A CLUSTER RANDOMISED FEASIBILITY TRIAL EVALUATING SIX-MONTH NUTRITIONAL INTERVENTIONS IN THE TREATMENT OF MALNUTRITION IN CARE HOME-DWELLING ADULTS

By

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Abstract

Evidence for nutritional interventions to address protein-energy malnutrition in the care home setting is lacking. To define outcomes and optimise the design for an adequately powered randomised controlled trial to compare the efficacy of established nutrition support interventions, a cluster randomised feasibility trial was undertaken. Ninety-three care home residents at risk of malnutrition were identified across six UK care home sites. Homes were cluster randomised to receive food-based intervention, oral nutritional supplement intervention, or standard care, for six months. Key outcomes were trial feasibility and acceptability of design, allocated interventions and outcome assessments. The trial design was feasible to undertake. Recruitment and retention targets for care homes and residents were met and the interventions were acceptable to residents and staff. Weight, body mass index (BMI) and mid-arm circumference were feasible and acceptable measurements to undertake, but measurement of function and patient-centred outcomes was hampered by dementia and immobility. A definitive trial comparing the efficacy of nutrition support interventions in increasing weight and BMI in malnourished care home residents can be conducted. However, this feasibility trial has highlighted a current lack of clinically relevant outcome measures, which are feasible to undertake in this setting.

Dedication

This thesis is dedicated to my partner, Mark, who has been a constant source of encouragement and support throughout. I am truly grateful. This work is also dedicated to my parents, Christopher and Elizabeth Stow, who have always taught me to work hard for the things that I aspire to achieve

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List of abbreviations

PEM	Protein Energy Malnutrition
ONS	Oral Nutritional Supplements
FB	Food Based
SC	Standard Care
RCT	Randomised Controlled Trial
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
CQC	Care Quality Commission
REC	Research Ethics Committee
MUST	Malnutrition Universal Screening Tool
BMI	Body Mass Index
MAC	Mid Upper Arm Circumference
TSF	Tricep Skinfold Thickness
MAMC	Mid Arm Muscle Circumference
FRC	Food Record Chart
FC	Fluid Chart
PROMs	Participant Reported Outcome Measures
QoL	Quality of Life
VAS	Visual Analogue Scale
HCRU	Healthcare Resource Usage
AE	Adverse Event

CHAPTER ONE: INTRODUCTION

MALNUTRITION IN THE OLDER ADULT POPULATION AND ITS NUTRITIONAL MANAGEMENT

This thesis considers the feasibility and acceptability of running an adequately powered definitive trial, evaluating nutritional interventions for malnutrition within care homes for older adults (over 65 years). This chapter will describe the condition of protein energy malnutrition (PEM) and its current nutritional management, and will relate this to the UK care home setting.

1.1 Protein- Energy Malnutrition in the UK

There is no universally accepted definition of malnutrition, but one of the most widely accepted, describes it as a 'state of nutrition in which a deficiency or excess (or imbalance) of energy, protein, and other nutrients causes measurable adverse effects on tissue/body form (shape, size and composition) and function, and clinical outcome' (Elia, 2003, p8). Within the scope of this thesis, the term malnutrition will be used to refer to under nutrition and involuntary weight loss. The recent literature suggests that involuntary weight loss can be categorised into three primary aetiologies; starvation, sarcopenia and cachexia (Thomas, 2007; Chapman, 2011; Yaxley and Miller, 2011). In clinical practice, differentiation is infrequent and there are no universally shared criteria for diagnosis. It is generally accepted however, that starvation, synonymous with protein-energy malnutrition (PEM), results in the loss of fat and fat-free mass due to protein-energy deficiency (Thomas, 2007), whilst sarcopenia is characterised by the loss of skeletal muscle mass and strength associated with ageing (Burton and Sumukadas, 2010). Cachexia is a multifactorial

metabolic syndrome, driven by inflammation and characterised by severe wasting of fat free mass, with or without fat mass (Muscaritoli et al., 2010). This thesis will focus largely on the condition of PEM (Stratton et al., 2003).

Often under-recognised and under-treated, PEM develops when energy intake and/or protein intake, chronically fail to meet the body's nutritional requirements (Hoffer, 1999). It can affect virtually every function and organ system of the human body (Correia and Waitzberg, 2003), predisposing individuals to disease and delaying recovery from illness (McWilliams, 2008). Those at risk are admitted to hospital more frequently, experience a reduced quality of life and have an increased risk of mortality (Gaskill et al., 2008; Heismayr et al., 2009; Brotherton, Simmonds and Stroud, 2010). In the UK, more than 1 million people over the age of 65 are malnourished, or at risk of PEM and the vast majority (93%) are resident in the community setting (Elia and Russell, 2009), where increased risk is associated with frailty and reduced physical independence (Stratton et al., 2003).

In 2007, the health and social care costs associated with malnutrition were estimated to exceed £13 billion annually, more than 10% of the public expenditure on health care (Elia and Russell, 2009). Characteristically, older adults deteriorate to a state of PEM more quickly than younger people and are known to be especially vulnerable to the associated adverse outcomes (Kubrak and Jensen, 2007). With the UK over 65 population (11.1 million in 2013) projected to increase by nearly 50% in the next 20 years (Office for National Statistics, 2013; Age UK, 2013), the prevalence of PEM and the cost to society and the individual is likely to increase significantly.

1.2 Recommendations for the nutritional management of PEM

There is no internationally agreed protocol for the nutritional treatment of PEM in older adults (Baldwin and Weekes, 2011). Widely used techniques to enhance oral dietary intake include food-based (FB) intervention (fortification to increase energy and/or protein density, provision of nourishing snacks and/or drinks) and/or the use of prescribed oral nutritional supplements (ONS) (NICE, 2006), 'dietary foods for special medical purposes' (FSMPs) (Commission Directive, 1999). The 'standard' ready-to-drink ONS contains 1 to 2.4kcal/ml and is composed of a combination of macronutrients and micronutrients (National Prescribing Centre, 2012). The British Dietetic Association (BDA) and The National Prescribing Centre (NPC) advocate, improving dietary intake first using fortification of conventional food and secondly by prescribed means (Prickett, 2007; NPC, 2012). However, few trials have evaluated the food-based approach and it remains unclear whether this intervention is able to improve clinical outcomes for malnourished individuals (Odlund Olin et al., 2003; Smoliner et al., 2008; Baldwin and Weekes, 2011).

Food-based intervention is considered more economical to the National Health Service (NHS) in England than prescribed ONS. In 2011, ONS incurred an annual spend of £105 million, a 10% increase from 2010 (NHS Business Services Authority, 2011). Many General Practitioner (GP) practices identified significant and increasing spends on ONS at this time, often accompanied by prolonged and inappropriate prescribing. Medicines Management teams subsequently imposed stricter prescribing guidance and encouraged greater use of food-based intervention (Hobday, 2010). However, the development of initiatives to reduce ONS usage has since prompted concerns about delayed appropriate prescribing (Brotherton et al.,

2010). Whilst there may be potential to improve oral dietary intake in a variety of ways, it is important to establish the effectiveness of both food-based and ONS interventions, to ensure that the most appropriate nutrition support is initiated promptly for vulnerable individuals, to minimise further deterioration in nutritional status.

1.3 The UK care home[1] setting

Care home residents are a distinct group of over 400,000 people (including 17% of those aged over 85) (Government Statistical Service, 2006), with very different mortality (Nimmo et al., 2006), health status, and health and care needs (Petty et al., 1998; Sinclair et al., 2001) from those of individuals, of the same age, residing in their own homes. Differences are often so pronounced, that research outcomes established for older people living within their own homes cannot be considered valid for care home residents and cannot therefore be used to guide best care practice (Bugeja et al., 1997; Bayer and Todd, 2000).

1.3.1 PEM in UK care homes

Care homes are arguably home to one of the UK's most vulnerable populations (Quince, 2013), 30% to 42% of whom are estimated to be at risk of malnutrition (Russell and Elia, 2010). PEM significantly impacts upon the physical and emotional well-being of residents and has been linked to, increased vulnerability to infection and pressure ulcers, clinical complications, depression and decreased quality of life (Cowan et al., 2004; Arvanitakis et al., 2009; Meijers et al., 2012). In 2012, The Care Quality Commission's (CQC) Dignity and Nutrition Inspections,

[1] In this thesis, the term care home is used to refer to all residential long-term care settings providing group living alongside personal and/or nursing care for older people and other adults

revealed that one in six UK care homes were failing to meet the nutritional needs of their residents (CQC, 2012), whilst data obtained from the Office for National Statistics, revealed that from 2003 to 2012, 1,158 care home residents suffered dehydration-related deaths, 318 residents died from starvation or severe malnutrition and 2,815 deaths were related to pressure sores (Office for National Statistics, 2012). Significant changes to culture and practice within the care home setting are required to improve nutritional care, and food and eating practices.

There is a tendency to avoid research in care homes, because of the methodological issues involved (Maas et al., 2002). Many studies specifically exclude care home residents on the basis that their inclusion would present the research team with ethical and practical difficulties (Watts, 2012) and a recent review revealed that the majority of epidemiological studies, either exclude care home residents at the outset, or fail to follow-up participants when they move into institutional care (Collingridge Moore and Hanratty, 2013). With an ageing population set to increase, care homes will play an increasingly vital role in supporting and caring for older people. The lack of evidence to support best practice has led to recommendations for more studies to be conducted in this setting (The Royal College of Physicians, 2000) and provides an opportunity to bring new ideas to the field.

CHAPTER TWO: LITERATURE REVIEW

NUTRITION SUPPORT INTERVENTIONS FOR PROTEIN ENERGY MALNUTRITION IN THE CARE HOME POPULATION

An initial broad scoping search into the use of nutritional interventions for PEM revealed that the majority of studies have used ONS as the intervention strategy, comparing effectiveness with placebo or standard care, predominantly within the acute setting. One Cochrane review was identified, which assessed the impact of food-based intervention on PEM within a variety of settings, but there was a lack of published evidence reviewing the impact of either intervention in the care home population. This chapter provides an overview of current evidence for the management of PEM using prescribed ONS and using food-based intervention, with a focus on the older community-based population, followed by a detailed analysis of research evaluating nutritional interventions within the care home setting.

2.1 The nutritional management of PEM in older adults using prescribed ONS: A broad overview of current evidence

Systematic reviews of nutritional interventions for PEM (Stratton et al., 2003; Milne et al., 2005; Koretz, 2007; Milne et al., 2009), have tended to focus on the effectiveness of ONS compared with placebo or standard care. In 2006, the National Institute for Clinical Excellence (NICE) conducted a systematic synthesis of best evidence, which has formed the basis of UK national policy on the management of malnutrition by oral, enteral and parenteral means (NICE, 2006). Study design was limited to published, systematic reviews, meta-analyses of randomised controlled trials (RCTs), and RCTs. Within the review of oral interventions, 40 RCTs were

identified, which assessed the effectiveness of ONS alone or alongside dietary advice, compared to standard care. The trials were small, with considerable clinical heterogeneity of patients and outcomes, but the results suggested significant weight gain with 1 to 3 ONS daily (300-900kcal) (n=22) and a meta-analysis indicated statistically significant reductions in complications (n=9) (post-surgical infective complications (n=6), fracture healing complications (n=1), pressure ulcers (n=2)) and mortality rate (n=25). The search strategies were not confined to specific patient groups, but there was a predominance of evidence from the acute setting and just 3 RCTs examined the effectiveness of ONS in malnourished older adults in the community. These trials suggested an increase in weight with ONS, but did not support the net mortality benefit identified within the meta-analysis.

In 2009, a Cochrane meta-analysis of 62 RCTs evaluated the effectiveness of ONS in undernourished adults over 65 years (Milne et al., 2009). Whilst the review reported a small, but consistent weight gain with ONS, the inclusion of primary outcomes of relevance to patients, such as functional measures and quality of life were lacking. The risk of bias (assessed in accordance with the Cochrane handbook, 1997) was rated highest with regards to allocation concealment, 'intention to treat' (ITT) analysis and blinding of outcome assessors, all of which may have affected the internal validity of the included trials. Severely malnourished individuals were frequently excluded for ethical reasons and the length of intervention was often short (less than 35 days for 17 trials), which may have affected the external validity of the findings. The authors rated the overall quality of the trials as poor.

