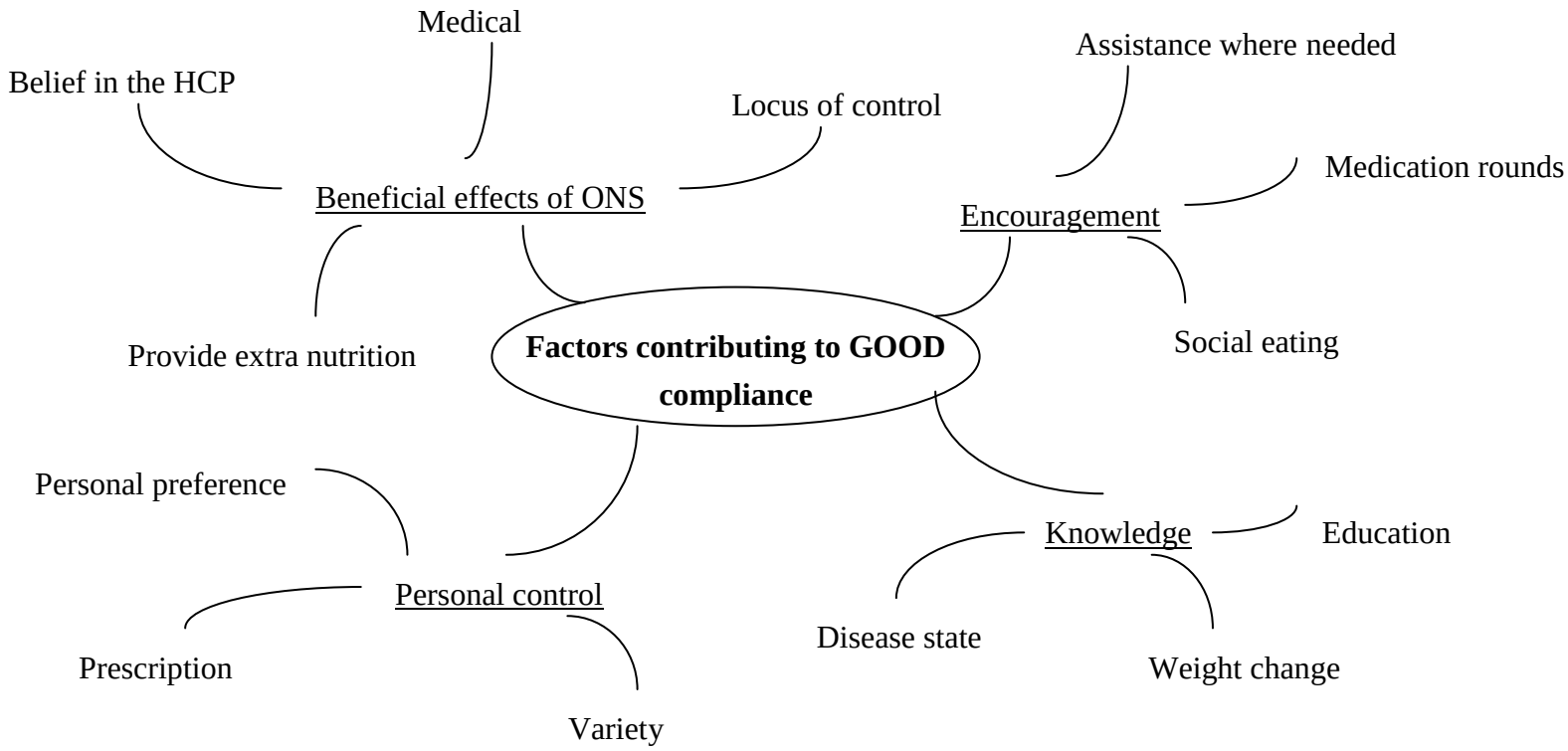


Figure 5.3 Mind-map of identified factors that contribute to poor compliance to ONS.

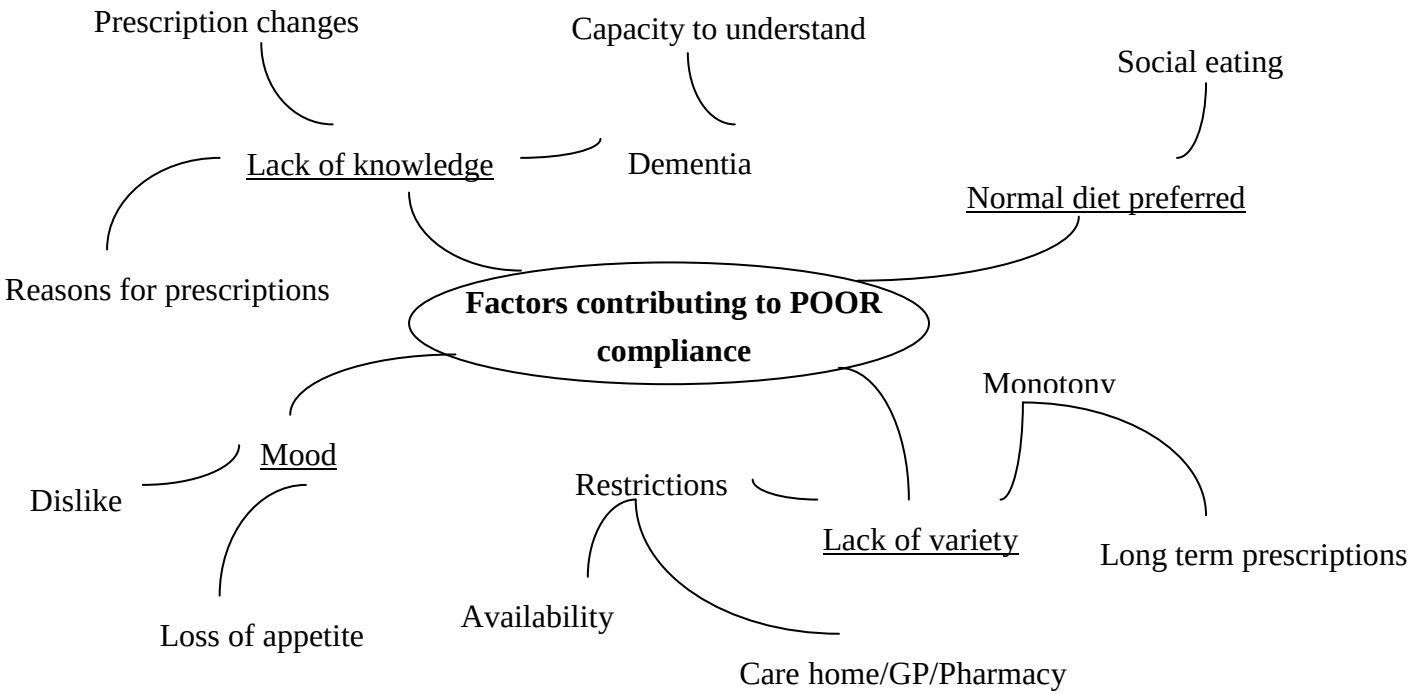


Table 5.2 Resident (R) and carer (C) responses: factors promoting compliance to ONS

Factor	Resident response	Carer response
Beneficial effects	*R7* "they've increased my weight"	*C7* "... you can see the benefit in those who have them"
	R4 "the nurse says they'll make me feel better"	*C3*"They help stabilise their weight"
	R1 "if I think it'll do me good then I'll finish it"	*C4* "they're for the extra calories and nutrition missing from their diets"
	R11 "I have a pureed diet... they make up for things I miss out on"	*C5* "... her pressure sore isn't healing so she's been put on them"
	R13 "I have Crohn's... take them as a build up"	
Encouragement	*R10* "the nurses tell me to drink them so I always have it all"	*C2* "staff will sit with them if they have a supplement... then they can help them if they're struggling"
	R6"when they open it and pour it out into a glass for me I will drink it"	*C3* "...with *a lot* of encouragement"
	R9 "I can't take the top off by myself or put the straw in... the nurse comes round to help me and I'm happy to drink it all"	*C3* "they sit together if they have a supplement at lunch... that helps them to finish it, knowing someone else is having one"
Personal control	*R2* "I don't have to drink it all at once"	*C8* "they get them with their medication so they're compulsory"
	R13 "they're good but I don't like vanilla"	*C2* "if they have a personal preference we tell the pharmacy"
	R12 "some days I have 1 or 2... I take them when I haven't eaten my big meal"	*C7*"we just had the drinks until recently. I've just ordered the desserts for one lady"
	R11 "I tried them all... tropical is best but they're all quite pleasant"	*C9* "...they can just help themselves when they want"
Knowledge	*R7* "to build me up"	*C9* "... even if they have dementia

	R11 "I wasn't eating anything from the supper tray so I needed more build-up things"	they'd like to try something different" *C1* "... brings them back to the normal diet or it's a substitute diet" *C8* "if we explain why they need them and what they're for then they'll take them" *C7* "they're losing weight and its related to their dementia" *C8* "...they're losing weight. We weigh them every month and the district nurse assess them"

Table 5.3 Resident (R) and carer (C) responses: factors affecting compliance to ONS.

Factor	Resident response	Carer response
Lack of knowledge	*R5* "no I don't know why I have to drink them... I'd sooner have a cup of tea" *R2* "... I used to take 2 a day at home, now I just take 1 [since moving into the care home] and I don't know why it's changed" *R11* "... don't know. When I got my weight back I just stopped taking them"	*C9* "... I do anyway [know why supplements are prescribed]... not sure if *they* do though" *C7* "... they have dementia so they don't understand why they take them" *C3*"... they have dementia so they don't realise what they're having"
Normal diet preferred	*R12* "I'd rather have normal food so I can eat out" *R2* "I'd like to have the soup [supplement] as a starter before my main meal"	*C3* "they prefer the high calorie soups fortified by the care home"
Mood	*R6* "I don't care for them... I don't	*C1* "it depends on their mood- not

	want to take them at all sometimes” *R8* “not very enjoyable...”	always. Some won’t drink any sometimes” *C6* “one resident normally refuses depending on their mood”
Lack of variety	*R2* “gets a bit boring, I need a change” *R8* “I get a bit bored with the same thing every day” *R2* “I tried different flavours at home but I’m not offered anything different here [in the care home]” *R4* “whatever the nurse hands out” *R3* “the nurses choose... they just bring 1 a day” *R3* “wouldn’t mind trying something different”	*C9* “they’d probably like to pick what they want even if they don’t really understand... those who can answer for themselves would probably like a choice in what they take” *C1* “the bottles are labelled with the prescription so they don’t get a choice” *C5* “it’s difficult to get a variety from the doctor” *C9* “we get bulk orders from the chemist. The doctor prescribes them then we get some for 2 weeks or maybe a month” *C9* “they either get yogurts or milkshakes. It’s just whatever the doctor sends”

The main findings from the interview questions of this study (discussed in more detail below) were that both carers and residents were able to identify common themes affecting poor compliance. From the carers viewpoint it was acknowledged that encouragement, support and promoting knowledge would be helpful in enhancing compliance. Residents highlighted their desire for variety within ONS to prevent boredom, to have personal control over their prescriptions, and the need for encouragement and assistance to take ONS. Compliance to ONS appears to depend on a number of factors discussed in more detail below; it is not known which of these factors contributes most to compliance levels, or whether these factors should be addressed alone or in combination in order to increase compliance.

5.4.6 Choice and variety

According to residents, the main factor leading to poor ONS compliance is the lack of variation offered in terms of the prescriptions. Most residents are only given 1 or 2 flavours of 1 type of ONS product and are not asked what they prefer. In most cases, they take what the carer or nurse gives them. Residents are not aware of the vast variety of product types and flavours available, and are also unaware that ONS can be served warm or incorporated into meals. The majority of ONS prescriptions are for sweet-tasting drinks causing monotony in supplementation therefore preventing good compliance (Baldwin and Weekes, 2011). Although in the first instance ONS are well accepted and well tolerated, there are variations in product preference between individuals particularly when ONS prescriptions are for a long period of time (Darmon et al., 2008). A taste preference study found that milk-based ONS were preferred over juice-based. Of the milk-based products, vanilla, coffee and strawberry were more highly rated than chocolate and neutral flavour. Tomato juice based drinks were favoured over apple and orange. It was concluded that compliance to ONS could be improved if variations in preferences towards the product types and flavours were considered when ONS are prescribed (Darmon et al., 2008). This is in line with the findings of Rolls et al. (1981) and Rolls, Rowe and Rolls (1982), that offering a variety of foods stimulates food intake.

Carer responses agree with that of resident responses in terms of the lack of variety, but explain that this is due to lack of control over the delivery which comes in bulk from the pharmacy after being prescribed by the GP. When referring to dementia patients it seems that carers believe that these residents should also be offered a choice in ONS even if they do not completely understand what is being offered. Any increase in engagement between carer, resident and the ONS prescribed could help increase awareness and therefore benefit compliance.

5.4.7 Encouragement

Care home staff indicated when encouragement and assistance improves compliance. By encouraging consumption, the carer can identify any particular needs of the resident and give help when assistance is required. Encouragement has been shown as a successful method to achieve a high compliance rate when ONS was offered to senile dementia hospital patients. Ninety-five percent of participants consumed all ONS

offered (Carver and Dobson, 1995). In this case, encouragement was not offered in response to the patient but rather was assumed to help given the limited ability of the participants to communicate. In another study, encouragement produced variable results; when poor compliance to ONS was identified over a 28 day period in post-operative hip fracture patients, the dietician offered encouragement to help enhance ONS intake. A mean compliance rate of 74% was found, but this ranged from 0-100%, despite the strategies employed by the dietician to increase compliance. Patient reluctance and inability to take ONS were identified as major factors affecting those with poor compliance (Bruce et al., 2003). Therefore, patient reluctance and their lack of interest in ONS might be modifiable either with extra encouragement or other strategies to facilitate compliance.

Encouragement and assistance were mentioned more when related to ONS administered at meal times or during medication rounds than when ONS was administered between meals. Similarly, Simmons and Patel (2006) found a greater time spent by staff assisting ONS intake at mealtimes, when staff are explicitly promoting intake, compared to the assistance given to residents receiving ONS between meal times. It is important that residents taking supplements outside of meals/medication rounds are offered the same amount of encouragement, and that these episodes are monitored to increase compliance.

5.4.8 Knowledge and perceived-efficacy

Residents identified ‘beneficial effects’ in relation to good compliance although specific knowledge as to why ONS are prescribed was lacking. Three residents mentioned weight increase, one of whom acknowledged that the prescription would stop once they had put on weight. Belief in the opinion of a HCP appears to aid compliance; awareness that ONS are prescribed by a doctor or given by a nurse motivates the resident to take the supplement even when they do not necessarily enjoy them. This is an example of perceived efficacy, the belief that ONS will have a positive benefit on health as predicted by the HCP, illustrated through the protective theory model (PTM) (reviewed in Weinstein, 1993). PTM suggests that motivation to protect against a negative outcome (in this case malnutrition), leads to the initiation of a health protecting behaviour (Floyd , Prentice-Dunn and Rogers, 2000). PTM includes a component of perceived- and self- efficacy, which is an important factor in motivational, cognitive and

affective processes (Bandura, 1992). In a study predicting intentions of participants to consume supplements that 'may improve memory', Cox, Koster and Russell (2004) concluded that perceived efficacy was the most important mediator of intention to consume supplements. When the resident has a specific medical condition for which they need ONS to enhance nutritional intakes they are more aware of the reasons why ONS are prescribed and are therefore more likely to consume the higher volumes required. Gazzotti et al. (2008) found a high compliance rate of 81% when older adult patients with a range of acute medical condition were given ONS. This high compliance level may partly be explained by the information given to participants that ONS would help to prevent deterioration.

Knowledge regarding ONS prescriptions for certain residents was mentioned often by carers; awareness that the main reason for ONS prescriptions was to increase weight was common although more specific reasons as to why residents were losing weight were not mentioned. Improved knowledge and awareness in carers is likely to lead to carers encouraging compliance. Care home staff have an important role in preventing malnutrition; thus sufficient training regarding benefits of ONS might impact upon nutritional intakes (Barchrach-Lindstrom et al., 2007). Although both nurses and care home staff are aware of their responsibility for the nutrition of residents, studies have shown that they lack sufficient knowledge and support to perform malnutrition preventative tasks (Perry, 1997; Kondrup et al., 2002). This lack of education towards the nutritional needs of resident can affect attitudes of care staff; Christenssen et al. (2003) found that 44% of care home staff had a negative attitude towards issues concerning eating and nutrition. The numbers of positive attitudes significantly increase after nutrition education and the implementation of a nutritional programme promoting nutritional 'individualisation'. By educating care home staff about nutrition, the nutritional status of residents has been shown to increase (Christenssen, Ek and Unosson, 2001).

Residents appear less willing to take their ONS prescription if they are unsure of the specific reason as to why they are prescribed, particularly when ONS replace the normal diet. The majority of ONS are liquid drinks but some older adults prefer a diet that contains varied textures and so prefer normal food to liquid supplements (Wells and Dumbrell, 2006). Carers also state that there is a lack of knowledge about prescriptions for residents particularly in dementia patients who may be unaware of what they are

being given. It should not be assumed that just informing the resident of the reasons for ONS at the initiation of the prescription is enough; many of the residents experience memory loss and/or have dementia and may need reminding daily of the importance of the supplements and asked to comply with prescriptions.

5.4.9 Personal control

Personal control over supplementation was also mentioned positively by the residents in terms of compliance during the interviews. If ONS are given at specific times e.g. meal times or medication rounds more assistance may be available to help with consumption, however the supplement has to then be consumed within a limited period of time. If the resident has the choice of when to receive their supplement they can then control the consumption and either have it all at once or they can sip it over the course of the day. Given personal control to those who can exercise this may help to increase awareness of the supplements and remind the resident of the importance of complying with the full prescription.

Control over the flavour and product type was also mentioned as an important factor that increased compliance; this directly links with the rationale of offering a variety of ONS to residents. Five residents mentioned a personal preference towards the type of product and appreciated being given a choice in flavour so that the ONS is enjoyed and not wasted due to dislike. Lad et al. (2005) examined factors that affect compliance to ONS identifying flavour, predictability and personal preference. By offering a variety of flavours, patients receive their personal preference, and therefore are more likely to comply with the prescribed volume of ONS. Similarly, by offering a choice of ONS varying in sweetness, consistency and temperature at serving, a high compliance rate of ~83% was achieved and ONS was reported as well accepted by Lauque et al. (2000).