Preserving physical independence, preventing functional disability and improving quality of life are important outcomes within the clinical care of older adults (Neelemaat et al., 2012). A recently published clinical trial, involving over 200 older

adults, was the first to demonstrate significant improvements in functional limitations, on comparing a multi-component nutritional intervention (energy and protein enriched diet, 2 ONS servings (600kcal), a calcium-vitamin D supplement and telephone counselling with a dietitian, for 3-months post hospital), with standard care (Neelemaat et al., 2012). It is unclear though, whether the observed improvement was due to the effects of ONS, another component, or a combined effect of the plan. With respect to quality of life, this trial, like others (Edington et al. 2004; McMurdo et al. 2009), found no significant difference between groups, after 8 to 12 weeks.

On consideration of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Balshem et al., 2011), the current evidence for ONS intervention in the older adult community-based population is low quality. Whilst the systematic review by NICE included only RCTs (associated with low risk of bias), the results were indirect in relation to the population of interest. The majority of trials were conducted in the acute setting in patients with various disease states. Milne et al (2009) focused on RCTs conducted with older adults, however the risk of bias was high and 42 of the 62 trials had less than 100 participants, reducing precision of results. To determine whether ONS intervention improves clinical and functional outcomes for older malnourished individuals in a community setting, adequately powered trials, with low risk of bias and sufficient length of follow-up are required.

2.2 The impact of dietary advice and/or food based intervention in the treatment of PEM in older adults: An overview of the evidence

A Cochrane systematic review and meta-analysis was the first to evaluate the impact of dietary advice and/or food-based intervention on PEM (Baldwin and

Weekes, 2007; 2011). Studies of patients with, or at risk of malnutrition, in any setting were included and 45 published RCTs and quasi-RCTs (n=3186) were identified, examining:

1. Dietary advice/intervention versus no advice/intervention **(12 trials)**
2. Dietary advice/intervention versus prescribed ONS **(8 trials)**
3. Dietary advice/intervention versus dietary advice/intervention plus ONS **(16 trials)**
4. Dietary advice/intervention plus ONS versus no advice/intervention and no ONS **(14 trials)**

Figure 1: Comparison groups in the Cochrane Systematic review (2011)
*Three of the 45 identified trials included two of the above comparisons, and one trial included three of the above comparisons.

Primary outcomes were mortality, morbidity and measures of nutritional status; although mortality and morbidity did not differ significantly between any of the groups. Results from the first 3 comparisons are considered most relevant to this review (Table 1).

Table 1: Summary of findings from three of the comparison groups in the Cochrane Systematic review (2011)

Comparison:	Findings related to measures of nutritional status:
Dietary advice/ intervention compared to no dietary advice/ intervention	**Significant improvements in body weight were seen with:** Interventions longer than 12 months (Mean Difference (MD) of 3.75kg, 95% Confidence Interval (CI) 0.97 to 6.53kg, p= 0.0081; 1 trial, n = 92) Interventions of up to 12 months duration (MD = 1.47kg, 95% CI 0.32 to 2.61kg, p = 0.012; 9 trials, n = 733). *Heterogeneity between trials was high (I^2 = 90%; P< 0.00001) and the reported effect size was influenced by 1 quasi-RCT with high risk of bias. **Significant increases in mid arm muscle circumference (MAMC) were seen with:** 2 trials (n = 130). A mean difference of 0.81cm was observed (95% CI 0.31 to 1.31cm, p = 0.0015), *although moderate heterogeneity existed between the 2 included trials (I^2 = 54%; P = 0.14). **Significant increases in energy intake were seen with:** 7 trials (n= 981), with a mean difference of 257.78 kcal/day (95% CI -0.74 to 516.30, P = 0.05). *Heterogeneity between trials was again high (I^2 = 98%; P < 0.00001).
Dietary advice/ intervention compared with ONS	No significant differences between groups for primary or secondary outcomes when dietary advice/intervention was compared with ONS.
Dietary advice /intervention compared with dietary advice/ intervention plus ONS	**Significant increases MAMC were seen with:** 3 trials (n = 492), with a mean difference of 0.89cm (95% CI 0.43 to 1.35cm, p= 0.00016) in favour of dietary advice/intervention and ONS. **Significant increases in handgrip strength were seen with:** 4 trials (n = 364). Handgrip strength was greater in those who received dietary advice/intervention and ONS (MD -1.67kg, 95% CI -2.96 to -0.37, p = 0.01). *The effect was determined to be moderately heterogeneous (I^2 = 50%, p = 0.11).

ONS = Oral Nutritional Supplements
*In each comparison, the authors have examined the differences between the results of the studies using the I^2 statistic, which describes the percentage of total variation that is the result of heterogeneity rather than chance (Higgins, 2003). Heterogeneity was categorised as low (I^2 of less than 33%), moderate (I^2 of 34 to 66%) or high (I^2 of 67% or more) (Baldwin and Weekes, 2011).

One trial (n = 96), which contributed data to the analysis for weight change and energy intake (comparison 1) was conducted with malnourished older adults

(Rydwik, 2008, cited in Baldwin and Weekes, 2011). No trials, which contributed data to the analysis in comparisons 2 or 3, specifically included older adults.

2.2.1 The evidence from the Cochrane review

This review suggests that dietary advice and intervention for PEM may improve weight and indicators of muscle mass, with or without ONS, but the findings are not specific to the older adult population and the evidence is low quality (in accordance with the GRADE guidelines, Balshem et al., 2011). The majority of included trials were affected by limitations in design and implementation. Most were not adequately blinded and descriptions of allocation concealment and sequence generation were lacking (assessed by the authors using the Cochrane Handbook, Higgins, 2011). Findings on weight change were attained from 1 quasi-RCT (Macia, 1991), with high risk of attrition and selection bias, and should therefore be interpreted with caution. Most trials provided information on intervention duration, however there was minimal information on the intensity or content, presenting a risk of indirectness of evidence in relation to interventions actually used in practice. The majority of trials were conducted in the outpatient setting, which limits transferability to other care settings and highlights the need for adequately powered, low risk of bias trials to assess the effectiveness of food-based intervention in the population of interest.

2.3 Malnutrition interventions within the care home setting: a systematic review

2.3.1 Systematic review method

A systematic review is a summary of primary research that attempts to identify, select, synthesise and appraise all high quality evidence relevant to a

specific research question, to be able to answer it (Cochrane, 1999). Such a review is usually based on RCTs that have met rigorous standards of quality and have low risk of bias. However, since data from RCTs may be insufficient to fully answer a research question, non-randomised study designs are sometimes considered (Norris et al., 2010).

Neither the Cochrane review, which addressed the use of ONS in older adults (Milne et al., 2009), or the Cochrane review, which assessed the evidence for food-based intervention (Baldwin and Weekes, 2011) made any specific conclusions regarding the treatment of PEM in care home residents. The preliminary scoping search of the literature identified a small number of RCT's investigating the effectiveness of nutritional interventions in care homes and highlighted a complete lack of observational studies or qualitative research. Given the absence of any relevant qualitative literature, a systematic review method was chosen and RCT study designs were considered.

2.3.2 Literature Search

The primary search strategy was a database search of: CINAHL, PubMed, Embase and Web of Science. PubMed contains more than 23 million citations for biomedical literature from MEDLINE, life sciences journals and online books and it was felt that relevant and peer-reviewed articles could be identified here (http://www.ncbi.nlm.nih.gov/pubmed). Bibliographies of the included articles and previously published systematic reviews were checked for other relevant literature, including books and book chapters. Titles, abstracts, and potential full-text articles were assessed for inclusion. The PICOS framework (Patients, Intervention, Comparison, Outcomes, Study Design) was used to facilitate the search (Table 2):

Table 2: PICOS (Participants, Interventions, Comparisons, Outcomes, Study Design) for meta-analysis and review.

Patients	Care home residents, with, or at risk of malnutrition
Interventions	Oral nutritional supplements (ONS), home-made milk based fortified drinks; fortification of normal food sources and dietary advice
Comparison	Standard/Usual care; or ONS compared to food-based strategies
Outcomes	**Primary outcomes:** Mortality, Morbidity (assessed by risk of hospital admission or readmission and length of hospital stay), measures of nutritional status (including change in weight, mid-arm muscle circumference (MAC), tricep skinfold thickness (TSF), hand grip strength) **Secondary outcomes:** Nutritional intake pre and post intervention, Measures of clinical function (immune function, cardiac function, respiratory function), Quality of life (QoL) or health state, and cost
Study Design	Randomised controlled trials (RCTs)
Confounding factors such as compliance and adverse events were also observed.	

Inclusion criteria were applied (Table 3) and searches were limited to English as resources were not available to have articles translated. Due to time constraints, it was not realistic to contact the authors of any articles for further data or for clarification. The searches were conducted in March 2014. All articles published before 21st March 2014 were included.

Table 3: Search terms and inclusion criteria

Search Terms	Inclusion criteria
Malnutrition/Protein energy malnutrition **AND** **Oral nutritional interventions/food fortification/oral nutritional supplements/nutritional treatment** **AND** **Nursing home/care home, residents/patients**	English language Up to March 2014 Adults >65 years Conducted in the care home setting Randomised Controlled Trials

The number of articles searched through each stage is described diagrammatically (Figure 2).

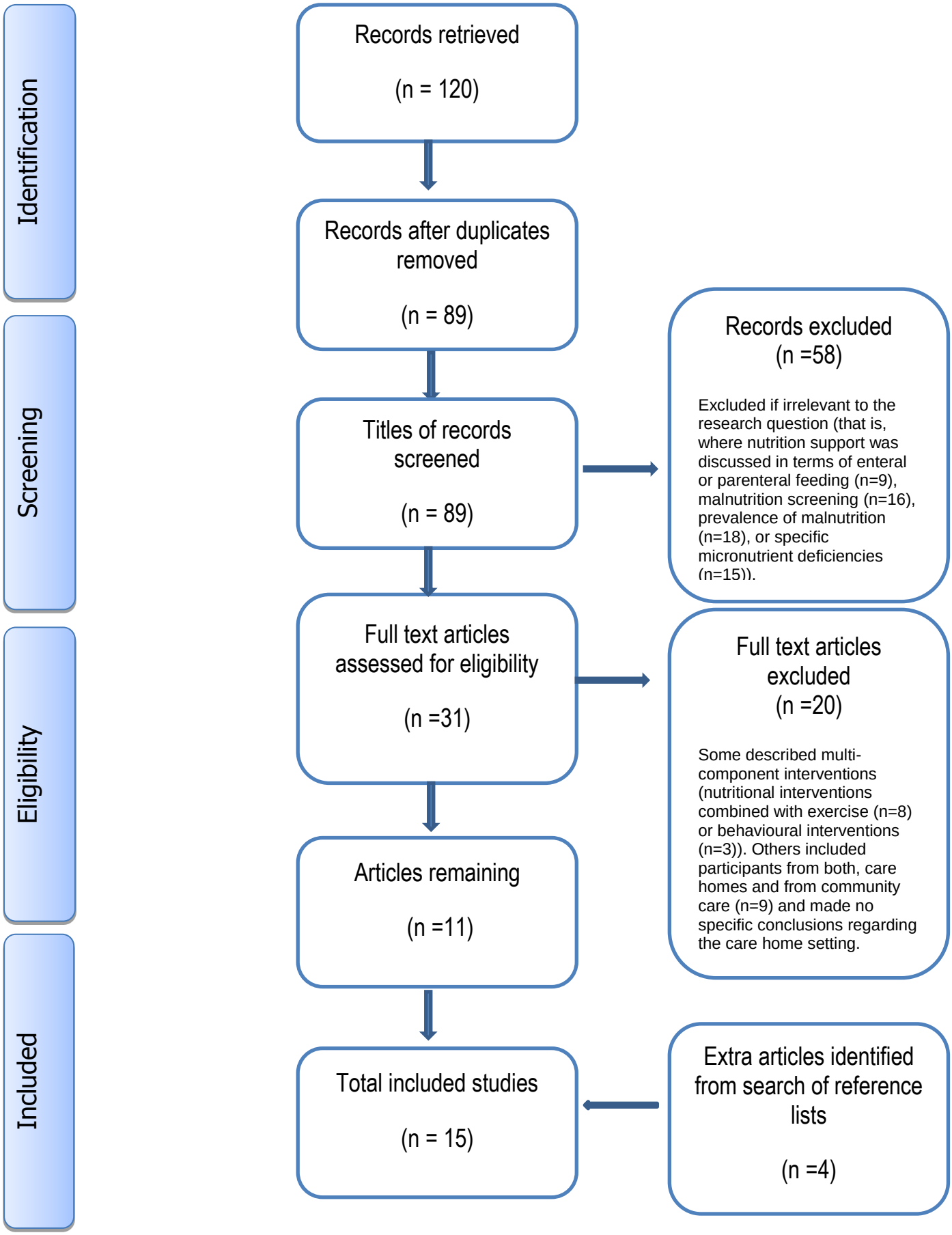


Figure 2: Flow chart for the selection of studies for the review (adapted from The Preferred Reporting Items for Reviews and Meta Analysis; PRISMA flow chart, Moher et al., 2009)

Fifteen original RCTs were identified. The trials examined 3 bodies of evidence; food-based intervention versus standard care (n=7), ONS intervention versus standard care or placebo (n=6) and food-based intervention versus ONS (n=2). The Cochrane Risk of Bias Tool was used to assess risk of bias for each trial (Higgins et al., 2011) (Table 7)[2], the GRADE system was used to rate the quality of each body of evidence (Balshem et al., 2011) (Table 8) and the PRISMA statement was used to guide evidence reporting (Moher et al., 2009).