Carers mentioned personal control over ONS highlighting their positive opinions towards giving choice in terms of ONS product type and flavour, and allowing residents to take their supplements when they want. It was stated by one carer that, in the case that a resident has a personal preference the pharmacy is notified, and by another that a different product type can be ordered even if it is for only one resident. It was also acknowledged that even with dementia, the resident should be given a choice; dementia patients may not be fully aware of ONS prescriptions but carers may be able to identify their likes and dislikes of different flavours.

5.5.1 Summary

As compliance to ONS in this group of older adult care home residents was quite high, responses regarding factors that affect compliance may be limited compared to older adults with low compliance. It is important to note that the group of residents interviewed were all in residential care and had good capacity to communicate; they were therefore likely to be more aware of their prescriptions and more likely to comply. To get a wider range of opinions to assess more factors affecting compliance, the same questions could be addressed to those with lower compliance rates.

The measure of compliance to prescriptions through participants self-report was a limitation of this study. Self-report may not have given an accurate rating of compliance because individuals tend to self- report intakes that are closer to perceived social norms rather than their true intake (Schoeller, 1990). Participants may have aimed to please the researcher by reporting a greater compliance that their actual compliance. Participants may have also based compliance on a single time point rather than an average compliance over an extended period of time. For greater accuracy, future studies should assess compliance through the measurement of ONS intake over a period of at least 7 days.

As with other foods and beverages, the sensory properties of ONS affect intake. Liking of ONS in this group was variable and dependent on the individual. The variety of ONS flavour and product type available (Stratton, 2000) allows for the personal preference for flavour, texture, consistency and temperature to be expressed, however, unless this variety is offered through GP prescriptions to the resident, they will not be able to make an informed choice. Lack of variety causes monotony and negatively affects compliance preventing a beneficial outcome for the resident.

Lack of knowledge both for the residents and carer could affect compliance. Memory loss will reduce ONS compliance. Residents may not remember who the prescribing practitioner was (Kennelly et al., 2009) or why they were prescribed ONS. In terms of perceived efficacy, it may be important that carers understand specific reasons for each resident’s prescriptions, and to remind residents daily of who prescribed ONS and the expected beneficial effects associated with high compliance. A belief in the opinion of the HCP could potentially drive a high compliance rate as a health protective behaviour (Floyd , Prentice-Dunn and Rogers, 2000; Cox, Coster, Russell, 2004).

Encouragement was identified as an important factor for increasing compliance. This is particularly the case in dementia patients who may be more dependent on staff and require more assistance (Carver and Dobson, 1995). Staff shortages may lead to lack of support for ONS intake. It is not always possible for care homes to increase staff levels due to financial constraints, and so methods to improve compliance must take into account current staffing levels and time restrictions of staff to complete their required jobs (Simmons and Patel 2006).

5.6 Model to improve compliance

The present research has identified areas that affect compliance both positively and negatively. Through analysis of responses from both residents taking ONS and carers involved in the distribution of ONS a model has been devised with suggested actions that could be taken to improve compliance (figure 5.4). The main focus of the model is to improve communication between HCPs, pharmacies and residents, and to promote interactions between these groups at all stages of the treatment process.

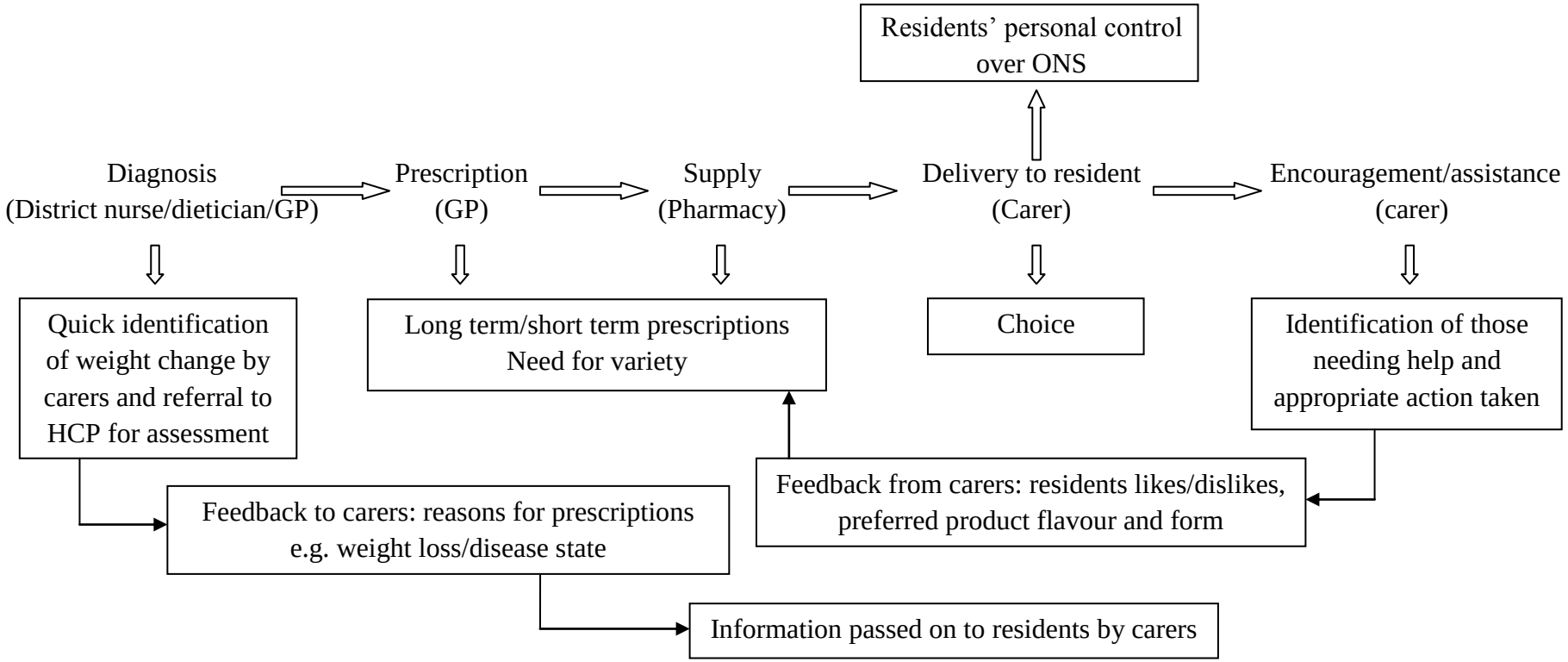


Figure 5.4 Model of the stages involved in ONS prescriptions and interactions between HCP, carers and residents that could help improve compliance to ONS

Chapter 6: Can compliance to oral nutritional supplement prescriptions be increased through the optimisation of care and the acknowledgement of personal preference?

6.1 Introduction

The model proposed to improve compliance to ONS (Figure 5.4.4; Chapter 5) suggests that strategies could focus on optimising the care offered to the resident including support, encouragement and monitoring, or could focus within the broad description of product specific options, such as ensuring that variety is offered and that personal taste is taken account of when ordering supplements. To improve compliance there is a need for interactions between residents taking ONS, carers delivering ONS and HCPs prescribing ONS.

Compliance can be assessed by the comparison of the prescribed volume and the actual volume intake; good compliance can be defined as a high percentage consumption of the prescription in order to meet nutritional requirements and minimise waste (Hubbard et al., 2012).

Compliance to ONS across different care settings is highly variable (Hubbard et al., 2012); ranging from 37% (Gosney et al., 2003) to 100% (Trejo et al., 2005). The method of compliance assessment also varies; this is partly due to reliance on self reported compliance in contrast to recorded intakes by a HCP or researcher. Lower compliance rates are reported when nurses, staff and researchers measure intakes (mean compliance rate of 55% across 9 studies, ranging from 37-68%) compared to the participant's self-reported compliance rates (mean compliance rate of 89% across 8 studies, ranging from 72-100%). Compliance rates reported by nursing and care home staff or researchers are likely to be more reliable than those compliance measurements which rely on self report (appendix 6.1).

Specifically in care homes, compliance rates have been reported to range between 54% (Bonnefoy et al., 2003) and 91% (Wouters-Wesseling et al., 2002). Despite this wide variation, only one study conducted within a care home employed methods to enhance compliance rates to ONS. Nursing staff were asked to offer help and encouragement to the residents administered ONS (although no details are given about how nursing staff

encouraged participants). Compliance to ONS was measured as volume consumed which was converted into a percentage of the 250 ml ONS offered per day. The high compliance rate of 91% recorded by the nursing home staff is likely to be more accurate than self-reported compliance. It was concluded that, by engaging methods to improve compliance, ONS consumption could be increased in care home residents (Wouters-Wesseling et al., 2002).

6.1.1Choice and variety

In healthy young and older adults, variety stimulates food intake, and monotony decreases food intake (Meiselman, de Graaf and Lesher, 2000; Zandstra, de Graaf and van Trijp, 2000). Pelchat and Schaefer (2000) investigated the effects of a 5-day liquid, sweet, monotonous yet nutritionally complete diet on food cravings in young and older adults. Older adults had significantly fewer cravings (intense desire or longing) for savoury foods compared to young adults. This suggests that older adults fail to respond to dietary monotony and might risk consuming diets lacking in adequacy. By offering a variety of ONS flavours and product types, appetite could be stimulated and thus compliance increased.

Intake of ONS may be affected by sensory specific satiety; the decline in liking of an eaten food in comparison to a non-eaten food (Rolls, 1986). Sensory specific satiety not only affects short-term intake in the hours following the consumption of a particular food, but the effect has been shown to remain for more than 24 hours (Hetherington et al., 2002). Consequently, compliance to ONS may be low due to a lack of desire to consume ONS in the same flavour on 2 consecutive days.

It is not only a lack of variety in flavour that can cause monotony, other sensory characteristics such as texture, consistency and appearance, if provided with no variation, can affect compliance. A review paper by McCrory et al. (2012) concluded that the amount eaten or the energy consumed is significantly greater with increased dietary (sensory) variety, and this finding is applied still when more than one sensory characteristic of the food is varied. Rolls et al. (1981) and Rolls, Rowe and Rolls (1982) found greater intakes when participants were offered 3 yogurts varying in flavour, colour and texture than when the yogurts varied in flavour or colour alone. It was

concluded that the more foods differ, the greater the impact of variety on nutritional intakes.

Single flavours of ONS received daily can promote loss of interest in prescriptions due to monotony. It is suggested that if flavour and form (texture, consistency and composition) are varied this could stimulate interest and intake of ONS (Meiselman, de Graaf and Lesher, 2000; Rolls et al., 1981; Stubbs et al., 2001 Zandstra, de Graaf and van Trijp 2005). This may be particularly true for those on long-term ONS prescriptions who typically only receive one type of supplement throughout the prescription period due to bulk ONS orders from the pharmacy as mentioned by participant C9 in chapter 5 (table 5.3) . These individuals are particularly at risk of poor nutritional intakes from ONS due to suffering from 'taste fatigue' (Nieuwenhuizen et al., 2010). This theory on the availability of ONS variety was supported by ESPEN guidelines on enteral nutrition; variety and alterations to the flavour, temperature and consistency of ONS are indicated to achieve better compliance to ONS and in turn increase energy, protein and other nutrient intakes in older adults (Volkert et al., 2006).

6.1.2 Engagement of care home staff

The extent to which care home staff engage with residents prescribed ONS, and the time that they spend assisting ONS consumption also influences compliance. Previous ONS interventions with care home residents who are at risk of malnutrition or who are malnourished use the researchers for the administration of the supplements. These studies tend to find significant gains in daily nutritional intakes and weight status due to the high compliance to prescriptions. Researchers provide encouragement to promote consumption and supply participants with a variety of supplement flavours and forms (Fiatarone et al., 1994; Lauque et al., 2000; Young et al., 2004). However, nursing home staff do not typically have this time and resources to dedicate to ONS intakes therefore results do not easily translate to normal practice; nor is it likely that such efforts are sustainable. Studies that rely on nursing home staff found that ONS is not always administered in accordance with prescriptions, encouragement and assistance is low, and so compliance is often poor or absent completely (Johnson, Dooley and Gleick, 1993; Kayser-Jones et al., 1998; Simmons and Patel, 2006). The problem may be attributable to inadequate staffing levels which affect appropriate administration and

cause and lack of encouragement for participants to consume ONS (Kayser-Jones et al., 1998).

6.1.3 Motivation and education

By giving care home staff specific instructions to record ONS intake, compliance can be enhanced through the increase in staff awareness of prescriptions. During a 12 week intervention staff were asked to manually record compliance, thus making them more aware and less passive towards ONS administration. This resulted in 19 out of 20 participants consuming all the supplements provided, while the remaining participant consumed 85% of what was offered (Carver and Dobson, 1995).

Supplement refusal has been observed in some care settings (Gray-Donald et al., 1995; Larsson et al., 1990); however, by offering encouragement this refusal rate can be lowered and compliance rates increased (Lauque et al., 2000; Wouters-Wesseling et al., 2002). When researchers 'strongly encouraged' nursing home residents to consume all the ONS they were offered and ONS were supplied in a variety of flavours and product types allowing for personal preference, compliance to ONS was >82.5% (Lauque et al., 2000; Wouters-Wesseling et al., 2002). However, with no baseline measurements, there can be no conclusions of whether encouragement, variety or both contributed to these high compliance levels. Both of these studies set out to evaluate the effect of ONS on variables such as body weight changes and nutritional status; the primary outcome was not compliance and so neither report a control compliance rate in which to compare their results. Consequently, there are no studies that specifically address the effect of methods to improve compliance to ONS and the impact this has on nutritional and weight status.

In chapter 5, one carer identified that by explaining the benefits of ONS to the residents when ONS are administered, the residents are more likely to comply with their prescription. This is an example of perceived efficacy; the perceived belief that a health behaviour will have a positive benefit (Weinstein, 1999). By informing participants about the beneficial effects of ONS, the protection theory model (PTM) is introduced, leading to motivation to protect against negative outcomes, and therefore the initiation of the behaviour to comply with ONS prescriptions (Bandura, 1992; Floyd et al., 2000). Previous research has suggested that compliance is greater when participants are given more information about the benefits of ONS to increase their knowledge of the clinical

effects of ONS; Gazzotti et al. (2003) achieved an 81.4% compliance rate when nurses explicitly stated to participants that ONS consumption would prevent deterioration.

6.1.4 Encouraging health behaviours

Behaviour change is hard to achieve for most health related behaviours; however a strategy which is known to be successful and has been well studied is the method of 'implementation intentions'. An intention is an instruction that an individual gives themselves to carry out a specific behaviour in order to achieve a certain goal (Triandis, 1980). Intentions typically take the form of "I intend to do/achieve X", and combine a number of cognitive processes including the deliberation about a behaviour, the standard performance required to perform the behaviour, the commitment to the performance and the amount of time and effort expected to be expended during the action (Gollwitzer, 1990; Ajzen, 1991; Webb and Sheeran, 2005). An intention however does not guarantee goal achievement. For a goal to be enacted a secondary act of willingness is instigated; this is the 'implementation intention', and furnishes the goal intention with a plan of specific when, where and how the individual will perform the behaviour (Gollwitzer, 1999).

Implementation intentions have been used to promote health related behaviours. A study by Sheeran and Orbell (2000) used implementation intentions to increase attendance to medical practices for routine cervical cancer screening. Those participants who formed implementation intentions were 23% more likely to attend screening than controls, concluding that this strategy has important implications for health benefits. Similarly, in a study aiming to promote exercise behaviour of male and female younger adults (age ranging from 16 to 41 years), participants were randomised into 1 of 4 groups; control, motivational phase (decision balance sheet; DBS), volitional phase (implementation intention), or a combination of both motivational and volitional phases. Separately, both intervention strategies produced increases in exercise frequency and improvement in fitness over controls. This was also true in the combined intervention group, which also led to better exercise behaviours than when implementation intention was used alone. It was proposed that in the combined intervention group, the DBS may have acted to remind participants of the implementation intention or increased commitment to it, and thus mediating the implementation intention-behaviour relationship (Prestwich, Lawton and Connor, 2003).

Implementation intention is however limited by the assumption that actions of behaviour are carried out rationally when in fact people often act habitually and spontaneously (Conner and Armitage, 1998). It is also assumed that behaviours are carried out under a person's volitional control. In practice, this control can be restricted by internal factors such as a lack of available information, skills and ability to carry out behaviours, or the absence of emotion towards behaviours, or can be restricted by external factors including the availability of resources and the dependence of the cooperation of others (Ajzen, 1991). Regarding ONS prescriptions in care homes, implementation intentions rely on the cooperation of both the carer and the resident; the carer drives the volitional and motivational control encouraging the residents to apply the health behaviour by consuming the ONS prescribed.

In older adults, the formation of implementation intentions appears to be particularly effective at improving prospective memory, which has implications for ONS compliance. Rather than relying on explicit recollection of information, which is a memory process that declines with age, implementation intentions rely on age-invariant automatic processes (Park, 2000; Park et al, 2002). In a study by Liu and Park (2004), older adult's memory for completing a self-monitoring assessment of blood glucose at 4 pre-determined times of day, for 3 weeks were assessed. Those who developed an implementation intention to perform the task, imagining what they would be doing the next day when they were required to carry out the monitoring, had an adherence rate of 76%. Those carrying out implementation intention were 32% more likely to perform the instructed task at the correct time than those who had simply rehearsed the times that they were to perform the task.

6.2 Aims and objectives

The objective of the present research study was to evaluate methods to improve compliance to ONS in older adult care home residents by entering participants in a 4 week intervention plus 1 week of natural compliance observation that acted as a control phase. Originally it was planned to have a control group in which participants would only receive their normal ONS prescription with no intervention, however due to the feasibility of participant recruitment, it was decided that participants would act as their own controls; this is discussed further in section 7.6.

Participants were randomised into 1 of 2 conditions; participants in condition CV were offered a *choice and variety* of ONS on a daily basis, and condition ME were offered *motivation and education* to enhance product interest and to engage both the participant and the carers on a daily basis. The primary outcome of the research was to assess compliance to ONS during the intervention phase and compare this to the control compliance phase and to the full prescription. Secondary outcomes included the assessment of weight change, BMI changes and changes to participant's risk of malnutrition (using MUST). It was hypothesised that both conditions would increase compliance above baseline compliance.

6.3 Method

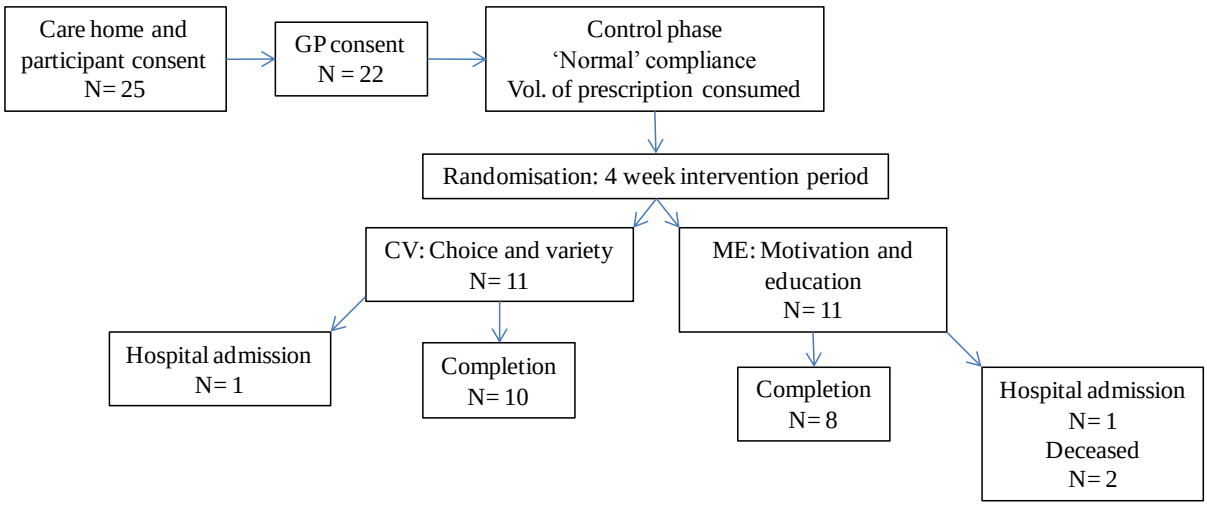


Figure 6.1 Methods flow diagram, summary of recruitment and participation.

6.3.1 Participants

Participants were recruited from residential care homes in the West Yorkshire area. Initially care home managers were sent a letter with an information sheet detailing the aims and procedure of the study and asking if they cared for any potential participants. One week later the researcher contacted the manager via phone call. Meetings were arranged with care home managers who were interested in taking part in the research and who cared for residents that fit the research inclusion criteria (table 6.1).

Table 6.1 Inclusion and exclusion criteria of participants

Inclusion criteria Participants must be:	Exclusion criteria Participants must not:
≥ 65 years	Be participating in another clinical trial
Male or female	Strongly dislike all of the flavours/forms
Currently prescribed ONS	of ONS being tested
Willing and able to participate; able to	Use tube feeds
understand the test procedure, form an	Be diagnosed with galatosaemia (inability
independent opinion and communicate this	to metabolise galactose)
opinion	
Able to give written on verbal consent	

The care home managers were asked to give their opinions of the capacity of each potential participant; only those with sufficient capacity to complete the study were asked to participate. With permission from the care home manager, the researcher approached potential participants to inform them of the study purpose and procedure.

A total of 25 participants were recruited and consented into the study; for 3 participants the GP did not allow entry into the study as it was perceived that their dementia was too advanced for the participant to take part, 2 participants passed away before study completion, and 2 participants were admitted to hospital (figure 6.1). Eighteen participants completed the study period, 13 of which were female. Mean age of participants was 84 years (71-97 years) and mean length of stay at the care home was 35 months (5-153 months).

6.3.2 Ethical considerations

The study was approved by the Ethics Committee at the Institute of Psychological Sciences at the University of Leeds, reference no. 09275- 06. The study was also reviewed and approved by the NHS Research Ethics Committee, reference no. 11/YH/0095.

Potential participants received an information sheet about the study and the researcher read this to them in order to inform them of the study protocol. Potential participants were given time to think about the study and ask any questions they may have had.

Information sheets with the researchers contact details were also sent to the relatives of potential participants; relatives were asked to consent to the participant's inclusion in the study and told they could contact the researcher at any time with questions or queries. In the case that the participant was able to sign their own name, they were asked to give written consent. If participants were unable to sign their name they were asked to give verbal consent in front of an impartial witness (care home manager or staff member) who then signed the consent form on behalf of the participant. Participants were told that the study was voluntary and they were free to withdraw at anytime and would not be required to give a reason. Data collected up to the point of withdrawal would be retained and used in the analysis of the research but no further data would be collected in relation to the participant. If during the study the participant lost capacity to consent they would be withdrawn and the same procedure would apply. All data collected from the study participants was kept confidential through a process of anonymisation; each participant was given a unique participant number, no identifiable information was kept will these numbers.

6.3.3 Randomisation process

Participants were cluster randomised according to care home; for logistical reasons, if more than 1 participant was recruited from the same care home, each of those participants were entered into the same condition for the intervention. Randomisation was manual; both conditions were assigned a code (CV and ME) these were written on separate pieces of paper and put in separate envelopes. On completion of the consent process the care home manager was asked to pick an envelope; the care home was then assigned the corresponding condition.

6.3.4 Materials

Care home managers were given the materials needed depending on the intervention the residents were randomised to receive along with an explanation of the procedure. Each week the researcher visited the care home to deliver a fresh supply of ONS and to take away empty and left over products.

ONS are available in a variety of product types and flavours; however care home residents are restricted on choice by the prescribing GP and supplying pharmacy. This causes monotonous supplementation and product boredom. To prevent this, and to

evaluate subsequent effects on compliance, participants randomised into the choice and variety condition (CV) were provided with variety packs each week. Each pack included 5 types of ONS product, each in 2 flavours (except yogurt which was offered in 3 flavours). These products are listed in table 6.2 along with their macronutrient and energy content. Participants were given a daily menu card (appendix 6.2) which visually presented a variety of ONS product type (description of product style i.e. milkshake/soup/dessert) and flavour. Each day care home staff were asked to present the menu card to the participants allowing them to choose the product type and flavour they would like. Care home staff were asked to let participants try samples of the ONS products if they were unsure of their liking/wanting of the product. Care home staff recorded the product type/flavour chosen on each day on a chart provided (appendix 6.3).

In ME participants were provided with their normal prescription in terms of product type and flavour supplied by the pharmacy. Product type and flavour were kept constant throughout the 4 week intervention however in the case that the resident was normally prescribed an alternative brand, their ONS were replaced (with permission from the participants GP) with the Nutricia products supplied by the researcher. The care home staff administering the ONS were asked to fill in a chart at the start of the day following the format of 'implementation intentions'; stating that they would "carry out X, at the time of Y" (appendix 6.4); they were asked to record the time that they intended to give the ONS to the participant, and then to check off the day once the supplement had been administered. In correspondence with the information recorded on this chart, the carers were asked to help the resident's record the same time on their own implementation intentions chart which was then displayed in a place where the resident would be able to see it (appendix 6.5). At administration of the supplements, care home staff were asked to inform the participants of the reasons why they were prescribed ONS and the possible beneficial effect of ONS. These details were provided to participants and staff on an information sheet designed for this population (appendix 6.6). Once the participant had finished taking their ONS they were given a sticker to place on the corresponding day of their personal sticker chart (appendix 6.7); the sticker represented a tangible reward for carrying out positive health behaviours. When used appropriately rewards can be an effective motivator for behaviour change (Cameron, Banko and Pierce., 2001; Dickinson, 1989). Rewards are most effective when the subject perceives

them as achievable, when they are awarded in contingency with performance and when they convey a message that they are for a behaviour that is both enjoyable and of high status (Dickinson, 1989; Lowe et al., 1998). The reward theory has previously been shown to be effective in promoting health behaviour change in children regarding fruit and vegetable consumption. The 'Food Dudes' intervention, aimed at children aged 4-11 years, resulted in a fruit consumption increase from 30% to 71%, and a vegetable consumption increase from 34% to 87%. Not only were intakes increased during the intervention whereby rewards were offered, but these high intakes were maintained by follow-up at 15 months (Horne et al., 2004). An example of a completed sticker chart and a c carers 'implementation intention' sheet can be found in appendix 6.8 and 6.9.

6.3.5 Oral nutritional supplements

The ONS required for the research was provided by Danone Research, Centre for Specialised Nutrition (Nutricia products, table 6.2). ONS were requested and sent to the researcher, and stored at the University of Leeds before being transferred to the participants at their care home during their participation in the study.

Table 6.2 ONS product details; volume, energy and protein content offered.

Fortisip product/flavour	Volume (ml)	Kcal/100ml (g)	Protein/100ml (g)
Bottle: Chocolate/Banana	200	240	6
Compact: Vanilla/Strawberry	125	150	9.6
Yogurt style: Raspberry/Vanilla and lemon/Peach and orange	200	150	6
Savoury soup: Tomato/Chicken	200	150	7.5
Fruit dessert: Strawberry/Apple	150 (g)	133	7

Each ONS was labelled with the participant number. ONS provided to participants in ME were also labelled with the date in which they should be taken. Volume of ONS dispensed to each participant was recorded, and later compared against volume consumed. This could then be converted into energy consumed.

During the study period, participants in ME received their normal ONS prescription in terms of product type and flavour (although the brand may have differed). Those randomised into CV received ONS of their choice in terms of product type and flavour.

All participants were offered at least their normal prescription but were informed that they could have extra ONS in they wanted, which was then recorded by care home staff on the charts provided.

6.3.6 Procedure

Before the intervention, control compliance was assessed for each participant; this provided a baseline compliance level. One week prior to the intervention participants (and carers) were told to take their normal ONS prescription but to keep empty packaging and leftover supplement. At the end of the control week, the researcher collected the empty ONS packaging and leftovers which were returned to the laboratory for measurement of volume consumed which was converted into energy intake (kcal).

At the end of the control week measures of weight (kg), height (estimation from ulna length, cm) and a weight from the previous 6 months was recorded for each participant. From this, BMI (kg/m^2) and MUST scores were calculated.

Participants were then randomised and entered into the 4 week intervention. At the beginning of each week the researcher visited the care home to supply participants with ONS for that week and to take away any leftover ONS. On the final day of the 4 week intervention, the measures of BMI, weight and MUST score were repeated so that any changes to participants over the 4 week period could be identified.

ONS were provided in boxes labelled specifically for each participant. Participants in the CV condition were provided weekly with variety boxes; care home staff were instructed to administer the participants chosen ONS each day and return the empty bottle/packaging plus any leftovers to the correct box. Carers were informed to offer at least the participants normal prescription in terms of volume, and if the participant

requested more they were allowed to take more. In ME, each participant was provided with a box labelled with their participant number, containing ONS for that week; in this case the ONS matched the prescription in terms of product type and flavour. Each ONS was labelled on the packaging with the participant number and date in which it should be administered. Again, carers were instructed to return empty/leftover ONS to the participant's box. In ME, each participant's box also contained extra ONS for the participant if requested. At the end of each week the researcher returned to the care home to collect empty/leftover ONS and to replace these with new ONS for the coming week. ONS containers were returned to the laboratory at the University of Leeds for the measurement of ONS consumed each day.

Compliance was measured as the volume of ONS consumed which was then converted into energy (kcal) consumed. Existing research evaluating compliance to ONS has used varying methods to measure compliance, for example the compliance review by Hubbard et al. (2012) detailed studies that report compliance as a mean percentage of the amount provided, or from the calculation of ONS prescription compared to ONS intake either from the mean volume consumed (ml), the mean energy consumed (Kcal/kJ), or from the number of portions of ONS completed (n). These varying methods could account for the wide range of reported compliance to ONS across different studies.

6.3.7 Statistical analysis

Weight, BMI and weight change were measured pre- and post-intervention; differences in the pre- and post- measures were analysed using a repeated measures ANOVA. Risk of malnutrition was also measured pre- and post-intervention; a relationship between these was determined using Pearson's correlation and a difference in MUST scores between time points was assessed using Chi-square. A violation of Chi-square assumption; that all cells will contain a count of at least 5 was found therefore the significance (p) value was derived from Fisher's exact test.

ONS intake was compared between the control week and the mean of the 4 week intervention using ANOVA. Differences across the 5 weeks (control week and 4 week intervention) were assessed using repeated measures ANOVA in which Bonferroni post-hoc was applied to identify specific differences between weeks. Data regarding ONS prescriptions was then screened for outliers identifying 2 participants prescribed 3

ONS per day (as a sole source of nutrition), these were removed and remaining data was re-analysed. Data is presented separately for both the full participant data set and the data once the outliers were removed.

A repeated measure ANOVA was used to compare control intake, mean intervention intakes and the prescribed amounts giving the overall compliance. ANOVA was used to assess the differences across the weeks. Bonferoni post-hoc was again applied. The data was then re-analysed once the outliers had been removed. Energy of ONS consumed was converted into percentage data for percentage compliance and analysed using repeated measures ANOVA.

Cost savings were calculated during the control phase and mean of the intervention weeks based on the NICE (2006) costing report. The cost of the ONS prescribed and the cost of ONS wastage was calculated and compared. Wastage was therefore extrapolated over a 180 day period.

6.4 Results

6.4.1 Weight change

Descriptive data concerning participant's weights and BMI are presented in table 6.3; measurements were taken at pre- and post-intervention.

Table 6.3 Participants descriptive data at pre- and post- intervention. Mean (SD) weight (g), weight change over 6 months (g) and BMI (kg/m^2).

	Pre-intervention	Post-intervention
Weight (kg)	50.71 (10.75)	51.43 (9.93)
Weight change over past 6 months (kg)	-1.83 (3.68)	0.66 (2.72)
BMI (kg/m^2)	20.33 (3.72)	20.83 (3.68)

There were no significant differences between conditions pre- or post-intervention. Although a repeated measures ANOVA revealed that the mean weight and BMI of all participants did increase over the 4 week intervention period this was non-significant ($F(1, 17)= 1.208$, $p= 0.287$ and $F(1, 17)=2.250$, $p= 0.083$ respectively). Mean 6 month weight change positively increased between pre- and post- intervention (mean

difference of 2.49 kg), this difference was significant ($F(1, 17)=8.681$, $p=0.009$) (figure 6.2).

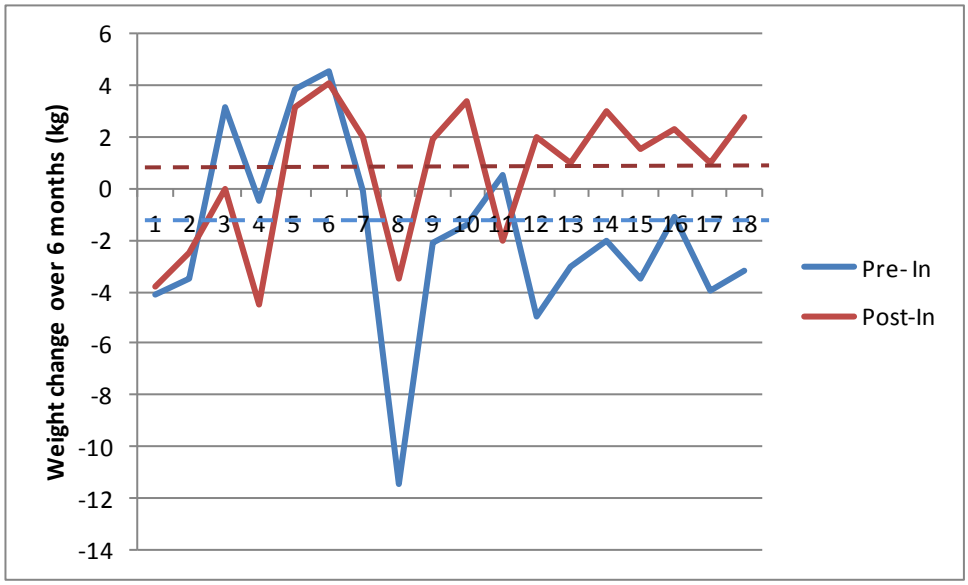


Figure 6.2 Weight change of each participant pre- and post- intervention. Average weight change was significantly different between Pre- and post- intervention, $p<0.05$.

Note: x axis represents each participant. Average weight change represented by dashed lines.

6.4.2 Risk of malnutrition

Collection of MUST scores revealed that pre- intervention 2 participants were at low risk of malnutrition (score 0), 6 participants were at medium risk (score 1) and 10 participants were at high risk (score ≥2). This gave a total of 16 participants at risk of malnutrition. Post-intervention, the number of participants at risk of malnutrition had decreased to 13; 5 were now at low risk of malnutrition, 1 participant was at medium risk of malnutrition, and 8 participants were at high risk of malnutrition (table 6.4). MUST scores pre- and post- intervention were significantly positively correlated, $r=0.584$, $p=0.011$. Chi-square revealed that the decrease in 'at risk' status of participants, although showed a trend, was not significant ($x^2=5.850$, $p=0.065$) (p value taken from Fisher's exact test statistic due to a violation of the Chi-square assumption that each cell will contain at least a count of 5).

Table 6.4 Number of participants at low, medium and high risk of malnutrition pre- and post-intervention.

		MUST score pre- intervention			
		0	**1**	**2**	**Total**
MUST score post-intervention	**0**	2	3	0	**5**
	1	0	1	3	**4**
	2	0	1	8	**9**
	Total	**2**	**5**	**11**	**18**

Note: MUST score 0 = low risk, 1= medium risk, 2= high risk. 'At risk'= no. of participants at medium + high risk.

6.4.3 ONS intake

Overall mean intake of ONS during the baseline week was 203.9 (±26.9) kcal. This intake was significantly increased over the intervention period to 324.4 (±63.8) kcal ($F(1, 17)= 5.496$, $p= 0.03$), highlighting a main effect of time. Repeated measures ANOVA revealed that mean intake was significantly different across the 5 weeks (control, week 1- week 4) ($F(4, 14)= 3.583$, $p= 0.01$). Post-hoc analysis showed that intake was significantly greater during weeks 1 and 3 of the intervention phase when compared to the baseline week ($p= 0.034$ and $p= 0.036$ respectively); weeks 2 and 4 also showed this trend ($p= 0.067$ and $p= 0.067$ respectively). Intakes of ONS did not differ between interventions ($F(3, 14)= 0.348$, $p= 0.791$) (figure 6.3).