2.3.3 A review of the findings

2.3.3.1 Food-based (FB) intervention for malnutrition in the care home setting

Seven original studies; 4 RCTs, 2 cluster RCTs and 1 cluster feasibility RCT examined the effect of FB interventions on clinical outcomes for care home residents. Interventions included diet supplementation with milk powder (n=1); two additional servings of dairy food daily (n=1); dietary modification to increase energy content (n=2); food fortification (n=1); increasing meal frequency (n=1) and provision of a homemade liquid supplement (n=1). The trials examined outcome measures meeting the inclusion criteria, including change in weight (n=3), body mass index (BMI) (n=3) or mid upper arm circumference (MAC) (n=1), physical function (handgrip strength, activities of daily living (ADL) score) (n=3), change in nutrient intake (n=5) and quality of life (n=1). Mortality and cost were not included as primary or secondary outcomes within any identified trials. All trials used a control of standard care, described as 'usual, care home meal provision' and follow-up varied from 4 to 15 weeks. A summary of the evidence is described (Table 4).

[2] Table 7 and Table 8 are located at the end of Section 2.3, pp. 27-31

Table 4: Summary of evidence for food-based interventions: methodological characteristics and major outcomes of included studies

Source:	Sample size	Population:	Design:	Food-based intervention	Resident compliance	Outcomes: Intervention vs. Control
Kwok, 2001	n = 47	Nursing home residents with poor intake in China. Mean age 81 ± 10 in IG and 80 ± 10 in CG. Mean BMI IG: 19.1, CG: 20.1	RCT, CG received same foods as IG	25g low lactose milk powder twice daily **+175kcal**	98.5% compliance	Weight change (kg): IG increased from 42.94 to 44.39, CG decreased from 46.73 to 46.39, NSD Grip strength, mental function, disability measures, NSD
Beck, 2002	n = 66	Undernourished nursing home residents in Denmark, mean age 84, mild to moderate cognitive impairment	RCT	Home-made oral supplement, **+384kcal**	Mean intake of: **380kcal**	Weight change (kg): CG 1.2 (-1.0-3.0) vs. IG 1.5 (-2.3-9.0), NSD
Odlund, 2003	n = 35	Nursing home residents in Sweden, median age 83 years, median BMI of 23.1	RCT	-Meals fortified with natural ingredients (cream, oil, butter) -Desserts fortified with cream, sour cream, hydrolysed starch. **+500kcal**	Not reported	IG: Energy intake increased from 23.5kcal/kg body weight to 31.9 kcal/kg body weight (P<0.001), ADL function was unchanged CG: No change in energy intake, ADL decreased significantly (P<0.001). 5 deaths (12.5%)
Taylor, 2006	n = 37	Residents of an extended-care facility, >65 years, receiving a texture-modified diet, Mean BMI: 20.4	Crossover design with random assignment and two 4-day study periods.	Provision of five daily meals **Energy content the same as for 3 meals**	**Consumed a mean of 80% of energy served**	Average energy intakes similar between the three- and five meal patterns (1,325±207 kcal/day vs. 1,342±177 kcal/day, respectively; *P*=0.6)

Smoliner, 2008	n = 65	Nursing home residents with, or at risk of malnutrition, 19 men and 46 women with a median age of 85.2 years Mean BMI IG: 21.6, CG: 22.5 Excluded residents with severe cognitive impairment	RCT	-Protein and energy-enriched soups and sauces -Two additional snacks high in protein and energy between meals. **+kcal unclear**	Not reported	Higher protein intake in the IG (62.6 ± 11.5 versus 74.3±18.3g/d, *P* = 0.007). Energy intake was similar in both groups Handgrip strength, fat free mass, Barthel Index and SF-36 NSD
Leslie, 2012	n = 41	Residential care home residents, BMI <18.5kg/m^2 Without acute disease. Mean age 91 ± 7 Mean BMI IG: 17.1, CG: 17.3	Cluster RCT across 21 residential care homes	-Double cream (50 ml) added to foodstuffs -Butter (8 g) added to potatoes. -250-ml fortified malted milk drink x 1 daily **Maximum of + 400kcal**	Not reported	Weight change (kg): IG: 1.3kg, p = 0.03, CG: -0.2 NSD, between group differences not significant Energy intake, NSD Attrition rate of 25%, including 7 deaths (17%)
Iuliano, 2013	n = 130	Care home residents from four care facilities in Melbourne, Australia 78% female mean age 86.5±5.6 years. Mean BMI IG: 23.7, CG: 25.4	Prospective feasibility RCT	Two additional servings of dairy foods daily **+kcal unclear**	Not reported	IG: Mean energy intake (+900kJ, P<0.001), protein intake (+25g, P<0.0001), proportion of estimated energy requirements (EER) (+18%, P<0.0001) CG: Mean energy intake remained below the EER, protein intake remained unchanged.

BMI= Body Mass Index; RCT= Randomised Controlled Trial; ADL= Activities of Daily Living; EER= Estimated Energy Requirements; IG= Intervention group; CG= Control group, NSD = no significant difference

Four trials, using interventions involving either enrichment of existing diet, or drink and/or snack swaps, found evidence for increased energy and/or protein intake in the intervention group (Beck et al., 2002; Odlund et al., 2003; Iuliano et al., 2013; Smoliner et al., 2013). One trial, which used an intervention of more frequent meal patterns, reported no difference in nutrient intake (Taylor and Barr, 2006). Two trials reported weight gain with FB intervention (Kwok et al., 2001; Leslie et al., 2012), but this was only significant in the energy-enriching approach (Leslie et al., 2012) and no evidence for any functional benefit was found (Kwok et al., 2001; Smoliner et al., 2013). This may be due to short intervention and follow-up, or may suggest that functional frailty in this population is influenced more by age-related morbidity and immobilisation than by nutritional intake. The trial, which attempted to assess quality of life (Leslie et al., 2012), found that residents were unable to fully comprehend the questionnaire, a barrier that has been reported previously (Hickson and Frost, 2004). Intervention compliance was reported in 3 trials, but only 1 (Beck et al., 2002) gave an indication of average intervention intake as energy consumed (380kcal).

Assessment of the risk of bias within food-based intervention trials (Table 7, pp. 27)

The risk of bias for each trial was assessed (Table 7 (Higgins, 2011)). Only 1 trial adequately described the method of randomisation sequence generation and allocation concealment and was assessed as low risk of selection bias (Leslie et al., 2012). Three trials described allocation of intervention at the cluster level (Odlund et al., 2003; Smoliner et al., 2008; Iuliano et al., 2013), but did not make any reference to a clustered trial design. No included trials were blinded to participants or personnel and blinding of outcome assessors was often unclear. It is acknowledged

that the challenge associated with designing a trial with adequate placebo for FB intervention is significant and whilst it might be possible to undertake blinded outcome assessment, this was not the case in many of the included trials, perhaps due to lack of funding. No trials included an intention to treat (ITT) analysis, and 2 were rated as being at high risk of attrition bias, where loss-to-follow up was described as high (20% and 25% respectively), but was not accounted for within the analysis. All trials reported on the pre-specified outcomes and were rated as low risk of reporting bias.

Overall rating of quality for the food-based body of literature (Table 8, pp.31)

The GRADE system (Balshem et al., 2011) was used to rate the quality of the body of evidence for FB intervention (Table 8). In the context of this review, quality reflects confidence that the findings of the included trials are correct. The overall rating was 'very low', due to limitations in the design and implementation of the included trials (Table 7) and identified indirectness of the evidence. Three of the 7 trials, did not specifically recruit residents with, or at risk of malnutrition, therefore the evidence may be indirect in relation to the clinical population of interest. The nature of the intervention was broadly defined within all trials, but the type, content and delivery method varied and was often poorly described, affecting external validity and making the trials hard to replicate. Although several trials indicated improvements in nutritional parameters, the potential benefit to functional and clinical outcomes is unclear, whilst patient-centred outcomes require further investigation. More adequately powered, low risk of bias trials are required to draw any definite conclusions.

2.3.3.2 ONS intervention for malnutrition in the care home setting

Six original RCTs, examined the effect of ONS in care home residents. The trials examined a number of outcomes meeting the criteria, including, change in weight (n=6), BMI (n=6) or MAC (n=2), physical function (handgrip strength, ADL score) (n=3) and change in dietary intake (n=2). One trial included quality of life (QoL) as a secondary outcome measure (Stange et al., 2012) and another included a 1-year follow up to observe mortality (Lee et al., 2013). Three included trials analysed fasting biochemistry pre-and post-intervention (Wouters-Wesseling et al., 2002; Manders et al., 2009; Lee et al., 2013). All 6 trials utilised a parallel design, but 3 compared ONS with a placebo supplement drink and 3 compared with standard care. Follow-up ranged from 60 days to 24 weeks. A summary of the evidence is described (Table 5).

Table 5: Summary of evidence for ONS interventions: methodological characteristics and major outcomes of included studies

Source:	Sample size	Population:	Design:	ONS intervention	Resident compliance	Outcomes: Intervention vs Control
Fiatarone, 2000	n = 50	Frail nursing home residents, mean age 88	RCT This study was a subgroup analysis of the larger FISCIT trial	Multinutrient liquid supplement (240ml) versus a non-nutritive (4kcal) placebo drink (240ml) **+360kcal**	**99% compliance with ONS (360kcal)** but decrease in habitual dietary intake	Significant decrease in habitual dietary intake, Gain in weight NSD. No effect on physical activity levels, muscle strength, depressive symptoms or cognitive function
Lauque, 2000	n =88	Elderly nursing home residents in Toulouse. Mean age 84±8 to 80±4	Semi-randomised Concurrent controls	Liquid supplements 4 different supplements offered: soup, fruit, dessert or a liquid **+300-500kcal**	Mean intake of: **393±23kcal in the at risk group** **430±20kcal in the malnourished group**	Malnourished group: weight gain of 1.5 ± 0.4kg, p<0.05. At risk group, weight gain of 1.4±0.5kg, NSD CG: no change in weight, BMI, grip strength, NSD
Wouters-Wesseling, 2002	n = 42	Psycho-geriatric nursing home residents in the Netherlands with low BMI. Mean age IG: 85±8 and CG: 79±9	RCT, placebo controlled	Complete micronutrient-enriched liquid ONS (125 ml) or Placebo (125 ml) twice daily between meals. **+270kcal**	Mean intake of: **91%/246kcal**	Weight change: 1.4±2.4 kg vs. -0.08 ±3.0kg, p = 0.02 Resident drop out: 17%

Manders, 2009	n = 176	Residents from three homes for the elderly, three nursing homes and three 'mixed' homes in the Netherlands. Mean age: 83 Mean BMI 25.3 (IG), 25.0 (CG)	Double-blind RCT, placebo-controlled, intervention trial	125ml nutrient enriched dairy drink x 2 vs. a placebo **+500kcal**	Median intake of **78%/390kcal** <50% compliance in 1/5th of population	Intake of energy, macronutrients, vitamins and minerals increased in IG and decreased or remained stable in the CG (P=0.001), Energy intake from normal foods decreased in both groups. Body weight increased by 1.4 kg in the IG and decreased by 0.6 kg in CG, NSD Resident drop-out: 33%
Lee, 2013	n = 92	Undernourished geriatric nursing home residents in Taiwan. Mean age in CG: 80.2±7.8, IG: 78.9±8.4. mean BMI CG: 20.31, IG: 20.43 Excluded residents not cognitively able to answer the questionnaire	Double-blind RCT	50 g/day soy-protein-based nutritional supplement containing all essential micro-nutrients **+250kcal, 9.5g protein**	Not reported	Intervention significantly improved (or minimized decline of): body weight (IG +0.08±2.72; CG -0.33±1.51), BMI, MAC, calf circumference and serum albumin and cholesterol concentrations (all $p < 0.05$) No significant effect on hemoglobin, hematocrit and lymphocyte count status.
Stange, 2013	n = 87	Nursing home residents with or at risk of malnutrition, in Germany, 90.9% female Mean age 87±6 years.	RCT	2 x125 ml ONS per day vs. routine care **+600kcal, 24g protein**	Median ONS intake: **73%/438kcal**	Body weight, BMI, and arm and calf circumferences increased in the IG and did not change in the CG (P<0.05). Assessment of function was hampered by dementia and immobility,

FISCIT= Frailty and Injuries in Later Life; ONS= Oral Nutritional Supplements; RCT= Randomised Controlled Trial; BMI= Body Mass Index; MAC= Mid Upper Arm Circumference; IG= Intervention group; CG= Control group, NSD = no significant difference

Five trials examining weight or BMI found evidence for improvements with ONS, which was significant in all but 1 (Manders et al., 2009). Two trials showed improvements in MAC and Calf Circumference (CC) (Lee et al., 2013; Stange et al., 2013) and 1 trial found evidence for a significant increase in overall energy, vitamin, and mineral intake (Manders et al., 2009), although energy intake from normal food was reduced. No evidence for any functional benefit was found, which may be due to short intervention and follow-up, or may illustrate the difficulty achieving functional improvements in this population. Assessment of function by Stange et al (2013) was reportedly hampered by dementia and immobility, which limited significance of the results. Intervention compliance was reported in 5 trials as mean or median energy intake (246 to 438kcal/day).

Assessment of the risk of bias within ONS intervention trials (Table 7, pp. 27)

Two trials adequately described the method of random allocation (Lee et al., 2013; Stange et al., 2013), but allocation concealment was not clearly described, or was not used in any included trials. Three trials (Wouters-Wesseling et al., 2002; Manders et al., 2009; Lee et al., 2013) were double-blinded to participants and personnel, but it was unclear if any of the included trials used blinded outcome assessment, placing them at unclear or high risk of detection bias. Losses to follow-up were accounted for in all trials, but ITT analysis was used in only 1 (Stange et al., 2013). The majority of included trials reported on pre-specified outcome measures, although the description of primary outcomes was unclear in 1 trial (Lauque et al., 2000) and although mortality was described as an outcome in another (Lee et al., 2013), it was not reported in results or discussion.

Overall rating of quality for the ONS body of literature (Table 8, pp. 31)

The quality of this body of literature was assessed as 'low' using the GRADE approach (Table 8). The quality level decreased due to limitations in the design and implementation of the included trials (Table 7) and due to identified indirectness of the evidence in relation to the population of interest. Two trials (Lauque et al., 2000; Manders et al., 2009) were conducted with residents that were not undernourished and 1 trial had numerous exclusion criteria, which meant that the study population was relatively healthy (Fiatarone et al., 2000). The 6 trials varied with respect to design, conduct and intervention energy content (270kcal to 600kcal/day) and it was difficult to directly compare findings, because 3 compared ONS to placebo, whilst 3 compared ONS to standard care. Standard care varied significantly and in 1 trial, even included provision of homemade snacks or ONS prescribed by a GP (Stange et al., 2013). Some evidence for a positive effect of ONS intervention on weight, anthropometry and nutrient intake was identified; however, more adequately powered, low risk of bias trials are required to determine whether the improvement in nutritional parameters can translate into improvements of functionality and patient-reported outcomes.

2.3.3.3 ONS intervention versus food-based (FB) intervention for malnutrition in the care home setting

Two RCTs compared FB intervention with ONS intervention in the care home setting. Both examined change in nutrient intake as the primary outcome measure and utilised a parallel design. The follow-up period was 6-weeks (Turic et al., 1998) and 12-weeks (Parsons et al., 2011) respectively. A summary of the evidence is described (Table 6).

Table 6: Summary of evidence for ONS intervention vs. food-based intervention: methodological characteristics and major outcomes of included studies

Source:	Sample size	Population:	Design:	Interventions	Resident compliance	Outcomes: Intervention vs. Control
Turic, 1998	n = 68	Care home residents at risk of malnutrition, from 4 Long term care facilities. Mean age ONS: 84±7.6, FB: 85 ±10. Mean BMI, ONS: 20±3.42 and FB: 20.6± 3.18	RCT	Daily food snacks x 3 vs. 3 x 8oz servings of ONS (711ml total) **+900kcal with ONS** **Snacks unclear**	Mean intake of: **611kcal**	ONS had significantly higher intake of energy and all nutrients p<0.001
Parsons, 2011	n = 104	Care home residents, at risk of malnutrition. Mean age: 88.3±7.7y, mean BMI 19.1±2.7kg/m2, 86% female	RCT	Two servings of ONS vs. written or verbal dietary advice **+600kcal with ONS**	Mean intake of: **333kcal±237**	Total energy intake: ONS: 1655±502kcal vs. FB: 1253±469kcal, p=0.001; Protein intake: ONS: 62.1±18.4g vs. FB: 49.6±19.9g, p=0.004, Appetite sensations, NSD Resident drop-out: 27%

RCT= Randomised Controlled Trial; BMI= Body Mass Index; ONS= Oral Nutritional Supplement group; FB= Food-based intervention group; NSD = no significant difference

One trial compared 3 energy-dense snacks daily to 3 servings of ONS daily (900kcal) and demonstrated an increased energy intake of 26-30% with snacks and 46-50% with ONS (Turic et al., 1998). The second trial compared ONS intervention with dietary advice (cognitive intervention) and showed increased energy and protein intakes that were 32% and 25% higher respectively in the ONS group (Parsons et al., 2011). Mean intakes of ONS intervention were 56% (Turic et al., 1998) and 68% (Parsons et al., 2011), but compliance with dietary advice or FB intervention was not reported.

There is a lack of published research that has compared the effectiveness of nutritional interventions in the care home population. The 2 identified trials were rated high risk of performance bias (Table 7), because of a lack of blinding and both had unclear risk of selection bias, due to an absence of discussion of allocation concealment during intervention assignment. The 2 trials differed greatly with respect to design, interventions and control and an overall rating of low quality was assigned, following assessment using GRADE (Table 8). The quality level was decreased due to identified limitations in the trial designs and implementation (Table 7) and because of indirectness of the evidence. One trial compared ONS to food-based snacks, but provided no information on whether the nutrient composition of the interventions was comparable, whilst the other compared ONS to written advice. To enable the efficacy of FB and ONS interventions to be compared in the care home setting, adequately powered, low risk of bias trials comparing interventions of equivalent nutrient content are required.

Table 7: Risk of bias in RCTs (assessed using the Cochrane risk of bias tool (Higgins et al., 2011))

	Selection Bias		Performance Bias	Detection Bias	Attrition Bias	Reporting Bias	Other bias	Overall risk of bias
	Random sequence generation	Allocation Concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting		
Food-based intervention vs. standard care								
Kwok, 2001	**High risk** Quasi-random allocation	**High risk** Allocation concealment not carried out	**High risk** Open-label	**Unclear risk** No information given regarding whether outcome assessors were blinded	**Unclear risk** Losses to follow- up disclosed, but ITT analysis not described	**Low Risk** All pre-specified outcomes were reported		**High**
Beck, 2002	**High risk** Semi-randomised approach described	**High risk** Allocation concealment not carried out	**High risk** Open-label	**Unclear risk** No information given regarding whether outcome assessors were blinded	**Unclear risk** Losses to follow- up disclosed, but ITT analysis not described	**Low Risk** All pre-specified outcomes were reported		**High**
Odlund, 2003	**High risk** Residents in one ward given intervention, residents in the other ward remained on regular diet. No information given on method of random allocation	**High risk** Allocation concealment not carried out	**High risk** Open-label	**High risk** Open-label	**Unclear risk** Losses to follow-up disclosed, but ITT analysis not described	**Low risk** All pre-specified outcomes were reported	**Unclear risk** Examples of energy-enriched diet given, but unclear if the same level of enrichment provided daily and no information on assessment of compliance. Could result in performance bias.	**High**
Taylor, 2006	**High risk** 'Participants were randomly assigned to one of the two groups'	**High Risk** No description of allocation concealment	**High risk** Open-label	**Unclear risk** No information given regarding whether	**Low risk** No loss to follow up	**Low risk** All pre-specified outcomes were reported	**Unclear risk** Implemented in a 'real life' setting, this limited ability to provide	**Medium**

	No information given on method of random allocation			outcome assessors were blinded			complete control. May lead to performance bias, but provide information on effectiveness in a typical setting.	
Smoliner, 2008	**High risk** 'Randomisation was done according to ward' No information given on method of random allocation	**High Risk** No description of allocation concealment	**High risk** Open-label	**Unclear risk** No information given regarding whether outcome assessors were blinded	**High risk** Losses to follow-up disclosed, but ITT analysis not described, despite attrition rate of 20%	**Low risk** All pre-specified outcomes were reported	**Unclear risk** FB interventions described inadequately- unclear how often energy enriched food was offered and in what quantities. Snacks not described. May lead to performance bias	**High**
Leslie, 2012	**Low risk** Cluster randomisation using a random permuted block design. All residents within the homes invited to participate	**Low risk** Carried out by a statistician with no contact with the homes	**High risk** No blinding of residents, staff or research team	**Unclear risk** No information given regarding whether outcome assessors were blinded	**High risk** Losses to follow-up disclosed, but ITT analysis not described, despite attrition rate of 25%	**Low Risk** All pre-specified outcomes were reported	**Unclear risk** Unclear information given on the intervention provided in terms of energy added for all residents (only maximum amount reported). No clear information on compliance. This could lead to performance bias	**Medium**
Iuliano, 2013	**High Risk** 'Two facilities were randomly selected for intervention' No information given on method of random allocation 'Probably not done'	**High Risk** No description of allocation concealment	**High risk** Open-label	**High risk** Open-label	**Unclear risk** No information given on losses to follow-up	**Low risk** All pre-specified outcomes were reported	**Unclear risk** Content of the interventions unclear. Method of determining whether residents were able to take 2 additional daily servings not described. May lead to performance bias	**High**

ONS intervention vs. standard care								
Fiatarone, 2000	**Unclear risk** Described as randomised placebo controlled but no information on method of random allocation	**Unclear risk** Not clear if allocation concealment used	**Unclear risk** The larger FISCIT trial was double-blinded	**Unclear risk** No information given regarding whether outcome assessors were blinded	**Unclear risk** Losses accounted for, but not clear if ITT analysis used	**Low risk** All pre-specified outcomes were reported		**Medium- High**
Lauque, 2000	**High risk** Semi-randomised trial. No information given on method of random allocation for group B	**High risk** Allocation concealment not used	**High risk** Open-label	**Unclear risk** No information given regarding whether outcome assessors were blinded	**Unclear risk** Losses accounted for, but ITT analysis not used	**Unclear risk** Outcomes reported, but description of primary unclear	Stated that the baseline groups differed significantly, likely due to assignment based on MNA score and semi-randomised design	**High**
Wouters-Wesseling, 2002	**Unclear risk** Described as randomised, but method not stated	**Unclear risk** Unclear if method of allocation concealment used	**Low risk** Double-blinded placebo controlled	**Unclear risk** Not mentioned if outcome assessors blinded	**Unclear risk** Losses to follow up accounted for, but ITT analysis was not possible	**Low risk** All pre-specified outcomes were reported	Patients in the intervention group were significantly older	**Low-Medium**
Manders, 2009	**Unclear risk** Described as randomised, placebo-controlled, but no information on method of random allocation. Unequal distribution used on basis of perceived ONS benefit vs. placebo. Dietary intakes assessed in a non-randomly selected subsample.	**Unclear risk** Potential confounding factors accounted for in allocation to treatment described, but method of allocation concealment not clear	**Low risk** Double-blinded trial to participants and personnel	**Unclear risk** No information given regarding whether outcome assessors were blinded	**Unclear risk** Losses to follow-up accounted for. Unclear if ITT analysis used. Noted differences between drop-outs and compliers may have resulted in bias.	**Low risk** All pre-specified outcomes were reported		**Medium**
Lee, 2013	**Low risk** Subjects were 'randomly assigned to	**Unclear risk** Unclear if allocation	**Low risk** Double-blinded trial	**Unclear risk** No information given	**Unclear risk** Losses accounted for,	**Unclear risk** Trial mentioned a one year follow up		**Medium**

	either the control or the experimental group by drawing pieces of folded paper from a bag	concealment used		regarding whether outcome assessors were blinded	but ITT analysis not used. No information on whether drop-outs differed significantly from compliers	to observe mortality within methods, but this was not discussed again in results or discussion		
Stange, 2013	**Low Risk** 'Randomisation was performed in blocks of 6 to 10 subjects per ward, to balance differences between the wards, by closed envelopes'	**Unclear risk** Not made clear if the allocation sequence was concealed from those assigning interventions	**High risk** Open-label	**High risk** Open-label	**Low risk** Losses to follow-up accounted for and ITT analysis used	**Low risk** All pre-specified outcomes were reported	The CG received usual care, but this included snacks and ONS when provided by family or a GP.	**Medium**
FB intervention vs. ONS intervention								
Turic, 1998	**Low risk** A randomisation schedule was created using a statistical analysis system, which used a pseudo-random variate	**Unclear risk** Not made clear if the allocation sequence was concealed from those assigning interventions	**High risk** Open-label-necessary due to the nature of the interventions	**Unclear risk** Not mentioned if outcome assessors blinded	**Unclear risk** Losses to follow up accounted for, but ITT analysis was not used	**Low risk** All pre-specified outcomes were reported	The FB group received 3 food-based snacks but these were not described, making the trial difficult to replicate	**Medium**
Parsons, 2011	**Unclear risk** Described as randomised, but method not stated	**Unclear risk** Unclear if method of allocation concealment used	**High risk** Open-label-necessary due to the nature of the interventions	**Unclear risk** Not mentioned if outcome assessors blinded	**Low risk** Losses to follow-up accounted for and ITT analysis used	**Low risk** All pre-specified outcomes were reported	Compared a physical intervention with a cognitive intervention	**Medium**