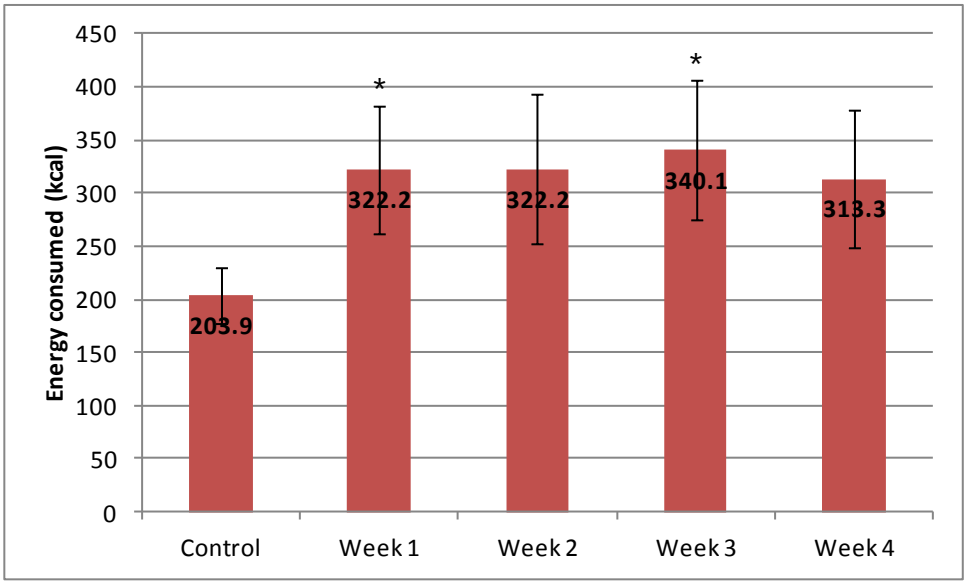


Figure 6.3 Mean (SEM) intakes of ONS (kcal) during the baseline week and each week of the intervention. *Significantly different from baseline, p<0.05.

There were no significant differences in ONS intakes between conditions at baseline or at each intervention week. The significant differences between overall intakes during baseline week and during the intervention were abolished when separated into CV and ME (figure 6.4).

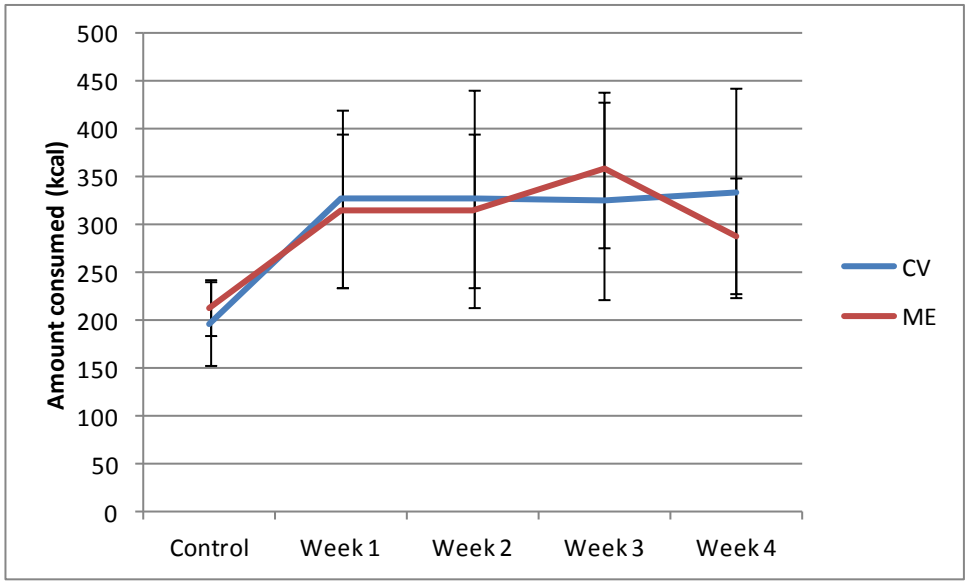


Figure 6.4 Mean (SEM) intakes of ONS (kcal) for CV (choice and variety) and ME (motivation and education) during baseline week and at each intervention week.

Two of the 18 participants were outliers with high volume prescriptions of 600 ml (900 kcal) per day. A repeated measure ANOVA was repeated after the removal of these outliers (1 participant from each condition). Intake was significantly different over time ($F(4, 11)= 3.037$, $p= 0.025$), however there was no time, condition interaction and no main effect between weeks.

6.4.4 Compliance

Mean volume of ONS prescribed to participants was 400 kcal/day (300-900 kcal). A repeated measures ANOVA showed that, at baseline the mean energy intake from ONS of 203.93 kcal/day (59.9%) was significantly lower than the prescribed volume ($F(1, 17)= 22.330$, $p<0.001$). However, during the intervention weeks mean intake increased to 324.44 kcal/day (93.1%); there was no significant difference between intake during the intervention and the prescribed amount ($F(17)= 0.887$, $p=0.359$).

The assessment of volume consumed during the control week indicating 'normal compliance' was recorded as 59.9%. Mean compliance during intervention weeks was significantly greater than control at 93.1%, achieving intakes close to perfect ($F(1, 17)= 5.496$, $p= 0.031$) (figure 6.5).

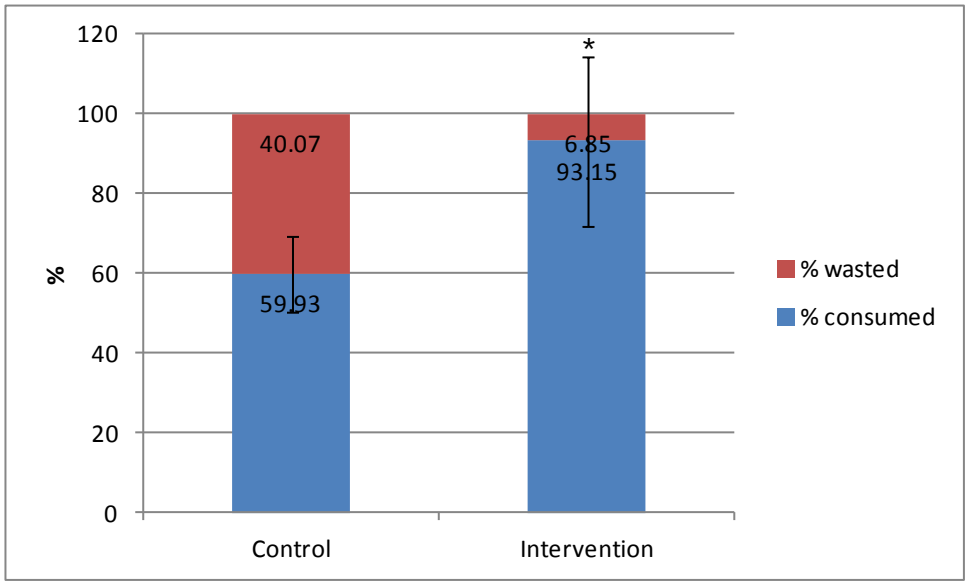


Figure 6.5 Mean (SEM) compliance to ONS of all participants at baseline (control week) compared to mean over 4 week intervention. *significantly different from control, $p<0.05$.

There were no significant differences between conditions for compliance at baseline or mean compliance over the 4 week intervention. In CV, mean compliance increased from 65.1% at control to 104.3% during the intervention (figure 6.6); some participants were requested extra ONS above their prescription.

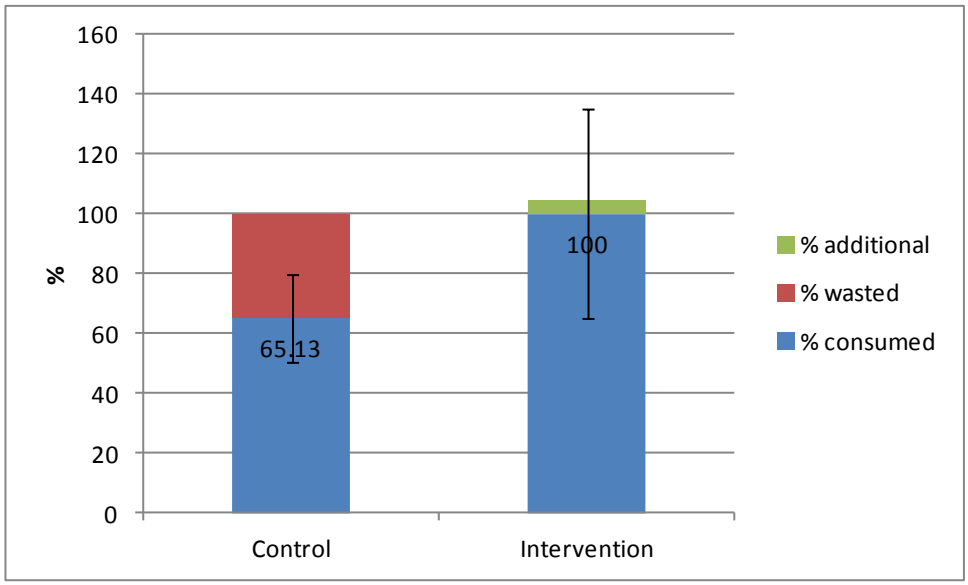


Figure 6.6 Mean (SEM) compliance to ONS of participants in CV at baseline compared to mean over 4 week intervention; % consumed, % wasted and % consumed in addition to the prescription.

In ME, mean compliance also increased between control and intervention weeks from 53.4% to 79.2% (figure 6.7). There was no significant difference in percentage change in compliance between CV (49.2%) and ME (25.8%).

Repeated measures ANOVA revealed a significant effect of time when analysing percentage compliance ($F(4, 13)= 2.972$, $p= 0.026$); compliance was significantly greater in week 3 than at baseline ($p= 0.042$), and week 1 showed a trend of higher compliance than baseline ($p=0.056$). After the removal of 2 outliers the effect of time remained ($F(4, 11)= 2.755$, $p= 0.037$), however there was no effect by week.

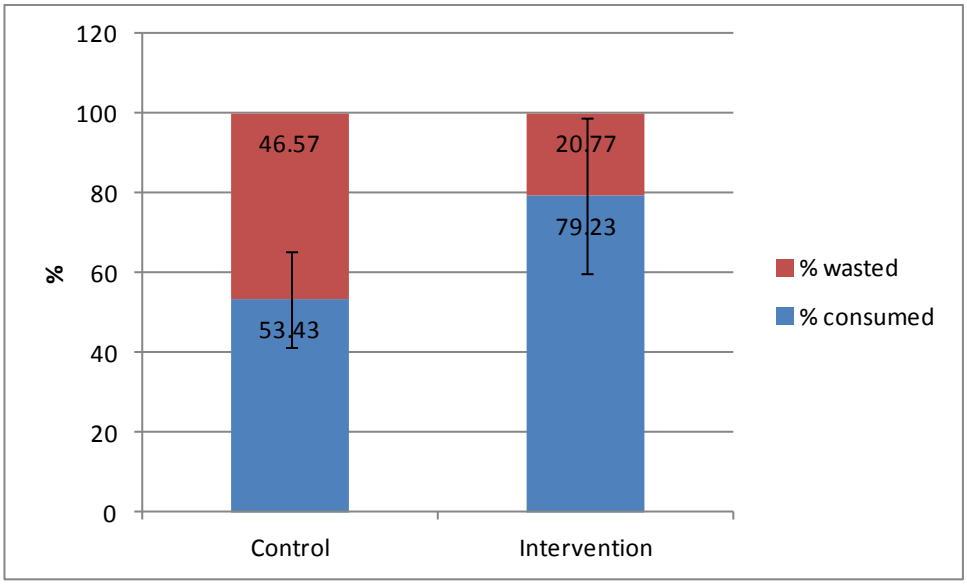


Figure 6.7 Mean (SEM) compliance to ONS of participants in ME at baseline compared to mean over 4 week intervention; % consumed and % wasted.

6.4.5 Cost

Based on the 2006 NICE costing report, the estimated cost of ONS in care homes in the UK is £1.71 per ONS. Using these figures, wastage cost was calculated per participant per day, and this was extrapolated to give a 180 day wastage cost for both baseline compliance and compliance during the intervention (table 6.5).

Table 6.5 Cost of ONS wastage per participant based an estimated cost of £1.71 per day according to the NICE costing report (2006). Baseline week compared to intervention, and extrapolated 180 day cost saving.

	% compliance		Wastage cost/day (£)		Wastage cost/180 days (£)		180 day saving (£)
	Baseline	Intervention	Baseline	Intervention	Baseline	Intervention	
Total	59.93	93.15	1.09 (0.25)	0.86 (0.24)	197.09 (45.84)	155.51 (43.76)	41.58 (33.67)
CV	65.13	104.28	1.17 (0.37)	0.97 (3.87)	211.43 (67.33)	174.27 (69.63)	37.17 (56.65)
ME	53.43	79.23	1.00 (0.36)	0.79 (0.28)	179.16 (64.15)	132.07 (50.28)	47.09 (32.07)

Overall there was a 180 day net saving of £41.58 per participant; in CV, 180 day net saving was £37.17 per participant, and in ME the net saving was £47.09 per participant. There was no significant difference in wastage cost per day or per 180 days between overall baseline and intervention weeks (mean difference of £0.23, $t(17)= 1.235$, $p=0.234$; mean difference of £41.85, $t(17)= 1.235$, $p= 0.234$ respectively) or in CV (mean difference of £0.21, $t(9)= 0.656$, $p= 0.528$; mean difference of £37.17, $t(9)= 0.656$, $p= 0.528$ respectively) or ME (mean difference of £0.26, $t(7)= 1.468$, $p=0.185$; mean difference of £47.09, $t(7)= 1.468$, $p= 0.185$ respectively). There was also no significant difference in extrapolated cost saving over 180 days between CV and ME; mean difference of £9.92 ($t(16)=-0.142$, $p= 0.889$).

6.4.6 Product choice

Figure 6.8 shows the product choices of the participants randomised into CV; the product choices are displayed as the total number of each ONS flavour and product type accepted by participants in CV.

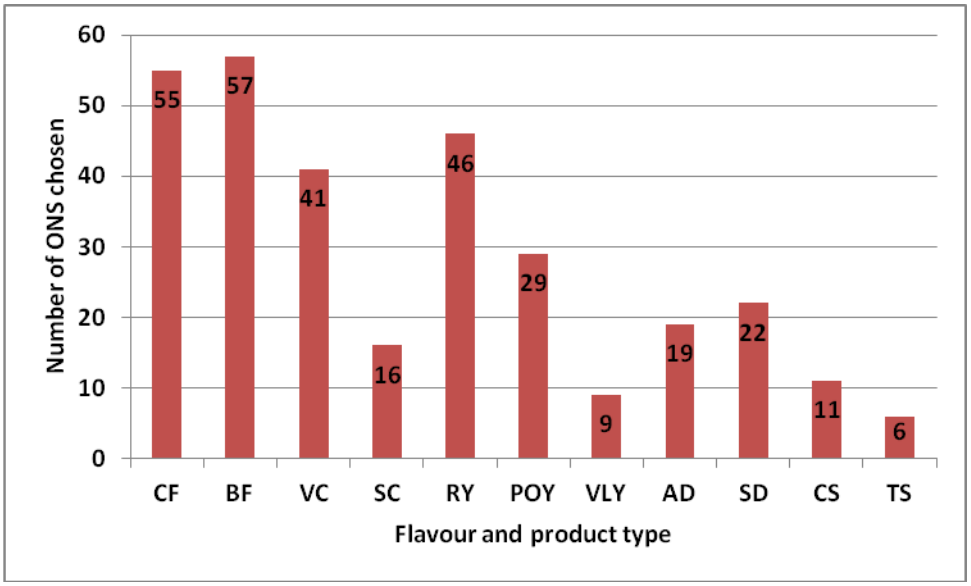


Figure 6.8 Number of each product flavour and type chosen (N= 311): CF= chocolate chocolate (200ml), BF= banana fortisip (200ml); VC= vanilla compact, SV strawberry compact (125ml); RY= raspberry yogurt, POY= peach & orange yogurt, VLY= vanilla & lemon yogurt; AD= apple dessert, SD= strawberry dessert; CS= chicken soup (fortisip multi-fibre), TS= tomato soup (fortisip multi-fibre).

The most commonly chosen product type was Fortisip bottle (200ml/300 kcal), chosen 112 times (36% of the time). The second most popular product was the yogurt style ONS (chosen 27% of the time); of these raspberry was the most well accepted flavour followed by peach and orange; vanilla and lemon flavour was reported by carers to often be rejected. Fortisip compact (125ml/300 kcal) was chosen 18% of the time; vanilla flavour was chosen more frequently than strawberry flavour. It was reported that apple and strawberry flavour Fortisip fruit desserts were well liked by 3 participants but rejected by 7 participants (in total chosen 13% of the time). Both chicken and tomato Fortisip savoury multi fibre soups were reported to only be offered to participants when it was convenient for the ONS to be heated in the microwave; consequently, both flavours of this product were not chosen often (5% of the time).

6.5 Discussion

The main aim of this study was to evaluate 2 specific methods to improve compliance to ONS; this was achieved by offering participants either a daily choice from a variety of ONS product types and flavours or offering motivation and education towards the ONS they were prescribed. Overall mean compliance significantly increased from baseline to intervention weeks. Baseline intake of ONS was 40% below the prescribed volume, during the intervention week, compliance increased to only 7% below the prescribed volume. In each condition separately, compliance increased from baseline to intervention; particularly when a choice was offered, compliance was increased to over 100% of the prescription. This result suggests that it is the monotony of long term prescriptions and the lack of acknowledgement of personal preferences in terms of product types and flavours that is the main contributor to poor compliance. These findings add to those of Lad et al. (2005) in which the views and attitudes of participants taking ONS were evaluated to find that taste, flavour, texture, predictability and personal preference all contribute to poor compliance.