ONS= Oral Nutritional Supplements; ITT= Intention to Treat; FISCIT= Frailty and Injuries in Later Life; MNA= Mini Nutritional Assessment; CG= Control Group

Table 8: Assessment of the quality of the evidence (Using the GRADE system (Balshem et al., 2011))

Body of evidence	Study Design and Initial quality	Factors that decrease the quality					Factors that increase the quality			Quality of the body of evidence
		Risk of Bias (Table 5)	Inconsistency of results	Indirectness of evidence	Imprecision of results	Risk of publication bias	Large effect	Dose-response gradient	Plausible biases underestimating intervention effect	
Food-based intervention vs. standard care	**RCTs- HIGH (+4)**	**Very serious (-2)**	**Most show similar results (0)**	**One type noted (-1)** Three trials (Odlund et al., 2003; Taylor, 2006; Iuliano et al., 2013) not undertaken with undernourished residents	**Unclear (0)** Few trials reported confidence intervals. Few participants (<100 in all but 1 trial), but insufficient information to downgrade.	**Unclear (0)**	**(0)** Not applicable- effect sizes were small and often non-significant	**(0)** Dose-response gradient not reported	**(0)** Risk of bias was high for most trials, but no evidence that this worked to underestimate the intervention effect	**+, very low**
ONS intervention vs. standard care or placebo	**RCTs- HIGH (+4)**	**Serious (-1)**	**Consistent (0)** Considered estimates of effect for Weight gain and BMI (most widely reported outcome)	**Two types noted (-1)** 1. Two trials (Lauque et al., 2000; Manders et al., 2009) not undertaken with undernourished residents. 2.Three trials compared ONS to placebo, the other 3 compared to SC	**Unclear (0)** Few trials reported confidence intervals. Few participants (<100 in all but 1 trial), but insufficient information to downgrade.	**Unclear (0)**	**(0)** Not applicable- effect sizes were small and often non-significant	**(0)** Dose-response gradient not reported	**(0)** Risk of bias was unclear or high for most trials across the criteria, but no evidence that this worked to underestimate the intervention effect	**++, Low**
Food-based intervention vs. ONS intervention	**RCTs- HIGH (+4)**	**Serious (-1)**	**Showed similar results (0)**	**One type noted (-1)** One trial compared ONS to snacks, the other compared ONS to advice	**Unclear (0)**	**Unclear (0)**	**(0)** Not applicable- effect sizes were small	**(0)** Dose-response gradient not reported	**(0)** Not observed	**++, Low**

BMI= Body Mass Index; ONS= Oral Nutritional Supplements; SC= Standard Care

2.4 The challenges of conducting primary research in the care home setting

Several trials within the systematic review highlighted the challenges of conducting research with the frail, dependent care home population (Leslie et al., 2012; Stange et al., 2013). The complexities involved have been discussed within several published articles and include, recruitment difficulties due to physical and/or cognitive impairments (Maas et al., 2002), the consent process (Maas et al., 2002; Hall et al., 2009), and the high attrition rates of older people from research (Maas et al., 2002; Ridda et al., 2008). Difficulties with receipt of consent was highlighted within a number of the included trials (Taylor and Barr, 2006; Smoliner et al., 2008; Stange et al., 2012), whilst drop-out rates of 25% to 33% were reported in others (Manders et al., 2009; Parsons et al., 2011; Leslie et al., 2012).

Individuals who drop out tend to be different from those that complete a trial (Estellat et al., 2009), which can result in attrition bias, although drop-out rates of up to 20% are generally considered acceptable (Schulz and Grimes, 2002). One reason for high attrition rates in care homes, is high mortality, which has been reported in published work from various countries (Raines and Wight, 2002; Van Dijk et al., 2005; Lee et al., 2009). A recent UK cohort study, which described 1-year mortality in care home residents compared with community-dwelling residents, found that 2,558 (26.2%) of care home residents died within 1 year, compared to 11,602 (3.3%) community residents (Shah et al., 2012). High mortality can considerably reduce the number of residents available for analysis at the trial end-point and has led to recommendations for expected mortality to be accounted for in sample size calculations (Zermansky, 2007).

The challenges inherent in care home research has led to malnutrition intervention trials including advanced dementia and immobility within the exclusion criteria (Fiatarone et al., 2000; Smoliner et al., 2008; Manders et al., 2009; Lee et al., 2013), despite these being well-established risk factors for malnutrition. As a result, knowledge of the actual effectiveness of nutritional intervention in this vulnerable population is limited and the clinical applicability of findings to those residents most at risk is often questionable.

2.4.1 Summary

To enable the efficacy of nutritional interventions to be compared within the care home population, an adequately powered RCT is required, using interventions that are homogeneous in nutrient composition, alongside a comparative standard care arm. Given the complexities involved in care home research, a feasibility trial was proposed prior to the initiation of a definitive RCT.

2.5 Research Question

Is it feasible and acceptable to run a definitive trial in the care home setting, comparing and evaluating FB intervention, ONS intervention and the standard care home diet for malnutrition?

2.6 Research Aim

To explore trial design, staff, and resident acceptability of the interventions and outcome measures and to provide data to estimate the parameters (sample size and intra-cluster correlation coefficient) required to design a definitive RCT.

CHAPTER THREE: METHODOLOGY

3.1 Research Design

3.1.1 Choice of methodology: A Prospective cluster randomised feasibility trial

A number of individual components make up complex healthcare interventions such as nutritional support in the care home setting, making it difficult to specify the 'active ingredient' of the intervention and to compare intervention variations (Medical Research Council, 2000). The RCT is the optimal study design to minimise selection bias (Kunz et al., 2007), to demonstrate potential causative effect (Ho et al., 2008) and to provide the most accurate estimate of an intervention's benefits (Medical Research Council, 2000). However, prior to evaluation in a definitive RCT, The Medical Research Council (MRC) framework (2008) recommends that complex interventions be investigated using preliminary studies, to optimise trial design, define outcomes and ensure feasibility. In light of the lack of adequately powered, low risk of bias trials evaluating nutritional interventions within the care home setting, a feasibility trial for a definitive cluster RCT was designed.

The feasibility trial assessed 3 arms; FB intervention, ONS intervention, and the standard care (SC) home diet for malnutrition, with 6-month intervention duration. A cluster design was chosen primarily to avoid contamination (Torgerson, 2001), because the care home staff at each site could not be expected to treat participating residents differently, but was also used for practical reasons. The aim of the trial was to assess the feasibility and acceptability of delivering and monitoring nutritional interventions in the care home setting, and hence the home was the unit of randomisation. Six care home sites were randomised into the 3 trial arms.

3.1.2 Trial Objectives

The trial objectives are outlined below (Table 9).

Table 9: The primary and secondary objectives of the trial

Primary Objectives	Secondary Objectives
1. To assess how many care homes for the elderly accept the invitation to participate in a nutritional intervention feasibility trial	1. To investigate the completion and accuracy of nutritional screening and questionnaire completion by care home staff
2. To determine whether the eligibility criteria for malnourished care home residents are too open or too restrictive, by estimating feasible eligibility and recruitment rate	2. To determine how many malnourished residents are able to participate in Participant Reported Outcome Measures (PROMs) and to complete the questionnaires.
3. To assess retention of care homes and residents, by estimating 3- and 6-month follow up rates	3. To pilot a Healthcare Resource Usage (HCRU) questionnaire
4. To investigate the acceptability of nutrition support interventions to malnourished care home residents, in terms of compliance, and to care home staff in terms of adherence to the intervention schedule	4. To measure key outcome domains (for completion rates, missing data, estimates, variances and 95% confidence intervals for the difference between the intervention arms) for malnourished care home residents including physical outcome measures and PROMs
5. To assess the acceptability and feasibility (and factors influencing this) of the different outcome measures as methods to measure efficacy of nutritional interventions within a definitive trial	5. To collect and synthesise data, from which the Intracluster Correlation Coefficient (ICC) and sample size of a definitive cluster RCT (CRCT) could be estimated

3.2 Ethical approval

All UK clinical trials are governed by 'The Research Governance Framework (RGF) for Health and Social Care' (Department of Health, 2005a). To meet the framework requirements, trial approval was required from a Research Ethics Committee (REC) (Appendix 1) and the Research and Development (R&D)

Department of the NHS trust sponsoring the research (Appendix 2), prior to commencement. The REC approved the consent, randomisation and intervention taking place at the care home level. However, the committee felt that the inclusion of residents lacking capacity in the collection of Participant Reported Outcome Measures (PROMs) could not be justified in accordance with the Mental Capacity Act (Department of Health, 2005b). They requested that those residents having capacity to complete PROMs, provide individual consent for this part. The trial was conducted in accordance with the Declaration of Helsinki of the World Medical Association (WMA, 2000) and the International Conference on Harmonisation Good Clinical Practice (ICHGCP) guidelines (European Medicines Agency, 2002).

3.3 Participants

3.3.1 Setting and population

The feasibility trial was conducted within the borough of Solihull, West Midlands, in England. Prior to trial commencement, 17 care homes providing accommodation for older adults (over 65 years), were receiving regular dietetic input to improve the identification and first-line management of malnutrition. Six, privately owned care homes, selected by purposive sampling to obtain a diverse sample based on type of care provided (residential or nursing/nursing and residential) were invited to take part in the trial. This enabled the evaluation of feasibility and acceptability across a range of care home settings.

3.3.2 Care homes (Clusters)

Prospective care homes were provided with a full explanation of the trial by the Primary researcher, a registered dietitian with a history of clinical input in all 6 homes. An invitation letter (Appendix 3) and an information sheet (Appendix 4) were sent to the Manager, followed by a face-to-face visit to enable discussion. Each care home was given 1 week to consider participating, after which, the manager was asked to sign a consent form (Appendix 5). The GP for each care home was informed in writing of their involvement (with the care home's consent to do so).

3.3.3 Care home residents

The process of resident screening, identification and consent (for those participating in PROMs) is outlined below (Figure 3).

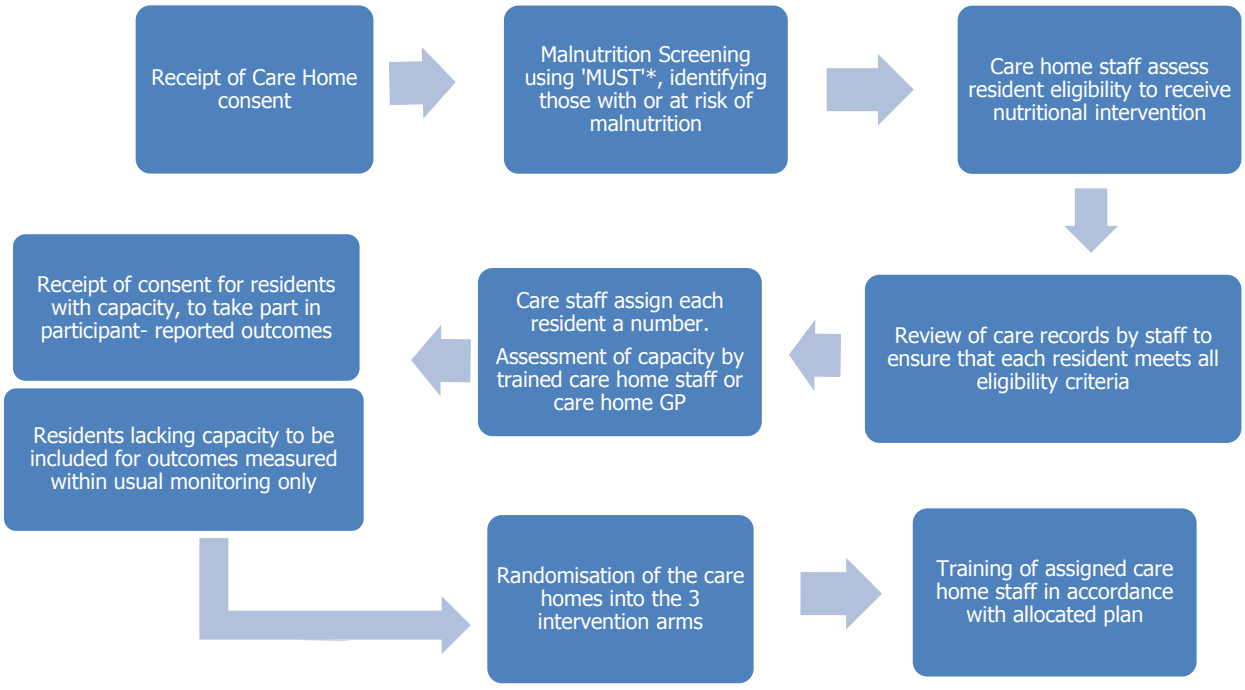


Figure 3: The recruitment and consent process: Eligible residents were identified using routine malnutrition screening, a review of care home records and consultation with staff

*'MUST'= Malnutrition Universal Screening Tool

All residents at risk of malnutrition, without a dietetic-led plan in place, were considered for eligibility within participating care homes (Care home screening log, Appendix 6). Care home staff with responsibility for conducting monthly nutritional screening (Nurses or Senior Carers), used the Malnutrition Universal Screening Tool ('MUST') (Appendix 7) to identify those at risk of malnutrition. 'MUST' classifies risk as low, medium or high based on body mass index (BMI), history of unintentional weight loss (%) and acute illness effect (Elia, 2003; NICE, 2006). 'MUST' has been validated for use in adults, has very good-to-excellent inter-observer reliability in care homes (kappa 0.8-1.0) and is acceptable to participants and healthcare workers (Elia, 2003).

The REC requested that assessment of eligibility be carried out by non-research staff. Care home staff therefore reviewed the records of those residents identified as medium or high risk of malnutrition, against the eligibility criteria (Table 10) consulting with the dietetic service and the GP, as required. Each resident eligible to receive an intervention was assigned a unique trial number (Trial Protocol, Appendix 8, p151-152).

Table 10: Eligibility criteria for residents to receive an intervention within the participating care homes

Inclusion criteria	Exclusion criteria
• A score of '1' or higher on the Malnutrition Universal Screening tool ('MUST'; Elia, 2003) • Able to eat and drink • Registered with a Solihull GP and subsequently eligible for the provision of healthcare services provided by the Heart of England NHS foundation Trust (HEFT)	• Receiving (or likely to receive in the next 6 months) tube or parenteral nutrition • Receiving nutrition support in the form of individualised dietetic advice or prescribed ONS. • Have a known eating disorder or illness, which requires a therapeutic diet incompatible with fortification and/or supplementation. This may include but is not limited to, Galactosemia or known lactose intolerance, chronic renal disease requiring dialysis, poorly controlled diabetes, in receipt of active cancer treatment, or liver failure. • On an end-of-life care pathway
	Exclusion criteria for Participant reported outcome measures (PROMs)
	• Non-native English speaking • Lacking the capacity to consent

An estimated 80% of care home residents have Dementia or severe memory problems (Quince, 2013) and it was anticipated that the eligible residents, would include individuals lacking the capacity to consent. In accordance with the requirements of the approving REC (section 3.2), these residents were excluded from taking part in PROMs. The decision to exclude non-native English speaking residents, with or without capacity, was based on the primary researcher's existing knowledge and experience of the population group and consideration of the finances available to run the trial. The primary researcher estimated that less than 5% of the resident and staff population would be non-native English speaking. This trial was conducted as part of a student Masters project and as such, had no additional

funding attached to it. This prohibited translation of information leaflets into different languages and the hire of an interpreter (Appendix 8, p150).

3.3.3.1 Individual resident consent for PROMs

Within the care home setting, capacity is assessed by trained care home staff, or the GP in accordance with the Mental Capacity Act (Department of Health, 2005b). Written consent was sought on an individual basis from eligible residents assessed as having functional capacity. Residents were provided with a full explanation of their required participation (Appendix 8, p153-154) alongside a Participant Information Sheet (Appendix 9). They were given 1 week to ask questions and decide whether they would like to provide information on quality of life, health state and dietary satisfaction. Each resident was asked to sign a consent form (Appendix 10).

3.4 Nutritional interventions

3.4.1 Food-based (FB) intervention in addition to standard care (3.4.3)

The content of the FB intervention was based on local nutrition support guidelines (Heart of England NHS Foundation Trust, 2012) and national guidance for best practice (NICE, 2006; PrescQIPP Nutrition Toolkit, 2012; Malnutrition pathway, 2012). Care staff and catering teams within the 2 homes randomised to FB intervention, received face-to-face instruction by the primary researcher to increase participating resident's daily nutritional intake by approximately 600kcal and 20-25g of protein. The interventions used included homemade enriched drinks, and/or between-meal fortified snacks (Table 11) (Appendix 11). The combination agreed by

the primary researcher and the staff was documented for each resident, at baseline and at three-months (Appendix 12) and intervention recipes were provided. Staff recorded intervention intake on the daily food record chart (FRC) as a proportion taken *(All; ¾; ½; ¼; refused)*

Table 11: Food-based intervention composition

Fortified drink and snack options	Volume per serving (ml)	Energy content (kcal) per serving	Protein content (g) per serving
Fruit fool	200	275	7.9
Chocolate mousse	150	410	10.95
Milkshake	200	306	9.8
Fruit smoothie	200	306	10
Milky coffee	200	278	10.6
Malted drink	200	304	12
Hot chocolate	200	306	10.6

3.4.2 ONS Intervention in addition to standard care (3.4.3)

Nursing and/or senior care staff within the 2 homes allocated to ONS intervention, received instruction by the primary researcher to increase the daily nutritional intake of participating residents by approximately 600kcal and 24g protein. The intervention consisted of 2 liquid ONS (Table 12), provided to residents under the control of a registered dietitian. Staff recorded intervention intake on the daily drugs chart as a proportion taken *(All; ¾; ½; ¼; refused).*

Table 12: Composition of the ONS types used within this trial

ONS	Volume (ml)	Kcal/ml	Energy content (kcal) per serving	Protein content (g) per serving
Fortisip Bottle (Nutricia Advanced Medical Nutrition)	200	1.5	300	12
Fortisip Compact (Nutricia Advanced Medical Nutrition)	125	2.4	300	12
Nutriplen (Nualtra Ltd)	125	2.4	300	12

*Nutritional information taken from: http://www.nutricia.ie/products and http://nualtra.ie/information-for/dietitian. Fortisip/Fortisip Compact was provided by Nutricia for the first 3-months of the trial. Nutriplen was provided by Nualtra for the second 3-months of the trial.

The primary researcher determined compliance with the FB and ONS interventions at 3- and 6-months, by calculating average intake from 3 non-consecutive FRCs or drugs charts. Compliance was categorised into 'compliant', if ≥ 75% of the advised food/beverage or ONS was consumed daily and 'non-compliant' if <75% was consumed.

3.4.3 Standard care (SC) arm

The purpose of the SC intervention is to provide a calorie-dense diet (Department of Health, 1992), through the provision of small, frequent, energy-enriched meals, alongside prompting and assistance from staff where required. SC was provided within all 6 homes, to ensure that no resident at risk of malnutrition was denied access to first-line treatment (National Ethics Advisory Committee, 2008). The 2 care homes allocated to SC only, continued to receive visits from the primary researcher, but individualised resident plans were not provided.

3.4.4 Intervention safety considerations

The primary researcher continued to make dietetic visits to all 6 care homes on a monthly basis. If a resident did not tolerate the allocated intervention (SC, FB or

ONS), or experienced a significant decline in nutritional status, a change in nutritional intervention was considered in accordance with local guidelines. Intervention change was recorded for all 3 trial arms at 3- and 6-months.

3.4.4.1 Adverse Events (AEs) and Serious Adverse Events (SAEs) (Appendix 8, p169-170)

This trial was considered low risk, because the nutritional interventions were already established options within the participating homes. Expected adverse events included:

- Mild gastro-intestinal side effects in response to a fortified diet or prescribed ONS, including diarrhoea, bloating, nausea and satiety.

It was decided to collect only targeted nutritional intervention related AEs and, serious AEs (SAEs) requiring hospital admissions that were due to avoidable malnutrition or dehydration (Appendix 13).

3.4.4.2 Risk of re-feeding syndrome on initiation of FB or ONS intervention

Re-feeding syndrome describes the severe, and potentially fatal electrolyte and fluid shifts that may be associated with metabolic abnormalities in malnourished individuals undergoing re-feeding by oral, enteral or parenteral means (Crook et al., 2001) after a period of starvation or fasting (Solomon and Kirby, 1990). Nutrition was commenced at 10kcal/kg/day for those residents identified as being at risk (Table 15) within the care homes allocated to FB or ONS intervention, increasing to provide the additional 600kcal and 20-25g protein by day 7. The care home GP was asked to monitor electrolytes and glucose for 3-days after intervention initiation (NICE, 2006).

3.4.4.3 Deteriorating swallow function (dysphagia) and increased risk of aspiration

Where onset of dysphagia was suspected by the care home staff or primary researcher during the 6-month intervention, a referral was made to the Speech and Language Therapy (SaLT) team as per usual practice. The intervention was adjusted to meet any subsequent modifications to dietary texture or consistency.

3.5 Measures

3.5.1 Process Measures

The primary interest was in assessing the feasibility and acceptability of, procedures for recruiting care homes and residents, the intervention types and schedule, retention of care homes and residents, procedures for measuring outcomes, and completeness of data collection (Table 13).

Table 13: Process Measures: Feasibility and Acceptability

Feasibility Considerations:	**Assessment:**
Recruitment of care homes	Number and proportion of homes approached and homes consented
The suitability of resident eligibility criteria	Number and proportion of residents at risk of malnutrition considered eligible and not eligible
Residents' willingness to participate in PROMs	Number and proportion of eligible residents that provided consent
Resident retention in the trial	Number and proportion of recruited residents remaining at 3-months and at 6-months, number and proportion of recruited residents that died during the trial
Data collection	Number and proportion of questionnaires and records that were available and unavailable or incomplete
Physical outcome measurement	Number and proportion of recruited residents that could and could not be measured at each data collection interval
Acceptability Considerations:	**Assessment:**
Resident acceptability of allocated interventions	Compliance and change of intervention in each trial arm
Staff acceptability of allocated interventions	Adherence and non-adherence to intervention plan
Resident acceptability of physical measurements	Number and proportion of recruited residents that accepted and refused measurements
Resident acceptability of PROM's data collection tools: Appetite and dietary satisfaction VAS tool, EQ5D VAS and questionnaire, COOP quality of life tool.	Number and proportion of questionnaires completed and not completed/refused

PROMs= Participant Reported Outcome Measures; VAS= Visual Analogue Scale

3.5.2 Demographic variables and resident characteristics

(Appendix 14).

Following confirmation of eligibility, care home staff recorded data for each resident on gender, primary diagnosis, capacity, height, and diagnosis of dementia and dysphagia (Table 14).