The total mean energy consumed from the ONS during the intervention weeks was approximately 120 kcal greater than during the control week although there were no differences in intakes between conditions. At control, intakes of ONS were significantly lower than the prescribed amount; this difference was removed during the intervention period and so participants were consuming ONS in amounts that related to the prescribed volumes. No difference of intakes between conditions suggests that both

interventions can improve compliance to ONS, but neither condition is more successful than the other.

The increase in rate of compliance during the intervention period results in less wastage of ONS, and may therefore be beneficial in terms of health economics. In 2006 the NICE costing report gave a figure of 7,955 persons living in care homes taking ONS prescriptions in the UK. Based on the 180 day cost saving per participant in this current intervention, UK NHS expenditure could benefit from a total 180 day saving of ~£330, 768.90 by employing an intervention strategy at administration of supplements to care home residents.

A limitation of previous ONS interventions that offer encouragement and motivation is that this engagement comes from the researcher (Lauque et al., 2000). This issue was addressed in the present study as the care home staff had the responsibility of administering ONS according to the methods of the intervention. Prior to the initiation of the research, the researcher informed the care home manager and the staff responsible for ONS administration of the aims and method of the study. Appropriate training was given so that care home staff followed the test procedure on a day-to-day basis ensuring that participants received the correct intervention. For long term effectiveness post-intervention, methods of training in nutritional encouragement could be implemented for care home staff so that the positive results seen during research are transferred into routine care management.

The ME condition employed both a motivational strategy, informing residents of the health benefits of taking ONS, encouraging ONS intake, and a volitional component, requiring carers to form implementation intentions to administer ONS to residents at a pre-determined time, thereby applying the behaviour. Although both strategies involved the resident participant, they were mainly the responsibility of the carer, for example, the resident completed implementation intentions but depended on the carer to help them and it was the carer who provided the motivation to consume. A previous study by Prestwich et al. (2003) combined both strategies to improve physical activity frequency and fitness levels over that of implementation intentions alone. An improvement to the present study would be to include a method that combines both motivational and volitional strategies for both the resident and the carer. However, the present research advances the current implementation intention literature; this type of research has

previously been conducted in younger adults and healthy older adults. This study has shown that the methods of implementation intentions can be adapted for more vulnerable and less cognitively able older adults living in care homes.

For implementation intentions to be successful an element of planning must be adhered to; in this case, both carers and residents were asked to specify daily the time at which they would administer/take the ONS prescribed ('when'). Other situational parameters that could have been used were the specification of 'where' and 'how'; through a meta-analysis, Gollwitzer and Sheeran (2006) showed that, by incorporating these three parameters into one intention, the intended behaviour would not easily be forgotten. A limitation of the present study was that only the 'when' parameter was used. Implementation intentions were adapted for use by vulnerable adults; the protocol was made simple for use within the busy care setting, and it was more appropriate to use just one parameter as there was a reliance on both carer and resident cooperation. The study could be improved by introducing the other two situational parameters; this could be a more effective method to increase compliance over a more longitudinal study.

As part of the motivation condition, rewards in the form of stickers were offered to participants on completion of their ONS each day. Participants were able to put their awarded stickers on a chart and see weekly progress of ONS intake. The main aim of this strategy was to engage the awareness of the resident to their ONS prescriptions and to offer a reward for good compliance in the attempt of a repeat of this behaviour through the intervention period. A reward strategy was used by Cooke et al. (2011) to increase children's (4-6 years) enjoyment of vegetables. Children were randomised to either receive vegetable exposure and a tangible non-food reward, exposure and a social reward e.g. praise exposure alone or no treatment (control). Over the study period (3 weeks plus 1 month and 3 month follow-ups in which rewards were removed), intake and liking of the target vegetable was increased in all groups, but was significantly greater in intervention groups than control. The effects on intake were however larger when the children received a tangible reward than when exposure was alone. Moreover, the effects on intake were only maintained at follow-up in the groups that received rewards. A social reward such as praise has no cost associations; if intake can be increased merely through motivation given as praise, this could have important implications on ONS compliance in care homes where cost is such a major concern.

In conclusion, the present study indicated that both methods of the intervention help to increase compliance; by offering either a variety of ONS in terms of product type and flavour and allowing for residents to choose their personal preference, or by encouraging consumption through education, motivation and providing a award system. This intervention had the advantage that participants were current users of ONS already experiencing the problems with full compliance to ONS prescriptions. The effects on compliance associated with the intervention were evaluated without the confounding factor of ONS as a novel food. The research is a testimony to the effects of engagement of the resident (offering a personal choice) and the support of the carer (offering motivation and increasing knowledge towards ONS) in the promotion of compliance. Both intervention methods were easy to administer and could be effectively integrated into normal nutritional care. The methods evaluated for this research could be integrated into NICE guidelines for nutritional support (CG32; NICE, 2006) and could be used for the promotion of person-centred care in which the nutritional needs and preferences of the resident are acknowledged (NICE, 2006).

Chapter 7: General Discussion

7.1 Thesis aims restated

This thesis had the main objective to evaluate methods to improve compliance to ONS in older adult care home residents. Within this, 4 main questions were addressed; Who is vulnerable to malnutrition risk in a care home setting? How can nutritional intakes of care home residents be increased at lunch times? What are the resident's opinions of the ONS they are taking and what are the barriers that affect compliance to ONS in care homes? What methods are appropriate to increase compliance to ONS in current ONS users?

The first aim was achieved by retrospectively collecting residents weights from those recorded in care plans, and screening residents for malnutrition risk at 2 time-points allowing changes in body weight over the year to be investigated. The second aim was accomplished by comparing the 'food first' approach using food fortification (NHS, Leeds 2010) with the use of ONS offered overtly and covertly. The barriers affecting compliance to ONS were then identified by interviewing current users of ONS and care home staff involved in ONS delivery to residents. From the responses, common themes could be identified and addressed in the final stage of the research. Lastly, methods to improve compliance to ONS were evaluated by conducting a 4 week intervention in which current users of ONS in care homes were randomised either to receive a daily choice of in terms of ONS variety (flavour and product type) or were given their normal ONS but offered motivation and encouragement to comply with their prescription.

7.2 Core findings

(1) Who is vulnerable to malnutrition risk in the care home setting?

Overall risk of malnutrition remains high in older adult care home residents; the results of this study were in line with malnutrition prevalence data for the UK (BAPEN, 2007, 2008, 2010), that >1 in 3 older adults are at risk of malnutrition. Risk of malnutrition remained stable between T1 and T2. This observed stability in MUST scores suggests that the use of a debrief letter to identify and recommend treatment strategies for those

at risk of malnutrition did help to prevented further decline of those at risk. However, with the lack of a follow up within the 6 months between T1 and T2, there was not enough support offered to ensure that actions taken were effective to move residents into a low risk category. However, risk of malnutrition significantly increased in residential care, whereas risk significantly decreased in nursing care.

At the initial screening (T1), those who had a VLW BMI had lost the most weight over the previous 6 months; by T2 weight had begun to stabilise and was beginning to increase in this group. Although unknown, a possible explanation for this could be vigilance in carer awareness of weight loss, promoting the initiation of the malnutrition management guidelines.

High risk of malnutrition was found to cluster in certain lower socio-economic areas. In these urban areas, there are a higher number of county-council run care homes when compared to more rural and higher social class areas; the county-council run care homes do not have the same resources as privately run care homes due to financial restrictions. Care home staff are more likely to be agency staff and so the consistency of carers seen in private care homes is not replicated; carers in county-council run care homes may not work in one place for prolonged periods of time and so build limited relationships with the residents, therefore are less likely to recognise deterioration or any changes in eating behaviours and habits.

(2) The use of food fortification and ONS to increase nutritional intakes. Is food first the best option?

An effective method to increase nutritional intakes of older adult care home residents is to increase the energy density of meals without increasing the weight (portion size). There is an age-related lack of compensation in response to the energy density of food; the weight of food eaten not the energy content prompts physiological signalling satiety. The use of both food fortification and ONS resulted in an increase in nutrient intakes. Food fortification promoted a small increase in intake of protein and fat while ONS promoted a small but significant increase in carbohydrate intake in comparison to the plain meal. It is also likely that supplementation through ONS produced the additional benefit of increasing micronutrient intakes; if taken regularly, this could help to address

any vitamin or mineral deficiencies often seen in older adults (Finch et al., 1998; Elia and Stratton, 2004).

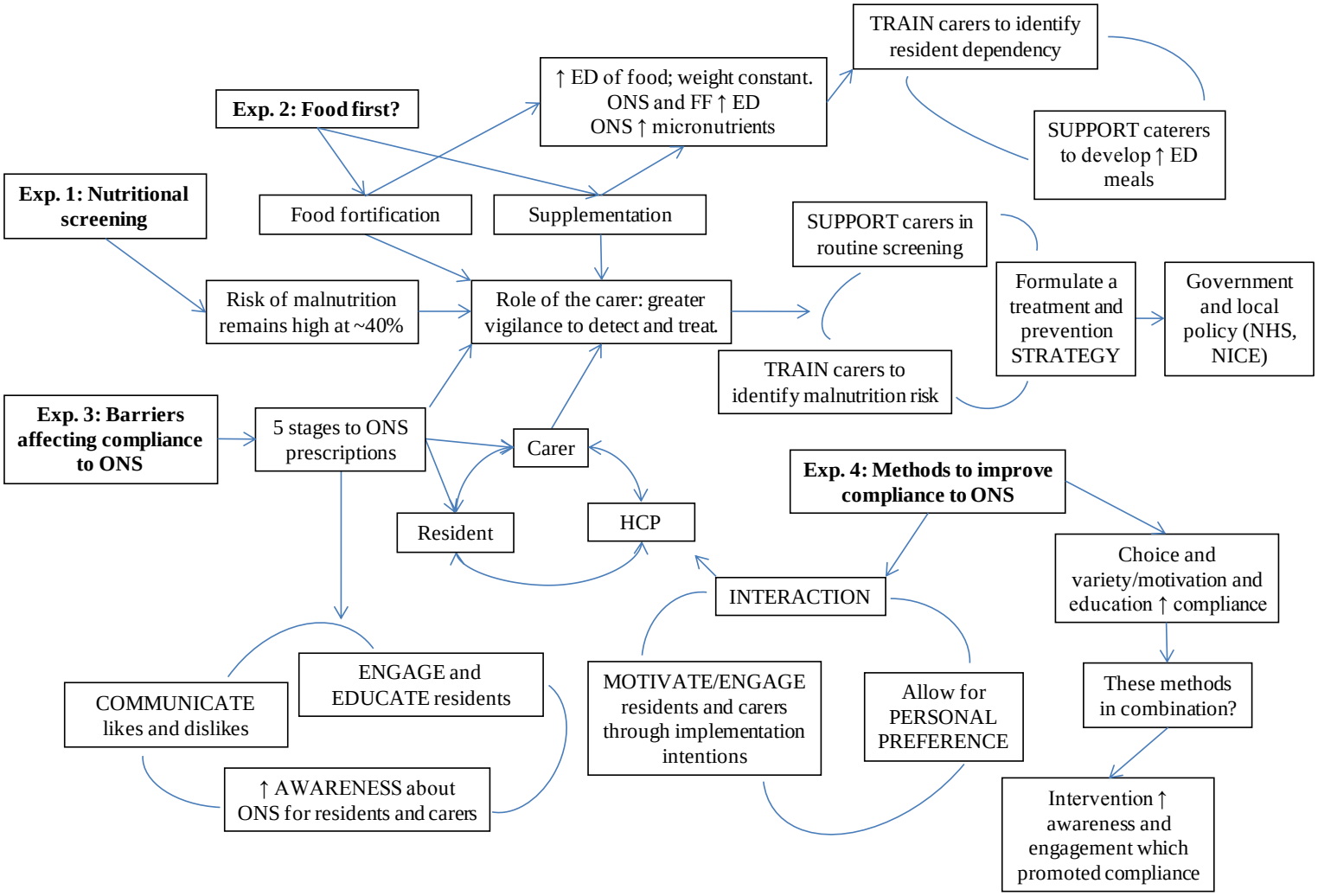
(3) What are resident and carers perspectives of oral nutrition supplements?

Both residents and carers identified common themes as barriers affecting ONS compliance. From the carer's perspectives, encouragement, support and the promotion of knowledge about ONS in terms of the benefits and reasons for prescriptions were identified as factors that would increase compliance to ONS. Encouragement to take ONS was also mentioned by residents and extra assistance when taking ONS. Residents clearly identified their desire for variety of ONS so personal preference and choice between products can be made. Variety also prevents monotony, particularly for those on long-term prescriptions or taking ONS as a sole source of nutrition. From these findings, a model has been developed with a suggested method to improve compliance to ONS (figure 5.4).

(4) Can compliance to oral nutritional supplement prescriptions be increased through the optimisation of care and the acknowledgement of personal preference?

Promoting awareness and engagement with prescriptions, regardless of how this is done, can increase compliance rates to ONS. By offering a choice from a variety of ONS or by motivating and improving both carer and resident knowledge about ONS, the level of compliance can be increased above that observed during standard care. The improved compliance rate achieved in the choice and variety group suggests that personal preference is valued by residents; this strategy prevents predictability in ONS. In the motivation and education group, compliance depended on the cooperation of both the carer and the resident in order for both the volitional and motivational aspects of the implementation intention technique to be effective in supporting ONS compliance.

Figure 7.1 Core finding of research with suggestions of methods to improve nutritional care.



7.3 Themes

7.3.1 The role of the carer

The role of the carer appears as the most dominant theme throughout each stage of this research, not only in the enhancement of compliance to ONS but in the identification of those needing nutritional support and in everyday nutritional care, as a way to promote greater nutritional intakes particularly in those at risk of malnutrition.

Although overall risk of malnutrition identified in chapter 3 remained stable between T1 and T2; the number of participants at risk of malnutrition in residential care significantly increased by T2 whereas in nursing care this number significantly decreased. These findings highlight the importance of the role of the carer in the identification and treatment of malnutrition. In care homes, carers have primary responsibility for nutritional management of residents. Carers are ideally placed to identify any change in weights, appetite and general well being as they come in contact with the residents on a daily basis (Davies, 2005).In nursing care, the high numbers of those identified as at risk in the debrief communication may have increased awareness among care home staff of the implications of malnutrition encouraging them to take action to treat and prevent further deterioration. It may have been that the nursing home carers were more vigilant after screening at T1, and strictly carried out screening routinely, assessing nutritional status changes month-by-month to identify those losing weight *before* weight loss reached a level of concern In residential care however, the number of residents identified as at risk was lower and so awareness about malnutrition may be less salient; any residents with underlying conditions affecting nutritional status that developed in the following 6 months may have gone unnoticed leading to a greater prevalence of malnutrition at T2.

The debrief communication given to care homes after T1 indicated the management guidelines for those identified as ‘at risk’ of malnutrition. As with routine nutritional care, in the case that risk of malnutrition was identified, it was the role of the carer to alert the appropriate HCP (GP, dietician or district nurse) for a more detailed nutritional assessment of the resident in question. Any therapy employed to treat malnutrition would require close monitoring in order to assess whether it was an effective and appropriate nutritional support strategy. Although this was primarily the responsibility

of the carer, it also required close input from the prescribing HCP to support the carer through the personal care of the resident, and to encourage the resident to comply to the therapy in order to achieve a benefit (Holder, 2003). The role of the HCP and the treatment prescribed to high risk participants was not assessed during the present research, but it is suggested that future research involves HCP participation so that specific treatments, compliance to treatments and outcomes can be evaluated.

Reluctance and inability of the resident to take ONS can contribute to poor ONS compliance (Bruce, 2003). Improved compliance could be achieved by the carer providing extra encouragement and assistance to residents at times of supplementation. This was indicted by care staff in response to the questions asked during the interviews presented in chapter 5; C2 stated that "staff will sit with them [the residents] if they have a supplement... then they can help them if they're struggling". However, the amount of assistance and encouragement given depends on the number of staff available and the amount of time that can be spent assisting residents during supplementation and at mealtimes. In a qualitative study across two nursing homes, Kayser-Jones and Schnell (1997) found that an inadequate staffing level greatly affected food intakes and nutritional care. Carers repeatedly described staff shortages at mealtimes; the consequence of inadequate staffing was a lack of personal care. Due to a lack of time, many residents with limited mobility were not moved to the dining area at mealtimes and so ate in isolation in their bed. In some cases, residents were able to eat independently but did so slowly; although these residents were given help by the carers, this was to encourage them eat faster rather than to assist their independent eating, and so over time their dependency would increase. It was suggested that provisions should be made to increase the carer-to-resident ratio at mealtimes, and to educate carers about enhanced nutritional care and feeding practices.

The role of the carer in the use of specific motivational methods to increase compliance to ONS had not yet been evaluated. However, in chapter 6 of this thesis, the use of tools promoting motivation and education as a method to increase ONS compliance were assessed. For this method to work effectively there was a high dependence on compliance by the carer. The carer was asked to conduct the volitional phase in which implementation intentions were carried out; the intention to administer ONS and the application of this intention by delivering ONS to the resident. For the motivational

phase, the carer was asked to inform the resident of the health benefits associated with ONS intake, thereby promoting the residents behaviour to consume and comply with their prescription (Prestwich, Lawton and Conner, 2003). By carrying out these tasks, compliance increased by 26%; almost 80% of ONS offered were consumed per day.

In reality, the low staffing levels in care homes impact on the likelihood that residents will receive encouragement to eat which may have serious consequences particularly for those who are more dependent and living in nursing care. In a study investigating social, cultural, environmental and clinical factors that influence eating behaviour in nursing homes, a member of nursing staff acknowledged that staffing levels during evening mealtimes was too low to provide quality nutritional care to the 90% of residents requiring assistance and encouragement with eating (Kayser-Jones and Schnell, 1997). ONS packaging was identified as a problem in 3 of the residents who had lost some mobility in their hands; packaging tends to be small bottles with screw caps, foil seals and detachable, sealed straws, all of which can be difficult to use and may put older adults off taking the supplements. With adequate staffing levels, these issues could be addressed to allow for extra help given to those who struggle to handle ONS.

Part of the role of the carer is to administer ONS at the correct time; however, the ideal time at which ONS are administered is an issue of debate within the literature. Although ONS consumption between meals (as a snack) has been shown not to affect meal time intakes (Johnson, Dooley, Gleick, 1993; Simmons and Schnelle, 2004), the volume of ONS consumed has been shown to be higher when ONS are administered at mealtimes due to the greater availability of staff to offer assistance and encouragement (Simmons and Patel, 2006). Total daily intakes were not assessed in chapter 4, however the results of study 2 demonstrated that participants ate for volume rather than energy density at meal times, and therefore by using ONS to fortify meals or giving ONS on the side of a meal, but keeping the total volume of food offered the same, energy intake can be increased above that of giving a plain meal. The increased levels of staff at mealtimes (Simmons and Patel, 2006) could justify ONS administration with meals. A staff member could be allocated the position of overseeing supplementation while all residents prescribed ONS are in one area (for example, the dining room); this would help to increase awareness towards ONS, promoting encouragement and motivation for the residents to comply with their prescriptions.

7.3.2 Variety and Personal preference

Age-related physiological changes result in a failure to respond to dietary monotony and therefore diets may be compromised. By offering variety, appetite can be stimulated (Rolls et al., 1981; Rolls, Rowe and Rolls, 1982). Although older adults may not be as responsive to variety as younger adults, by making variety available, there is a potential to achieve optimum nutritional balance (Pelchat and Schaefer, 2000). Similarly, for ONS consumption, it has also previously been suggested that intake could be increased by offering variety (Gray-Donald et al., 1995; Lauque et al., 2000; Krondl et al., 1997). The themes identified in chapter 5 added to this; in the opinions of current ONS users, the lack of variation offered was the main factor leading to poor compliance. Residents are not aware of the vast variety of flavour and product types available suggesting that, even at the point of prescription by the GP, residents were not offered a choice.

In chapter 6, results demonstrated that ONS compliance can be increased by offering a choice in flavour and product type. Compliance was increased to over 100% of the prescription; participants were more likely to ask for more ONS if they were allowed to choose their preferred flavour and product type at the time ONS was offered. This is in line with previous research by Weenen et al. (unpublished manuscript) in which compliance was reported as high over a 4 week period by offering a choice of ONS, twice daily by presenting care home residents with menu cards displaying 7 products. Participants rated product liking highly and did not experience the effects of product boredom on intake.

As with carer and resident responses recoded in Chapter 5, Dunne (2009) concluded that consumption of ONS would be enhanced by administering supplements in the patients preferred flavour. In an initial audit of hospital patient's preference to ONS, Harcourt-Watkins and Morgan (2012) found that patients would be more compliant with their prescriptions if they were given a choice in flavour. The lack of choice offered was attributed to the current nursing practice and lack of knowledge towards ONS prescriptions and availability. Harcourt-Watkins and Morgan (2012) developed a poster for clinical use to raise awareness of personal preference to both nurses and patients, highlighting the variety of flavours available of each product. Although no compliance rate was stated, the poster increased awareness to taste fatigue which can occur when patients are offered only one flavour of supplement, and it was concluded that nurses

should offer choice in flavour where possible. The use of a poster was similar to the use of the menu card in Chapter 6 which made residents (and carers) visually aware of different flavours and ONS product types available, and allowed them to make a choice of which product to have daily. An advantage of this study over the research by Harcourt-Watkins and Morgan (2012) was that compliance level to ONS was recorded and could be compared to a control compliance level, revealing an increase in compliance of almost 40%.

The availability of ONS variety is far greater in the hospital setting where there is an abundance of ONS due to the low cost (NICE, 2006) and high number of patients taking ONS prescriptions, compared to care homes where ONS are more expensive and less prescriptions are given. Carers in chapter 5, identify that care homes have no control over the variety of prescriptions. Due to the restrictions from the pharmacy and prescribing GP, ONS are delivered to care homes in 'bulk', with normally just one or two flavours of the same product allocated to each resident. The introduction of variety packs may help to increase variety in care homes but may not be cost effective due to waste of unwanted flavours/product forms.

According to the Mental Capacity Act (2005), "A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success" (pg. 1). It is also stated that "A lack of capacity cannot be established merely by reference to; (a) a person's *age* or appearance, (b) a condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity" (pg. 2). It should not be 'assumed' that a care home resident cannot make a choice with regards to the flavour or type of ONS they receive. In chapter 5, both participants R3 and R4 mention that the nurses choose the type of ONS they receive; in line with the Mental Health Act, if a variety is available, the choice should lie with the resident. Even in the case that the resident is diagnosed with dementia, C9 acknowledges that they would appreciate trying "something different". The diagnosis of dementia tends to be used as an 'umbrella' term; however, the difference between early stage- and late stage dementia should be acknowledged. At early stages, the resident may still have capacity to choose a particular flavour of ONS that they like and if reminded daily of the reasons behind their ONS prescription, awareness may be increased thus increasing compliance. By introducing a choice, and allowing residents

to try ONS samples prior to the prescription being written, either verbal on non-verbal communication could give an indication of the personal preference towards different products. In the case that the resident can communicate verbally, they could simply state the ONS they would like to be offered. Equally, in the case that the resident cannot communicate a verbal opinion, the use of facial expression observation could allow the carer or HCP to make an informed decision of the products that would give the highest compliance rates. From the judgement of emotions through direct observation, it is possible to assess preferences and aversions in dementia patients (Lawton, 1994). The Philadelphia Geriatric Centre Affect Rating Scale (Lawton, Haitsma and Klapper, 1996) is a reliable tool that measures the occurrence of specific emotions; pleasure, anger, anxiety/fear, sadness, interest and contentment. It does this by listing the expressive signs related to each emotion, for which a trained member of staff can observe and rate to give a judgement of the patient's emotional state.

Behavioural and environmental factors that contribute significantly to malnutrition such as; adequacy and quality of assistance, regarding resident's personal preferences, and preventing social isolation by encouraging dining room eating (Simmons, Osterweil and Schnelle, 2001; Amella, 1999; Kayser-Jones and Schnelle, 1997) can be reversed. By addressing these psychological and social factors, nutritional intakes of meals can be improved without the extra cost implications of ONS prescriptions. In nursing homes where the capacity of some residents to communicate their opinions is low, the preferred choice of nutritional treatment to malnutrition often goes amiss; clinical practice guidelines for nutritional care in nursing homes recommend that these 'alternative' methods are recognised and implemented before the use of ONS (Thomas et al., 2000). In a study that evaluated family members preferences towards the nutritional treatments that their relative would receive in the nursing home, and for the improvement of long term care, a preference for 'other nutritional interventions' over ONS and pharmacological approaches was found. These included the improvement of food quality and quality of feeding assistance, the provisions of small meals and snacks throughout the day, and the allowance for residents to eat in their preferred setting (Simmons et al., 2003). This has implications for ONS compliance of those currently taking ONS in nursing homes; without support from family members it is likely that adherence to prescriptions is low. It was suggested that a future research direction would be to evaluate residents' responsiveness to behavioural and environmental

interventions that were identified as most desirable by the family members (Simmons et al., 2003).

7.3.3 Perceived efficacy

Perceived efficacy is a component of the PTM and is an important factor in regards to motivational, cognitive and emotional processes that generate health related behaviours (Bandura, 1992). In terms of ONS compliance, perceived efficacy can drive intention to consume; there is a certain amount of 'trust' allocated by the care home resident to the HCP and carers. If the HCP and carers relay the expected beneficial effects of taking ONS, residents are more likely to comply with their prescriptions. Perceived efficacy was highlighted as a theme from resident responses in chapter 5; it appeared to be a stronger mediator than the enjoyment of consumption for ONS compliance. Self-reported compliance was 80-100% whereas enjoyment of consumption was rated between 'unpleasant' and 'neither unpleasant nor pleasant'.

For implementation intentions to be successful, there must be an element of planning; action planning is an extension of an intention in which specific situational parameters are specified, for example, 'when', 'where' and 'how' (Guitierrez, Dona et al., 2009). Action planning mediates the intention- behaviour relationship through perceived efficacy. Perceived efficacy is the moderator of this relationship and has been found to be important at all stages of the health behaviour change process (Bandura, 1997). For those with higher levels of perceived efficacy, planning an intention is more likely to lead to goal achievement as the individual feels more confident about translating planned behaviours into actual behaviours (Gutierrez-Dona et al., 2009). The educational component of the motivation and education arm presented in chapter 6 promoted perceived efficacy; residents were informed and reminded daily of the health benefits relating to ONS intake. The resident's confidence in the ONS products was increased by this method, driving the intention and implementation of ONS consumption.

7.4 Compliance to drug medication; are ONS medications or food?

It is not only compliance to ONS prescriptions that is poor; it is estimated that 20-50% of patients do not take their drug-based medications correctly (do not complete prescriptions) and so are 'non-compliant' to prescriptions (DiMatteo, 2004; Osterberg

and Blaschke, 2005). Poor compliance to medication has been attributed to both 'unintentional non-adherence' and 'intentional non-adherence'. Unintentional non-adherence occurs when capacity and resource limitations prevent a patient from implementing their treatment regime, and can be due to individual constraints such as memory loss and poor dexterity, or environmental aspects such as access and costs to acquire prescriptions. Intentional non-adherence arises from a lack of motivation to begin and continue prescriptions, and occurs as a result of the patient's beliefs, attitudes and expectations (Horne et al., 2005). There is likely to be an interrelationship between intentional and non-intentional non-adherence in which internal factors such as motivation and capacity are moderated by external factors such as the quality of communication between the patient and HCP, access to resources and the restrictions of local policies and practices (Horne et al., 2005).

Recent interventions attempting to improve patient's compliance to prescriptions are in support of using psychological determinants of behaviour change for the potential application in medication compliance (Hardeman et al., 2005). A recent study applied a psychological approach to promote medication compliance in Type II diabetics (Farmer at al., 2012). A two- component approach was developed to address both intentional and non-intentional non-adherence elements affecting compliance through The Theory of Planned Behaviour and Implementation Intentions. The motivational component targeted cognitive determinants and underlying beliefs about the intention, and the volitional component defined plans of behaviour implementation to facilitate the translation of intentions into action. Results showed that compliance was significantly greater in the intervention group (77.4%) than the control group (69.0%) who received just standard care. Approaches that address both the intentional and non-intentional barriers affecting compliance were shown to be useful for enhancing ONS compliance in care homes in Chapter 6. Participants offered motivation and education to consume ONS in addition to stating the intention to take ONS, showed increased compliance by almost 30% above their baseline compliance level.

The observed low compliance rate to medications prescribed for asymptomatic conditions has implications for the long-term treatment of malnutrition with ONS. When the weight of a malnourished individual begins to increase or stabilise, the visible symptoms of malnutrition may become less obvious. The individual or carer may

perceive them/themselves as ‘cured’, contributing to a declining rate of compliance. This issue is further affected by the length of ONS prescriptions which on average are for 180 days (NICE, 2006). Poor compliance rates were found to be positively associated with longer duration treatment programmes in a study evaluating predictors of compliance to back pain medication (Costa Alexandre et al., 2002). Similarly, medication compliance is inversely related to the number of doses of medications prescribed per day; a systematic review by Claxton, Cramer and Pierce (2001) concluded that better compliance is achieved when daily dosage regimens are less frequent across a variety of therapeutic classes.

Unlike a drug-based medication (e.g. pills), ONS come as high volume liquids that apply to the rules of satiety and satiation. ONS are not one mouthful like a single pill or spoonful of medicine; they take time to consume. The way in which ONS are treated, as a medication or as a food, affects the best methods to enhance compliance. If ONS are regarded as food, for example in Chapter 4 where they were either incorporated into a meal or given on the side of a meal, the social element of eating should be taken into account as well as the product palatability, sensory properties, monotony of supplementation, and the satiety effect that may prolong consumption over a few hours. These issues are not usually considered a problem with drug-based medications; consumption is usually fast and does not depend on palatability and so there is no issue of monotony. Despite the differences, the methods that have been researched for the enhancement of compliance to drug-based medications (Horne et al., 2005) can be applied to prescriptions of ONS, with the adaptation of increased time to consume and an appreciation that compliance will impact on appetite and satiety.

7.5 Implications for nutritional care and public health

From the themes identified throughout the research in this thesis there are key messages that can be suggested with the aim of improving nutritional care in care homes. Primarily, these are based around the role of the carer (figure 7.2).

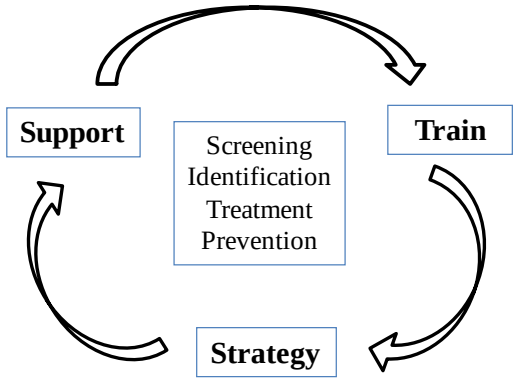


Figure 7.2 Model of considerations for improving nutritional care in care homes

There appears to be a need to improve the support and training of the carer so that they can carry out effective and efficient screening for malnutrition, and initiate strategies to motivate, encourage and educate those residents at risk of malnutrition through personalised a treatment and prevention care plan.

7.5.1 Screening recommendations

In addition to the recommendations for future screening practice detailed in the BAPEN reports (Russell and Elia, 2008, 2009 and 2011), the present research has highlighted the importance of supporting carers during monthly nutritional screening audits. To carry out these audits effectively, carers could be trained to accurately measure resident's weights, and to identify those at risk of malnutrition by looking back over weights from the previous 3-6 months in each individuals care plans. It is suggested that carer training includes specific information about how to document the monthly weights and the nutritional scores of residents correctly and consistently (e.g. all carers using metric measures) in the care plans.

For those identified as at risk of malnutrition, the carer is first in line to initiate appropriate action to treat and prevent further health deterioration. In the first instance, care homes could be given access to a nutritional advice support teams through which staff could be trained to commence non-medical methods to improve daily nutritional intakes, such as food fortification (chapter 4) and snacking to increase nutritional intakes. If the resident does not show signs of weight improvement through use of these, and remains of clinical concern, the resident can then be referred to the GP or dietician for the continuation of treatment under the HCPs supervision (Russell and Elia, 2008,

2009 and 2011). At the stage of referral it is important that there is good communication between the HCP, the carer and the resident to ensure that all stages of the treatment strategy (whether through non-medical nutritional support or through the use of nutritional supplements) can be fulfilled successfully.

7.5.2 Improving nutritional intakes

The evidence in which NHS Leeds (2010) policy on food first is based remains to be lacking in terms of proven beneficial effects for patients; the focus is still largely on the lower initial cost of food first rather than the long-term well-being of the individual receiving the intervention. As shown in chapter 4, nutritional intakes of care home residents can be increased by fortifying meals to increase the energy density, without increasing the meal volume (Bell, Roe and Rolls, 2003). For this to happen, catering staff would need to be made aware of which meals (for which residents) require increased energy, and would need to have the appropriate training to understand suitable methods of meal fortification. Although information is available in document form (Food Standards Agency, 2007), training and support for caterers and carers regarding meal fortification and the enhancement of nutritional care is currently lacking across the UK.

In Scottish care homes, the Care Commission, Scottish government and Care homes for older people Dieticians Network (2009) piloted a programme aiming to promote nutritional care for care home residents. Chefs, carers and managers were made ‘champions’, and were trained to support improved nutrition and hydration of residents. The aim of the projects were to challenge current nutritional care practices, identify areas in which improvements could be made, and improve staff attitudes and awareness towards nutritional needs. Although no specific measures of improvements were made, champions reported improved intakes through the basic changes of choice, availability and accessibility of food and drinks to residents. There was however a high rate of champion drop-out during the programme. This was due to the length of commitment and level of work required to initiate and complete the projects. There was also a lack of continued dietetic support after the initial training, and so future recommendations include more thorough input from dieticians to support nutrition champions throughout the programme. Future studies could implement similar nutritional care programmes, championing a member of care staff to take charge of nutritional care practices within

the care homes, and train them to increase awareness of methods to improve nutritional care and to support care staff to make improvements. There is a requirement for outcome measures associated with this type of intervention to assess the appropriateness in terms of effectiveness (both clinical and cost outcomes), efficacy and ease of implementation.

The Protected Mealtime Policy (Hospital Caterers Association, 2004) was developed by the Hospital Caterers Association and Royal College of Nursing to improve 'mealtime' experience and nutritional care, and to ensure mealtimes are a key social activity for hospital ward patients. At ward mealtimes, non-emergency clinical activity is halted so the ward can be tidied and patients prepared to have a meal. Patients are given space to enjoy their meals and the nurses and housekeepers are given the time to assist those that need help. This initiative could be expanded to include other care settings such as care homes in an attempt to emphasise the importance of eating to maintain health and in the treatment of malnutrition. Unnecessary interruptions can be eliminated allowing carers to be focussed on the residents eating and so identification of those in need of assistance can be more efficient. The residents can be given the time to enjoy their meals and the social aspects of eating whilst in a relaxed, clean and tidy atmosphere (Hospital Caterers Association, 2004).

7.5.3 Improving compliance to ONS

In terms of practicality and cost-effectiveness, methods such as offering motivation, encouragement and education may be more quickly and easily integrated into care practice than introducing variety packs of ONS to give care home residents a choice in flavour and product type. The 'support- train- strategy' model (figure 7.2) can be applied to increase compliance; *support* carers to deliver ONS to the resident in an appropriate manner in which the resident's preference to setting and product temperature is acknowledged. Carers could to be given extra *training* to enhance their ONS product knowledge and the reasons for ONS prescriptions; this information can then be relayed back to the resident as a method to motivate and encourage ONS intake. This *strategy* to increase ONS intakes is suitable across care homes and other care settings but does depend on the carer; time management needs to be taken into account so that resident meal times and supplementation times are protected and provided in a pleasant environment with an atmosphere that encourages higher intakes.

A summary of medication compliance by Horne et al. (2005) suggested that actions taken towards non-compliance of prescriptions could acknowledge the beliefs and active decision making of the patient, but also recognise the practical barriers that reduce patient ability to take the medication. In the case of ONS prescriptions, the same points of action could be taken but acknowledgement should be made to the extra encouragement needed for ONS intake as supplements cause satiation, and that prescriptions are likely to be long-term and so issues of monotony must be addressed.