Table 14: Demographic variables and characteristics collected at baseline

Characteristic:	Reason for baseline data collection
Height (m) In each care home, height is measured and documented within a resident's care record on admission	-Height is required to determine Body Mass Index (BMI) (Weight(kg)/Height ($m^{2)}$) -Reliable measurement can be challenging within the elderly population owing to vertebral compression, reduced muscle tone and changes to posture (World Health Organisation, 1995). -If measurement with a freestanding stadiometer is not possible, staff are trained to ask residents or relatives for self-reported height or to use ulna length to estimate height from the length of the forearm -Ulna length is measured in accordance with 'MUST' (Elia, 2003), between the olecranon process and the styloid process, with the resident's arm bent across the chest. Measured values are used to calculate height using standard equations (Bassey, 1986; Elia, 2003). **The technique used by care home staff to measure height was recorded for each resident; to assess the most frequently used measure within this population.**
Diagnosis of Dementia	The presence of dementia could pose a challenge to the assessment of physical outcome measures (Stange et al., 2013). **Diagnosis of dementia was determined from care home records**
Diagnosis of Dysphagia, defined as a difficulty in swallowing	-Presence of dysphagia can affect nutritional status, and the acceptability of the nutritional interventions. A relationship between dysphagia and malnutrition has been demonstrated in Finnish nursing home residents (Suominem et al., 2005). **Diagnosis of Dysphagia and any recommendations for modified texture and/or consistency of food and fluids were determined from care home records**
Risk of re-feeding syndrome	Residents at risk were identified at baseline through 'MUST' screening, if they had: BMI < 16kg/m^2 Weight loss >15% during the last 3- 6 months No/negligible dietary intake for 10 consecutive days (NICE, 2006). **(Management throughout the trial is described in section 3.4.4.2)**

'MUST' = Malnutrition Universal Screening Tool

3.5.3 Outcome measures

The systematic review (section 2.3) found a lack of low risk of bias, high quality evidence for all reported outcomes within the care home setting. One objective of this trial (Primary objective 5, Table 9) was to evaluate feasibility and acceptability of a range of outcome measurements, to establish those most appropriate for a definitive trial (Table 15). Missing outcomes data is a potential source of attrition bias, which may affect estimation of intervention effect, comparability of intervention arms, and representativeness of the trial sample (European Medicines Agency, 2001). National guidelines (National Research Council, 2010), advocate a considered approach to trial design to limit missing data to less than 20% (Schulz and Grimes, 2002). In this trial, data completeness of ≥ 80% was required (Section 3.9.2), for an outcome to be considered for a definitive trial. Outcome measures were assessed in the 3 arms at baseline (following consent, prior to randomisation and group allocation), and at 3- and 6-months of intervention duration. The primary researcher and the care home staff were responsible for assessment on all participating residents. To enhance the quality and consistency of staff assessed outcomes, a training session led by the primary researcher was provided, consisting of:

- Training on the protocols surrounding assessment and recording of outcome measurements
- Discussion on adverse events and their reporting
- Mock completion of data collection instruments and forms

Table 15: Outcome measures piloted in the trial

Measure	Completed by	Assessment time			Measurement properties
		B	3-months	6-months	
Physical outcome measures					
Weight (kg) Care homes are required to weigh residents at least monthly to promote adequate monitoring (CQC, 2010).	Care home staff	√	√	√	Serial measurements of body weight can identify a change in nutritional status (Loreck et al., 2012). Unintentional weight loss of greater than 10% within 3 - 6 months indicates PEM (NICE, 2006). Measurement in care homes can be problematic due to immobility, disability or a lack of appropriate equipment (Hickson and Frost, 2003). The number and proportion of residents that could or could not be weighed was recorded at each data collection interval. Guidelines for weighing procedures in care homes recommend routinely weighing residents on the same type of class III approved scale to ensure consistency and minimise error (Simmons et al., 2009). To assess adherence to guidelines, the type of scale used (Standing, Chair or Hoist) was recorded at each data collection interval. Weight does not differentiate between fat, fat free mass (FFM) and fluid. Fluid retention, oedema and ascites can therefore limit the usefulness of body weight assessment. A correction can be subtracted from measured weight to account for the presence of additional fluid (Elia, 2003).
Body Mass Index: BMI (kg/m^2) Calculated monthly by care home staff using: BMI = Weight(kg) / Height(m^2)	Care home staff	√	√	√	BMI is used for 'MUST' screening and for calculating nutritional requirements (Todorovic and Micklewright, 2011). A BMI of less than 18.5kg/m^2 is a universal indicator of PEM (NICE, 2006). The cut off range is based on the effect on morbidity and mortality (WHO, 2004). BMI ranges were derived from individuals aged 18-65 years. The use of BMI to define underweight in the older adult population is therefore associated with some limitations: - BMI is unable to distinguish between FFM and fat mass and therefore does not reflect the redistribution of body fat in older age. - BMI assumes the relationship between weight and height is constant throughout the

					adult lifespan, excluding height reduction and resulting in an underestimation of underweight in the older adult population (Hickson and Frost, 2003).This limitation has led to the increased use of alternative height measures when accurate standing height cannot be determined (section 3.5.2) - BMI is based on weight and therefore may be unreliable in the presence of confounding factors such as distorted fluid balance (oedema, ascites or dehydration) (Prentice and Jebb, 2001). BMI should be used as part of the overall assessment and not as a standalone measure of nutritional status (Beck et al., 2013) BMI was collected from care home 'MUST' records at each data collection interval. At three- and six-months, the primary researcher calculated a repeat 'MUST' score for two randomly selected residents per care home and compared the overall score and the scores for each step with that recorded by staff. This enabled competence in calculating BMI and malnutrition risk to be assessed.
Mid Upper Arm Circumference (MAC) (cm)	Primary researcher	√	√	√	Measurement of the circumferences of the extremities is an alternative approach to determine body composition (Loreck et al., 2012) and is particularly useful when oedema is present as the upper arms are not usually affected. MAC provides an estimate of subcutaneous fat and arm muscle (Bruno de Carvalho-Silva, 2012) and has been established as a useful indicator of malnutrition risk (Powell-Tuck and Hennessey, 2003; Harris et al., 2008). It is an independent predictor of mortality in older adult care home residents (Allard et al., 2004). A recent cross-sectional study showed that the reproducibility of MAC when measured by 2 different observers is acceptable for clinical purposes in a care home setting (mean difference 0.3cm (-0.16 to 1.3cm). Mean differences between an upright and a laying down position were also assessed for each observer. No systematic differences were observed: 0.1cm (-2.0 to 2.2cm) and 0cm (-1.9 to 2.0cm) respectively) (Wijnhoven et al., 2012). The primary researcher measured MAC in centimetres using a tape measure (SECA 201) according to standardised procedures. Where possible, the mean of 3 measurements was recorded to minimise measurement error (NHANES III, 1988). To assess the feasibility and acceptability of this measurement in the care home population, the number of residents that refused to have the measurements undertaken, or for whom measurement was not possible, was recorded.

Tricep Skinfold thickness (TSF) (mm)	Primary researcher	√	√	√	TSF is reflective of subcutaneous fat mass and distribution (Bruno de Carvalho-Silva, 2012). It can be used alongside MAC as an alternative approach to evaluate body composition and to assess nutritional status, particularly in individuals with fluid retention. TSF is regarded as an easy to access and reproducible measurement (Wang et al., 2000), although inter observer reliability was shown to be problematic in a large epidemiological study (Ulijaszek and Kerr, 1999). To assess the feasibility and acceptability of measurement in the care home population the number of residents that refused to have the measurements undertaken, or for whom measurement was not possible, was recorded. An acknowledged drawback of the technique is the lack of sensitivity to small changes (<0.5kg), which may hamper the ability to detect nutritional depletion (Loreck et al., 2012). In this trial, TSF was primarily used to enable MAMC to be calculated (see below). The primary researcher measured TSF with a Slimguide calliper (HaB Essentials), according to standardised procedures. Where possible, the mean of 3 measurements was recorded to minimise measurement error (NHANES III, 1988).
Mid Arm Muscle Circumference (MAMC) (cm) MAMC (cm) = MUAC (cm)- 3.14 X TSF (cm)	Primary researcher	√	√	√	MAC and TSF can be used to calculate Mid Arm Muscle Circumference (MAMC), an indicator of protein stores and an estimate of lean muscle mass. This measurement is regarded as an early indicator of nutritional depletion (Wannamethee et al., 2007) MAMC has been shown to be a better surrogate of DEXA- measured Lean Body Mass (LBM) than BMI (Gibney and Ljungqvist, 2005; Nooro et al., 2010). It's reduction, may be a sign of PEM or sarcopenia (Nooro et al., 2010)
Handgrip strength (kg)	Primary researcher	√	√	√	Handgrip strength is an index of general upper extremity strength, strongly associated with functionality (Takata et al., 2008; Sallinen et al., 2010). Low values are associated with falls (Sayer et al., 2006), disability, poor health-related quality of life (Syddall et al., 2009) and increased hospital stay (Kerr et al., 2006). Recently, the measurement has gained attention as an indicator of nutritional depletion and because of a potential capability to detect improvements in nutritional status following nutrition support intervention (Norman et al., 2010). The psychometric properties of the technique have been found to be valid and reliable in populations without cognitive impairment (Peolsson et al., 2001), but not when used on elderly subjects with severe dementia (Alencar et al., 2012). To assess feasibility in a population with varying levels of cognitive impairment, the number of residents that refused to participate, or for whom the measurement was not feasible,

					was recorded. Handgrip strength was measured using the Smedley hand held dynamometer (Model 12-0286) on the non-dominant arm (Todorovic and Micklewright, 2011). Where possible, residents were asked to complete the measurement 3 times on the dominant arm. Due to varying levels of cognitive impairment, it was felt that resident understanding of how to undertake the measure would be poor initially, but improve during the process. The highest achieved measure was therefore recorded.
Nutritional intake assessment					
Energy (kcal)	Primary researcher from care home staff completed records	√	√	√	To ensure compliance with Outcome 5 (Meeting nutritional needs) of the Essential Standards of Quality and Safety (CQC, 2010; RCN, 2010), care home staff are required to complete daily food record charts (FRCs) and fluid charts (FCs), to monitor the dietary intake of those with, or at risk of malnutrition. Meals and snacks are recorded on the FRC alongside portion size consumed *(All, 3/4, ½, ¼ or refused)*. All fluids (type and volume) taken are recorded on the FC. The primary researcher measured and recorded the size/capacity of usual tableware (bowls, plates, glasses) within each care home, at baseline. At each data collection interval, the FRCs and FCs were used to assess the average daily food and fluid intake over 3 non-consecutive days. The primary researcher determined daily energy (kcal) and protein (g) intake using the dietary analysis software, Diet Plan 6 (Forestfield Software Ltd, UK). This software is pre-installed with the complete set of UK food tables. The feasibility and acceptability of using care home documentation to evaluate nutritional intake was assessed. The number of unavailable or incomplete FRCs and FCs were recorded for each care home.
Protein (g)		√	√	√	
Fluid (ml)		√	√	√	

Healthcare resource usage (HCRU)					
HCRU Questionnaire	Care home staff		√	√	Health-care resource usage data is used alongside health outcomes data to calculate the Incremental Cost-effectiveness ratio (ICER) (Weinstein and Stason, 1977), defined as the ratio of the difference in cost, to the difference in effectiveness between two intervention strategies. Effectiveness can be defined as a clinically meaningful event experienced by an individual, for example Quality Adjusted Life Years (QALYs) (calculated from the EQ5D tool- see below). Health Economists use many instruments to estimate resource use for cost-effectiveness evaluations, but a 2012 review established little evidence of reliability testing (Ridyard et al., 2012).The healthcare resource-usage questionnaire (Appendix 15) piloted within this trial was developed from consideration of existing instruments submitted for use in residential care settings on the 'MRC Database of Instruments for Resource Use Measurement' (DIRUM). The questionnaire was piloted by the care home staff, from baseline to 3-months, and from 3-months to 6-months for each eligible resident. Data was collected on all hospital admissions (emergency and appointment; short and long stay), GP call-outs (not routine) and visits from, district nurses, tissue viability nurses, consultants, dietitians and speech and language therapists (SaLT).
Participant Reported Outcome Measures (PROMs)					
Health state: EQ5D-5L[3]	Eligible residents	√	√	√	A core component of economic evaluations in healthcare is the use of preference-based instruments to measure changes in health state. The EuroQol-5D (EQ5D-5L) questionnaire, a standardised multi-dimensional health state classification (Brazier et al., 2004) was piloted within this trial. The questionnaire consists of a Visual Analogue Scale (VAS), which records self-perceived health status on a scale of 0-100, and a descriptive system, comprising 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), recorded with an ordinal five level code. The descriptive system

[3] The Euroqol group granted permission to use the tool within this trial

					can be used to generate a single index-value for health state (Rabin and De Charro, 2001), scored in this trial using an algorithm based on a sample from the adult UK population (Herdman et al., 2011). The EQ-5D has been demonstrated to be responsive, reliable and internally consistent in the normal population and with those that have dementia (Ankri et al., 2003)
Appetite and dietary satisfaction: Visual Analogue Scale (VAS)	Eligible residents	√	√	√	A VAS is a measurement instrument used to measure a characteristic or attitude that ranges across a continuum of values (Wewers and Lowe, 1990). The scale is composed of a horizontal line, 100mm in length, anchored by word descriptors at each end. Participants are asked to mark along the line, at the point corresponding to their overall feelings. VAS are often used within appetite research and several studies have indicated that measured food intake appears to be related to the perceptions of hunger and fullness assessed using VAS (Flint et al., 2000; Parker et al., 2004). In this trial, 'hunger', 'appetite', 'dietary satisfaction', 'pleasantness of meals', 'pleasantness of snacks' and 'pleasantness of drinks' were each measured across a 100mm VAS (Appendix 16).
Quality of life: COOP[4]	Eligible residents	√	√	√	Quality of life was assessed using the Dartmouth Primary Care Cooperative Information Project (COOP) Quality of life chart, a brief, easy to complete questionnaire that is sensitive to subjectively important change (Jenkinson et al., 1995). The COOP has been validated in general primary care settings (McHorney et al., 1992), and was piloted in this trial with a care home population.
Loss to follow-up					
Loss to follow-up	Care home staff	√	√	√	The number of residents that changed intervention arms, that were withdrawn from the trial, or that died during the trial (Appendix 17) was collected by care home staff, along with reasons given. Residents that withdrew or died were not replaced.