7.5.4 Health inequalities

The Marmot Review (2010) states that health inequalities result from social inequalities. There appears to be a social gradient in reference to health; the lower the person's social status, the worse the person's health. This was highlighted in the prevalence of malnutrition risk in West Yorkshire care homes; it was observed that risk of malnutrition was highest in pockets of lower social economic classes. Lower social class have previously been shown to predict poor health status (Cheng et al., 2002). Care homes funded by the state often lack resources and have lower staffing provisions affecting nutritional care through low food quality, low GP budgets for nutritional therapy, and limited time for assistance with residents ADL affecting food intake particularly in less mobile residents.

Cost is a major issue surrounding the use of ONS, particularly in the community where ONS are estimated to cost £0.88 more than in hospitals (NICE, 2006). The cost has implications in the treatment of malnutrition; ONS are less available in poorer community care homes due to financial restrictions despite the higher risk of malnutrition within these areas. There is a need to assess the financial impact of ONS use in the community over a long term period; does the initial short-term cost of ONS lead to long term savings due to prevention of future GP visits and hospital treatment and stay?

7.6 Research limitations

There were a number of sampling issues brought to light as a result of conducting research with older adult care home residents. Ethically it was not possible to recruit residents who were not of the capacity to understand the test procedures and give consent to participation. However, in reality, it is these residents who are most at risk of

malnutrition due to their increasing dependency and vulnerability. This was shown in chapter 3; the greatest risk of malnutrition was seen in nursing homes where 24 hour nursing care is required due to the progressive disease states and frailty of the residents. The present research was also highly dependent on the willingness of the care home manager and care staff to take part. If staff were not willing to cooperate or were too busy to help at some stages of the research (e.g. gathering ethical consent; completing questionnaires; complying to test procedures), the research could either not be conducted or would not have yielded reliable results. As a result of this, the number of care homes and residents taking part was limited. In the final stage of the research (chapter 6), residents recruited were required to be taking current prescriptions of ONS, not given ONS as a result of the research. Due to the high cost, less and less older adults at risk of malnutrition are being prescribed ONS and those that are commonly lack the capacity to communicate their opinions and give consent to the research procedure. This resulted in a low number of participants contributing to the research in chapter 6.

The measurement of malnutrition risk through use of MUST is limited by the requirement of changes to BMI and/or significant weight changes for movement between 'risk' scores. Scores are limited to 0, 1 or ≥2, which give a broad measure of nutritional status by assessing anthropometric measures and acute disease state. To assess small changes in weight and BMI, a more discrete measure of nutritional status may have been appropriate for the short term interventions in chapters 4 and 6. As well as anthropometric measures, the MNA (Vellas et al., 1999) also involves a general assessment (lifestyle, medications and mobility), a dietary assessment (number of meals per day, autonomy of eating) and a subjective assessment (self-perception of health and nutrition) (Vellas et al., 1999). However, the MNA is longer and more complicated to complete than MUST, relying on input from care home staff in cases where residents have difficulties answering questions. MUST can be carried out solely by the researcher and participant providing there is access to the participants care plan and was therefore a more appropriate choice for this research.

A limitation mentioned in chapter 5 was the use of self-report to measure compliance. Studies of ONS compliance have used varying methods to report compliance such as the mean percentage consumed of the amount provided, the number of portions consumed or the mean volume or energy consumed (Hubbard et al., 2012). Self-report

may have been an unreliable measure of ONS intake as individuals tend to self- report intakes that are closer to perceived social norms rather than actual intake (Schoeller, 1990). A more appropriate measure would have involved the exact measurement of ONS intake over a period of at least 7 days.

A potential limitation in chapter 6 was a lack of a control group. The logistical barriers of recruiting care home residents who were current users of ONS, of the capacity to give informed consent, and able to participate throughout the study period, as well as recruiting willing care home managers to allow the research to go ahead in the care home limited the number of participants that could be included. It was therefore decided that, only two intervention groups would be included but participants would act as their own control through the assessment of 'normal' compliance over a baseline week. In terms of ethical considerations surrounding RCT, it has been suggested that the use of a placebo to evaluate the effectiveness of new treatments for conditions in which proven treatments are already in existence is an unethical approach to research (Rothman and Michels, 1994). In this case, with-holding an intervention by including a control group could have been deemed unethical, as the literature promoting the rationale for offering a variety and introducing implementation intentions to change health related behaviours is so strong.

The effect that ONS has on subsequent food intakes were not assessed during the chapters 4 or 6 studies. To measure nutritional intakes under normal circumstances, the participant themselves would complete a food diary, however due to the frailty of participants; it would be the responsibility of the carer to complete the diary. Due to time restraints, care home managers were unwilling to participate in tasks that would be time-consuming and therefore may affect the quality of care given to the care home residents. However, it is important to note that the slight increases in weight and BMI observed during the intervention in chapter 6 where ONS were given daily suggest that the consumption of ONS did not replace dietary intakes from food but in fact contributed to extra nutritional intakes. There were also no concerns made aware to the researcher regarding food intakes at mealtimes of residents participating in either of the studies.

7.7 Suggestions for future research

Economically, longer term studies are required to assess *both* the initial cost of ONS and the cost savings associated with the beneficial effects of using ONS as a treatment method. There is a need to develop and apply a cost analysis model for a complete economic analysis that follows the patient from the initial diagnosis of malnutrition through all care settings involved in the treatment (e.g. care home and hospital), and the use of ONS throughout this period. The model should also take into account the time spent by health workers to care for the patient and the cost of stay in the treatment institution (Elia et al., 2006).

Although the initial cost of ONS is greater than that of food fortification, it is unclear whether the long term clinical outcome of a malnourished patient would improve more with ONS over food fortification or vice versa. A suggestion for future research would be to look at the effects of both methods on nutritional intake and micronutrient deficiencies and how these impact on underlying illness.

A number of studies have now concluded that nutritional intakes can be increased by offering assistance during episodes of feeding (Kayser-Jones and Schnell, 1997; Simmons, Osterweil and Schness, 2001). This however requires either greater numbers of care staff or greater demands on time spent by carers assisting a meal or snack times. Future research could compare the time spent encouraging and assisting ONS consumption given with meals compared to between meals, and assess outcomes such as total daily nutritional intakes and weight change to draw conclusions as to the most effective time to administer ONS.

Compliance to ONS, as with other medications is a dynamic process that may change over time, and therefore cross-sectional studies are limited with a lack of follow-up. Compliance needs to be measured longitudinally to investigate patient choices, and how compliant behaviour changes over time. In particular, the intentional and non-intentional non-compliant issues that influence older adults need to be examined. Patient's perceptions of their personal needs for ONS in different situations and stages of illness need to be explicitly addressed (Horne et al., 2005).

There are only a limited number of studies that systematically evaluate the direct effects of the prescribing consultation of medications and compliance behaviour (Haynes,

1976; Hall et al., 1998; Jenkins et al. 2003). Future studies are required to focus on the effects of the initial consultation at which ONS are prescribed. There should also be an attempt to evaluate the extent to which consultation skills training can improve compliance and how patient's behaviours are influenced differently depending on the source of the health care message. Focus should be on the influence of HCP beliefs and the prescribing process and content. There is also a requirement to expand knowledge on methods to equip the HCP and patients to deal with the cognitive and emotional challenges related to appropriate prescribing and optimal compliance (Horne et al., 2005).

7.8 Conclusion

Prevalence of malnutrition and risk of malnutrition in care home residents remains high, and is at its highest in more vulnerable nursing home residents compared to residential care, and is of particular concern in those who are already at a low weight. ONS can be prescribed as a method to treat malnutrition by increasing daily nutritional intake (macro- and micronutrients), but the effectiveness of ONS depends on the individual achieving a high compliance rate.

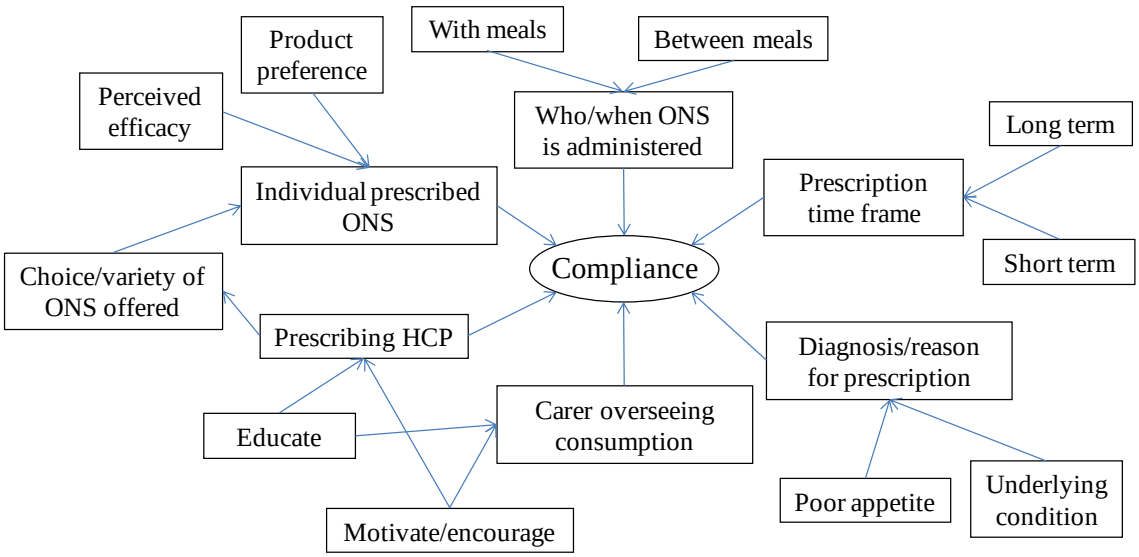


Figure 7.3 The relationship between the person, product, prescription and carer on the impact of compliance to ONS.

Factors that impact on compliance are numerous; a summary of these factors is presented in figure 7.3. Compliance appears to depend on; the personal preference and

perceived efficacy of the individual prescribed ONS; the products prescribed and whether they come in a single flavour or product type or whether there is a variety offered; the time at which ONS are offered, taking into account the laws of satiety that may affect subsequent intakes; the length of time that an individual is required to take ONS prescriptions; the underlying condition or ageing effects on appetite that are the cause of malnutrition; the economic health status of the individual and the area in which their care home exists; the role of the prescribing HCP; and finally (and arguably most importantly) the carer who oversees all stages of malnutrition, from diagnosis, to treatment, to recovery. Due to the frailty, vulnerability and dependency of care home residents prescribed ONS there is a large responsibility of the carer to assist and encourage the consumption of ONS in order for compliance to be achieved and the established beneficial effects of ONS to be realised.

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Appendix

Appendix 1.1 Net cost saving associated with ONS use in malnourished patients in hospital and community settings

Adapted from Elia et al. (2005) and Russell, (2007).

Setting	Patient group	Net cost saving per patient	
Hospital		Bed-day	Complications
	Abdominal surgery (6 papers)	>£700	~£200
	Orthopaedic surgery (2 papers; UK and Swiss study)	UK: £445 Swiss: £4490	£483 £895
	Non-surgical (3 papers; 2x older adult care wards, 1x stroke patients)	OA care wards: £330 Stroke: ~£2100	Not calculated £116
	Surgical and non-surgical (1 paper)	£1306	Not calculated
Community	Short term ONS *prior* to hospital admission (3 papers)	£688 per patient	
	ONS *following* hospital discharge (2 papers)	1) £688 on bed-day and £65 on complications 2) £790 on length of stay	
	Observational study of GPs. Group 1, rare ONS prescribers. Group 2, frequent ONS prescribers	Increased community cost with ONS prescriptions offset by reduced number of hospital admissions and cost of hospital care	

Appendix 2.1 Consent form (example for all studies)

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Consent Form

Malnutrition Universal Screening Tool Study
Ethics ref. No. 10096

Name of Researchers: Emily Norris
Faye Shelton

Name of Supervisor: Professor Marion Hetherington

Please initial boxes

1. I confirm that I have read and understand the information sheet dated 26/05/10 (Version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Leeds where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Participant _____ Date _____ Signature _____

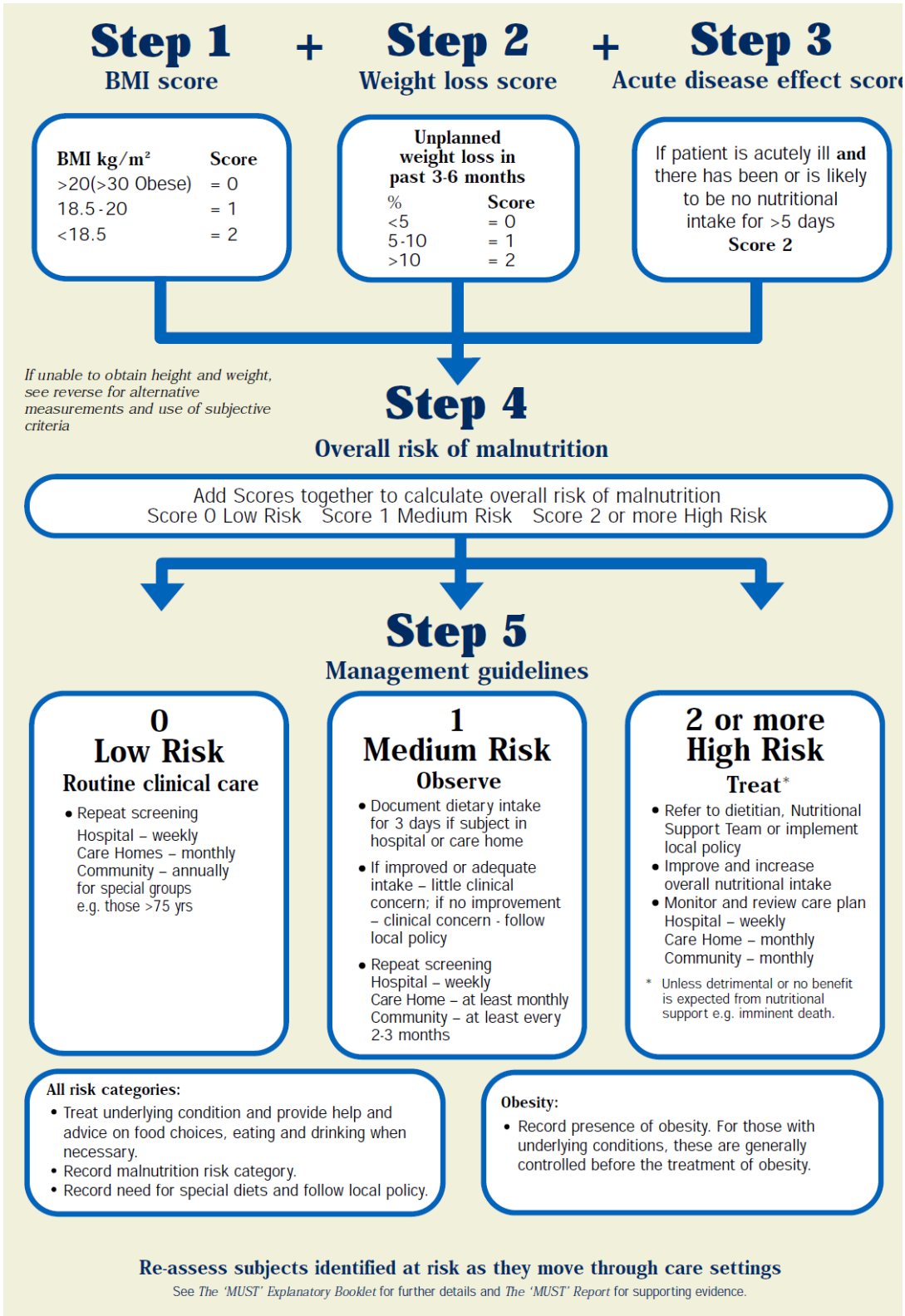
Name of Researcher _____ Date _____ Signature _____

In the case that written consent cannot be given, a member of the care home staff may witness the participant's verbal consent and sign the consent form on their behalf.

When completed: 1 copy for participant; 1 copy (original) for researcher site file.

Version 1 Date: 26/05/2010

Appendix 3.1 Malnutrition Universal Screening Tool (MUST)



Appendix 3.2 Screening pro forma for use with MUST

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Screening Proforma

ONS Compliance Study
Ethics ref. No. 10096

Care home No.:	
Participant No. :	

Date:	

Diagnosis:

Participant Details:

D.O.B:	
Gender:	

Age:	
Date of admission:	

MUST Measurements:

Height:	metres	Past 2 months
Weight:	Kg	Past 2 months
BMI:	Kg/m^2	$<20kg/m^2$=1, $<18kg/m^2$=2
% Unintentional weight loss:	%	Past 3-6 months
Acute disease score:		
MUST score/category		High (2), medium (1), low (0)

Document to be filed in site file once completed.

Appendix 3.3 Example debrief letter sent to care home managers to identify residents at risk of malnutrition and to advise action to be taken

UNIVERSITY OF LEEDS

Institute of Psychological Sciences
Leeds
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07793141676

Assessing the Nutritional Status of Older Adults Living in the Care Home Setting

Dear [redacted]

Thank you and everyone at [redacted] Care Home for participating in the nutritional screening study- I really appreciate your help and it was good to meet you and spend some time in the care home.

We were looking to get a MUST (malnutrition universal screening tool) score for each resident that participated, and from this we can work out their nutritional status:

Score 0 = Low risk of malnutrition- routine care should be maintained.
Score 1 = Medium risk of malnutrition- observations needed for dietary intakes.
Score ≥2 = High risk of malnutrition- Treat by informing the GP or dietician, the nutritional support team or implement the local policy.

Participants 75, 77, 82 and 83 had MUST scores of 1 indicating medium risk. These scores were determined due to the low BMIs of these participants (MUST = 1).

In this case, nutritional intakes should be observed and weight monitored, but this weight loss could be a consequence of other complications (e.g. hospital admissions, disease) and this should be taken into consideration.

Participant 79 had a MUST score of 2 or above indicating high risk. This is due to the participant's very low BMI (MUST = 2), and also due to a drop in weight from 48.1kg to 45kg, a weight loss of 3.1kg (5-10% of overall body weight = MUST score of 1).

For this resident I would advise that they are observed with the possibility of informing their GP or dietician, particularly if weight or dietary intake continues to decrease.

All other participants had a MUST score of 0, so in terms of their nutritional status they are all fine.

If you would like any more information, or would like to discuss the results in anymore detail please do not hesitate to contact me (details at the top). These results are specifically for your care home, but when we have the results of the whole study I will send you another letter highlighting them.

Thank you again,

Emily Norris.

Appendix 4.1 Simplified Nutrition and Appetite Questionnaire (SNAQ)

Questionnaire 1: Appetite Assessment Tool

Please complete the questionnaire by circling the answer which applies to you:

1. **My appetite is**
   a. Very poor
   b. Poor
   c. Average
   d. Good
   e. Very good

2. **When I eat**
   a. I feel full after eating only a few mouthfuls
   b. I feel full after eating about a third of a meal
   c. I feel full after eating over half a meal
   d. I feel full after eating most of a meal
   e. I hardly ever feel full

3. **Food tastes**
   a. Very bad
   b. Bad
   c. Average
   d. Good
   e. Very good

4. **Normally I eat**
   a. Less than one meal a day
   b. One meal a day
   c. Two meals a day
   d. Three meals a day
   e. More than three meals a day

Appendix 4.2 Ratings of hunger, fullness and desire to eat

Office use only:

Date:…… Code: …… Condition: …….. Time: ……

Questionnaire 2: Ratings of Appetite Before Lunch

For this questionnaire, please read each question and then circle the statement that best represents how you are feeling at this moment

For example:

How TIRED do you feel **at this moment**?

Not tired at all	Hardly tired	Neither tired nor not tired	Slightly tired	Extremely tired

1. How **HUNGRY** do you feel at this moment?

Not hungry at all	Hardly hungry	Neither hungry nor not hungry	Slightly hungry	Extremely hungry

2. How STRONG is your DESIRE TO EAT at this moment?

Not strong at all	Hardly strong	Neither strong nor not strong	Slightly strong	Extremely strong

3. How FULL do you feel at this moment?

Not full at all	Hardly full	Neither full nor not full	Slightly full	Extremely full

Please take a bite of your lunch and answer the following questions:

4. How PLEASANT is the TASTE of your meal?

Not pleasant at all	Hardly pleasant	Neither pleasant nor not pleasant	Slightly pleasant	Extremely pleasant

5. How PLEASANT is the TEXTURE of your meal?

Not pleasant at all	Hardly pleasant	Neither pleasant nor not pleasant	Slightly pleasant	Extremely pleasant

Office use only:

Date:…… Code: …… Condition: …….. Time: ……

Questionnaire 3: Ratings of Appetite After Lunch

For this questionnaire, please read each question and then put a mark through the line that best represents how you are feeling at this moment

For example:

How TIRED do you feel **at this moment**?

Not tired at all	Hardly tired	Neither tired nor not tired	Slightly tired	Extremely tired

1. How **HUNGRY** do you feel at this moment?

Not hungry at all	Hardly hungry	Neither hungry nor not hungry	Slightly hungry	Extremely hungry

2. How STRONG is your DESIRE TO EAT at this moment?

Not strong at all	Hardly strong	Neither strong nor not strong	Slightly strong	Extremely strong

3. How FULL do you feel at this moment?

Not full at all	Hardly full	Neither full nor not full	Slightly full	Extremely full

Appendix 4.3 Differences in Likert scale ratings; Chapter 4, study 1

Differences in appetite ratings pre- and post- meal, and liking of the meal ratings between the 4 exposures to the test meals (2x overt; 2x covert) were assessed using repeated measures ANOVA. No significant differences were found;

Pe-hunger $F(3,30)= 0.152$, $p=0.833$; pre-desire to eat $F(3,30)= 0.357$, $p=0.719$; pre-fullness $F(3,30)= 2.963$, $p=0.071$; taste of meal $F(3, 24)= 1.000$, $p= 0.410$; texture of the meal $F(3,24)= 1.908$, $p= 0.155$; post-hunger $F(3,24)= 0.819$, $p= 0.496$; post-desire to eat $F(3, 24)= 0.826$, $p=0.493$; post-fullness $F(3,24)= 0.203$, $p=0.894$.

Mean ratings for hunger, desire to eat and fullness pre- and post- text meal for each condition are shown in figures 4.4 (overt) and 4.5 (covert). There were no significant differences in mean ratings between conditions;

Pre-hunger, $t(10)= -0.166$, $p= 0.871$; pre-desire to eat, $t(10)= -0.820$, $p=0.432$; pre-fullness, $t(10)= 1.921$, $p= 0.084$; post-hunger, $t(10)= 0.922$, $p= 0.378$; post-desire to eat $t(10)= 1.854$, $p= 0.093$; post-fullness, $t(10)= 0.000$, $p=1.000$.

Appendix 4.4 Differences in Likert scale ratings; Chapter 4, study 2

There were no differences in the ratings made pre- meal between conditions (NM, FF, OS, CS);

Hunger, $F(3, 15)= 1.120$, $p= 0.372$; desire to eat, $F(3, 15)= 0.593$, $p=0.629$; fullness, $F(3, 15)= 1.460$, $p= 0.265$.

There were no differences in ratings made post-meal ratings between conditions;

Hunger, $F(3, 15)= 0.613$, $p= 0.613$; desire to eat, $F(3, 15)= 0.429$, $p= 0.580$; fullness, $F(3, 6)= 0.550$, $p= 0.666$.

Appendix 5.1 Nutritional supplement questionnaire: Resident version

UNIVERSITY OF LEEDS

Identifying factors that affect compliance to oral nutritional supplements

Ethics Ref. No. 09275-11

Nutritional Supplement Questionnaire

Answers should be made as appropriate on this questionnaire. Answers to questions marked with (*) should be recorded anonymously with permission from the participant.

Participant no.: _____ Admission Date: _____ Gender: _____

Date of Birth: _____ Weight on Admission: _____ BMI: _____

Height: _____ Current Weight: _____ Prescribed Supplement: _____

Additional notes: _____

(1) How long have you been taking nutritional supplements? (please tick)

Before care home admission ☐ Since care home admission ☐ Date _____

(2) Do you know why you are taking nutritional supplements?*

(3) How many nutritional supplements are you prescribed per day?*

(4) a. Do you finish all the nutritional supplements that you are prescribed? (please circle)

Always or nearly always	Most of the time	Half of the time	Less than half of the time	Hardly ever or never

b. Why do you leave some of the supplement?*

(5) How do you rate the supplements you are prescribed? (please circle)

a. Taste	Very unpleasant	Unpleasant	Neither unpleasant nor pleasant	Pleasant	Very Pleasant

Comments*

b. Texture	Very	Unpleasant	Neither	Pleasant	Very

	unpleasant		unpleasant nor pleasant		Pleasant

Comments*

c. Enjoyment of consumption	Very unpleasant	Unpleasant	Neither unpleasant nor pleasant	Pleasant	Very Pleasant

Comments*

d. Presentation of the product e.g. packaging	Very unpleasant	Unpleasant	Neither unpleasant nor pleasant	Pleasant	Very Pleasant

Comments*

e. Smell	Very unpleasant	Unpleasant	Neither unpleasant nor pleasant	Pleasant	Very Pleasant

Comments*

(6) How happy are you with the size of the supplements you are prescribed? (please circle)

Very unhappy	Unhappy	Neither unhappy nor happy	Happy	Very happy

Comments*

(7) Are you offered, or have you been offered a variety of supplement flavours to choose from? (please circle)

a. Yes/No
b. If yes, what flavours are you offered? *
c. What is your preferred flavour?*

(8) Are you offered, or have you been offered a variety of supplement forms to choose from e.g. juice drinks, milk drinks, soups, yogurts, desserts? (please circle)

a. Yes/No
b. If yes, what forms can you choose from?*
c. What is your preferred supplement form?*

(9) At what time of the day are you offered your nutritional supplement? (please tick)

The same time everyday ☐ Different times of the day ☐

At meal times ☐ At medication rounds ☐ Other times in the day ☐

(10) Do all the different nurses/carers give you the same supplement? (please circle)

Yes/No

(11) How do you take the supplements you are given? (please tick)

Use a straw ☐ Straight from the bottle ☐ Poured in a cup or glass ☐

(12) At what temperature do you receive your nutritional supplement? (please tick)

Cold from the fridge ☐ Room temperature ☐ Hot ☐

(13) What are your opinions of the nutritional supplement(s) that you receive?

a. Likes*

b. Dislikes*

c. Do you feel that the nutritional supplements benefit you?

Yes/No

Please explain*

d. Would you like to try other flavours or forms of nutritional supplements? *

Appendix 5.2 Nutritional supplement questionnaire: Carer version

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Identifying factors that affect compliance to oral nutritional supplements

Ethics Ref. No. 09275-11

Nutritional Supplement Questionnaire

Answers should be made as appropriate on this questionnaire. Answers to questions marked with (*) should be recorded anonymously with permission from the participant.

Care Home participation No. : Supplements prescribed in care home:

Additional notes: _____

(1) Do you know why some of your residents are taking nutritional supplements?*

(2) On average, how many nutritional supplements are you prescribed per day for each resident?*

(3) a. Do the residents finish all the nutritional supplements that you are prescribed? *

b. Why do they leave some of the supplement?*

(4) How are the supplements rated?*

(5) How happy do you think the residents are with the size of the supplements they are prescribed? *

(6) Are the residents offered, or have they been offered a variety of supplement flavours to choose from? (please circle)

a. Yes/No
b. If yes, what flavours are you offered? *
c. What is the preferred flavour?*

(7) Are the residents offered, or have they been offered a variety of supplement forms to choose from e.g. juice drinks, milk drinks, soups, yogurts, desserts? (please circle)

a. Yes/No
b. If yes, what forms can you choose from?*

c. What is the preferred supplement form?*

(8) At what time of the day are the residents offered your nutritional supplement? (please tick)

The same time everyday ☐ Different times of the day ☐

At meal times ☐ At medication rounds ☐ Other times in the day ☐

(9) Do all the different nurses/carers give out the same supplement? (please circle)

Yes/No

(10) How do the residents normally take the supplements they are given? (please tick)

Use a straw ☐ Straight from the bottle ☐ Poured in a cup or glass ☐

(11) At what temperature do you administer the nutritional supplements? (please tick)

Cold from the fridge ☐ Room temperature ☐ Hot ☐

(12) What are your opinions of the nutritional supplement(s) that you administer?

a. Likes*

b. Dislikes*

c. Do you feel that the nutritional supplements benefit the residents? (please circle)

Yes/No

Please explain*

d. Do you think the residents would like to try other flavours or forms of nutritional supplements? *

***Appendix 6.1 Recorded rates of compliance and methods to report compliance* (Adapted from Hubbard et al., 2012).**

Author	Setting	Compliance rate	Method of reported compliance
Self reported:			
Chapman et al., 2009	Free-living older adults	87.8%	Assessed over the phone, subjects self-reported % compliance
Fearon et al., 2003	Hospital	72%	ONS consumption records kept daily by patients
Gianotti et al., 2002	Hospital	93%	Patients kept written record of ONS consumed
Hubbard et al., 2009	Community	92%	Patients recorded compliance in daily diary
Norman et al., 2008	Hospital	79%	Patients recorded daily ONS intake
Read et al., 2007	Hospital	85%	Patients recorded compliance
Steiner et al., 2003	Hospital	97.6%	Patient reported compliance recorded
Trejo et al., 2005	Community	100%	Recorded by patient or caregiver
	Mean Compliance	88.3%	
Reported by HCP, staff or researcher:			
Bonnefoy et al., 2003	Retirement homes	54%	Assessed by study nurse
Botella-Carretero et al., 2008	Hospital	51.4%	Consumption accurately measured by investigator
Bourdel-Marchasson et al., 2000	Hospital	48%	ONS intake recorded by nurses
Gosney et al., 2003	Hospital	37%	Researchers weighed and recorded ONS consumption

Joosten and Vander Elst, 2001	Hospital	54%	Volume of fluid remaining in glass measured by researchers
Kayser-Jones et al., 1998	Nursing homes	55.1%	Event analysis
Roberts et al., 2003	Hospital	61.3%	Nurses recorded compliance
Simmons et al., 2006	Nursing homes	64%	Research staff document volume consumed
Turic et al., 1998	Residential care homes	68%	Consumption recorded and monitored by staff
	Mean compliance	55%	

Leeds Aging Research: Successful Aging

Nutritional Supplement Menu Card

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Which supplement would you like today?

Fruit Dessert
Apple or Strawberry

Yogurt
Raspberry, Peach & Orange or Vanilla and Lemon

Milkshake
Chocolate or Banana

Savoury Soup
Cream of Chicken or Cream of Tomato

Small Milkshake
Vanilla or Stawberry

Appendix 6.3 Product preference form

Emily Norris
Institute of Psychological Sciences
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UNIVERSITY OF LEEDS

Evaluating Methods to Improve Compliance to Oral Nutritional Supplement (ONS) Prescriptions

Which nutritional supplement did the participant(s) choose to have today?

Participant No. .....

Product type:

Fruit dessert: Apple or Strawberry

Savoury soup: Tomato or Chicken

Yogurt: Raspberry, Peach and orange or Vanilla and lemon

Fortisip milkshake: Chocolate or Banana

Fortisip compact (small) milkshake: Vanilla or Strawberry

Date	Product choice

Appendix 6.4 Implementation intentions, ONS record sheet (carers)

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Evaluating Methods to Improve Compliance to Oral Nutritional Supplement (ONS) Prescriptions

Supplementation chart: Please write down at what time on each day that the participant will receive their ONS, and tick off once they have received their ONS.

Participant No.....

Day	Date	Time that ONS will be given	ONS given? (√/X)
Week 1			
1	/ /	am/pm	
2	/ /	am/pm	
3	/ /	am/pm	
4	/ /	am/pm	
5	/ /	am/pm	
6	/ /	am/pm	
7	/ /	am/pm	
Week 2			
8	/ /	am/pm	
9	/ /	am/pm	
10	/ /	am/pm	
11	/ /	am/pm	
12	/ /	am/pm	
13	/ /	am/pm	
14	/ /	am/pm	
Week 3			
15	/ /	am/pm	
16	/ /	am/pm	
17	/ /	am/pm	
18	/ /	am/pm	
19	/ /	am/pm	
20	/ /	am/pm	
21	/ /	am/pm	
Week 4			
22	/ /	am/pm	
23	/ /	am/pm	
24	/ /	am/pm	
25	/ /	am/pm	
26	/ /	am/pm	
27	/ /	am/pm	
28	/ /	am/pm	

Appendix 6.5 Implementation intentions, ONS record sheet (residents)

My Nutritional Supplement Plan

Many people find it helpful to make a plan for when they are going to take their nutritional supplements.

Today is Monday

'I will take my nutritional supplement at.....'

Today is Tuesday

'I will take my nutritional supplement at.....'

Today is Wednesday

'I will take my nutritional supplement at.....'

Today is Thursday

'I will take my nutritional supplement at.....'

Today is Friday

'I will take my nutritional supplement at.....'

Today is Saturday

'I will take my nutritional supplement at.....'

Today is Sunday

'I will take my nutritional supplement at.....'

Appendix 6.6 The benefits of ONS; promoting knowledge

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Why Are Nutritional Supplements Good For Me?

We have noticed that you are losing weight and this might be making you feel unwell. You may have also lost your appetite and might not be eating all of the meals you are given.

If you take a nutritional supplement daily, this might make you feel better.

You will be increasing the amount of energy you are eating and you will be getting some extra nutrients which will benefit your health.

If you take all of the nutritional supplements you are given they might help you to put on some weight which will make you feel stronger and may help prevent you from getting ill and having to go and see your doctor.

My Nutritional Supplement Chart

UNIVERSITY OF LEEDS

Have you had your nutritional supplement today?

Week beginning	Monday	Tuesday	Wednesday
Date:			
Thursday	Friday	Saturday	Sunday

Appendix 6.8 Completed supplement sticker chart (condition ME)

My Nutritional Supplement Chart

Have you had your nutritional supplement today?

Week beginning	Monday	Tuesday	Wednesday
Date: 11/11/11 Friday			
Thursday	**Friday** Start here	**Saturday**	**Sunday**
			

Appendix 6.9 Completed implementation intentions ONS record chart by the carers

UNIVERSITY OF LEEDS

Evaluating Methods to Improve Compliance to Oral Nutritional Supplement (ONS) Prescriptions

Supplementation chart: Please write down at what time on each day that the participant will receive their ONS, and tick off once they have received their ONS.

Participant No. 0205

Day	Date	Time that ONS will be given		ONS given? (√/X)
		Week 1		
1	4 / 11 / 11	9am	am/pm	J Jones
2	5 / 11 / 11	10.30	(am)/pm	A-Hirst
3	/ /		am/pm	
4	7 / 11 / 11	10.35	(am)/pm	Fwoodward.
5	8 / 11 / 11	10:30	am/pm	S. Hardy
6	9 / 11 / 11	10-30	(am)/pm	K Parker
7	/ /		am/pm	
		Week 2		
8	/ /		am/pm	
9	/ /		am/pm	
10	/ /		am/pm	
11	/ /		am/pm	
12	12 / 11 / 11	9.30	(am)/pm	Wynder Jones
13	13 / 11 / 11	10.25	(am)/pm	J Jones
14	14 / 11 / 11	10-55.	(am)/pm	SB
		Week 3		
15	15 / 11 / 11	1030	(am)/pm	SMithorell.
16	16 / 11 / 11	10 30	(am)/pm	fiona.
17	17 / 11 / 11	1045	(am)/pm	SB
18	18 / 11 / 11	10 30	(am)/pm	fiona
19	19 / 11 / 11	9.45	(am)/pm	Rose.
20	20 / 11 / 11	10.15	(am)/pm	Rose
21	21 / 11 / 11	10.15	(am)/pm	Angie/Rose
		Week 4		
22	23 / 11 / 11	10-45	(am)/pm	Sharon.
23	/ /		am/pm	
24	24 / 11 / 11	10.45	(am)/pm	angie
25	25 / 11 / 11	9.45	(am)/pm	Rose
26	26 / 11 / 11	9am	(am)/pm	J Jones
27	27 / 11 / 11	11am	(am)/pm	J Jones
(28)	28 / 11 / 11	9.15	(am)/pm	Julie.