MUST = Malnutrition Universal Screening Tool; PEM= Protein Energy Malnutrition; FFM= Fat Free Mass; DEXA= Dual Energy X-Ray Absorptiometry; NHANES = National Health and Nutrition Examination Survey ; CQC= Care Quality Commission; RCN= Royal College of Nursing; MRC= Medical Research Council

[4] **The Dartmouth COOP project granted permission to use the chart within this trial**

3.6 Sample size

No formal sample size calculation was performed, as the key outcomes were concerned with recruitment, retention and the feasibility and acceptability of the trial (Arain et al., 2010). Any investigations of changes in study parameters were exploratory only. Based on the capacity of the selected care homes (29 residents, to 72 residents) and the risk of malnutrition within the UK care home population (30-42%), it was estimated that between 9 (30% of 29) and 30 (42% of 72) residents could be considered for receipt of the nutritional intervention within each care home. It was decided that this estimated sample size of n= 50 (6 x 9) to n=180 (6 x 30) would provide sufficient data to assess trial feasibility (Lancaster, 2004).

3.7 Cluster randomisation (Figure 4)

3.7.1 Sequence generation

The random allocation sequence was generated using a computer-generated random number list at the University of Birmingham Clinical Trials Unit. To minimise the time delay between care homes agreeing to participate and implementation of the interventions, care homes were randomised once eligible residents had been identified. This approach is recognised as a means of overcoming delays between recruitment and intervention implementation in cluster trials and was felt to be particularly relevant with the frail, care home population (Eldridge et al., 2009).

3.7.2 Allocation concealment mechanism

Concealment of intervention allocation was achieved by giving responsibility for sequence generation and allocation to a statistician independent of the running of the trial. Completing the screening and consent process prior to sequence

generation also minimised selection bias, by ensuring that decisions were not influenced by the assigned intervention.

3.7.3 Implementation

The primary researcher provided the statistician with the list of care homes that had consented. The statistician stratified and matched clusters according to care type (1 nursing and 1 residential home per pair) and then consecutively numbered all matched pairs. The random allocation sequence was generated and pairs were assigned to intervention allocation. The statistician notified the primary researcher of the allocations and each care home was then informed. Staff within each site received training from the primary researcher to support delivery of the allocated intervention and/or a refresher on SC.

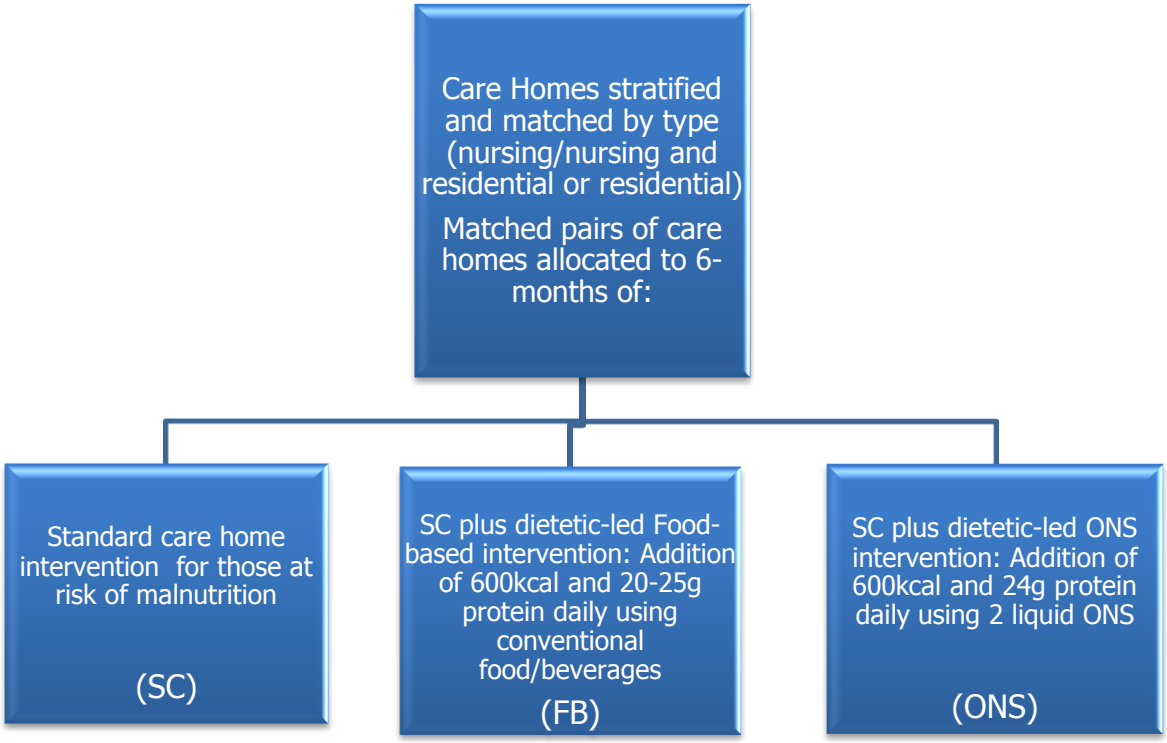


Figure 4: The randomisation process: Randomisation was stratified for type of care (residential or nursing/nursing and residential) to minimise differences in care home characteristics over the interventions.

3.7.4 Blinding

Residents were recruited prior to random allocation of care homes to the 3 arms. As consent was sought at the care home level (aside from PROMs), individual residents were not told of the care home intervention assignment. If a resident questioned the different drink, or snack provided, they were told it had been ordered by the dietitian and would be good for them. This approach mirrored usual care.

Due to the nature of the interventions and the obvious differences between them, it was not possible to blind the staff delivering them. This means that there may have been differences in the way residents were treated in the dietetic-intervention (FB or ONS) and SC homes, perhaps exposing them to external factors other than the interventions of interest. However, nutrition support interventions often involve contextual factors that cannot be separated from the intervention itself, such as who delivered the intervention, assistance provided and the setting. It is also acknowledged that the care homes allocated to SC were not providing a placebo. This trial arm also involved delivery of nutrition support, which may have minimised the differences in resident treatment between trial arms.

Blinding of outcome assessors and data collectors is important to ensure the unbiased ascertainment of outcomes and the internal validity of a RCT (Karanicolas et al., 2010). This trial had only 1 primary researcher, responsible for communicating intervention allocation to participating homes and conducting outcome assessments. It was therefore impossible to blind the researcher to the assigned intervention. To minimise bias, the chosen outcome measures were objective and not easily influenced by the observer. In a definitive trial with funding for additional research

staff, it should be possible to use observers who assess outcome measures without knowledge of the intervention group.

3.8 Research Governance

3.8.1 Data Monitoring/Trial Steering Committee (DM/TSC)

A joint DMC/TSC, which included 3 independent members (a statistician; a dietitian and a member of a patient and public involvement panel), was established prior to trial commencement (August 2013). The DMC/TSC met in January, April and July 2014 to review AEs, mortality and intervention changes. A final meeting was held in November 2014 to discuss the trial findings and inform the evaluation.

3.8.2 Data handling (Appendix 8, p174-175)

In accordance with the ICHGCP (2002) and the RGF for Health and Social Care (2005), all participant data that allows identification must be protected. Each eligible resident was assigned a unique trial identification code by care home staff. The list of codes was held at the care home site, in a locked cupboard. No resident identifiable information left the site, with the exception of a signature, for residents that consented to PROMs. All information collected for the trial was entered onto a secure computer database, accessed by the primary researcher only.

3.9 Statistical Methodology

Statistical analyses were performed using IBM SPSS, version 21 and Microsoft Access 2010.

3.9.1 Data analysis

As effective hypothesis testing requires a powered sample size (Arain et al., 2010), analysis was limited to, descriptive statistics and an exploratory analysis

to provide estimates of key parameters and inform the design of a definitive trial (Lancaster et al., 2004).

Baseline categorical variables were summarised using proportions (n (%)) and were compared between intervention arms using the chi-square test, or the Fisher's exact test when 1 or more cells had an expected frequency of 5 or less. All continuous baseline data were tested for normality using Kolmogmorov-Smirnov and were summarised as mean (standard deviation (SD)) or median (interquartile range (IQR)). Where data was normally distributed, variables were compared between intervention arms using one-way ANOVA; otherwise Kruskall-Wallis was used. Analysis of baseline data was used to characterise the overall sample and highlight imbalances between the trial arms.

Screening logs completed within each care home provided information on the numbers of residents screened using 'MUST', and the reasons for not entering the trial. This data, alongside categorical data collected on care home and resident withdrawals, changes to resident intervention, mortality, healthcare resource usage, adverse events and compliance was summarised (n (%)) and used to inform aspects of feasibility and acceptability reporting (Table 16). Continuous outcome measures were summarised as means (SD) or medians (IQR) at 3- and 6-months and mean changes were calculated from baseline to 3- months and 6- months, along with 95% confidence intervals. The mean difference between ONS and SC and FB and SC were calculated at 3- and 6-months, along with 95% confidence intervals. This data was used to review the sensitivity of the outcome measures to change and inform which outcome measures are most appropriate to take forwards into a definitive trial.

3.9.2 Assessment of feasibility and acceptability

A priori, it was specified that the 5 primary trial objectives (Table 9 and Table 16) would be considered successful if the following were met:

Table 16: Feasibility and acceptability success criteria

Primary objectives	Success criteria
Recruitment of care homes:	Recruitment target of 6 met in the time available (3 months)
Resident eligibility criteria and recruitment	Favourable difference shown in number at risk of malnutrition and number that were deemed eligible (≤20% difference) Estimated resident recruitment target of n≥50 met (Section 3.6)
Retention of care homes and residents	Retention of 100% for care home sites Retention of ≥65% for residents at 6-months follow up, accounting for expected high mortality (Shah et al, 2012) and attrition rate (Manders et al., 2009; Parsons et al., 2011; Leslie et al, 2012).
Intervention acceptability to residents and staff	Intervention change of ≤10% for each intervention Given that the clinical benefits of ONS (unknown for FB) are seen with 1-3 servings (300-900kcal) daily (NICE, 2006; Stratton and Elia, 2007): - ≥80% of residents to be compliant with ≥50% dietetic-led intervention dose (≥300-450kcal), - ≥60% of residents to be compliant with ≥75% of the dietetic-led intervention dose (≥450-600kcal) ≥85% staff adherence to intervention schedule
Feasibility and acceptability of the outcomes piloted	Data completeness of ≥ 80% (see section 3.5.3) Reported and recorded values were considered complete. Unknown and blank values (due to lack of recording, resident refusal, inability to measure) were considered missing values.

ONS= Oral nutritional Supplements; FB= Food-Based

3.9.3 The Intracluster correlation coefficient (ICC)

To determine the optimal sample size for a definitive cluster RCT, calculations will be required, which involve the number of clusters, the number of individuals within clusters and the power, significance level and effect size being sought (Donner et al., 2003). As the residents within a care home are more likely to be similar, the variability of treatment effects within clusters and the power to detect true differences between intervention arms is reduced (MRC, 2000). To account for this, an estimate of the magnitude of the Intracluster Correlation Coefficient (ICC), which compares within-group variance to between-group variance (Killip et al., 2004) will be required for the primary outcome measure to be taken forward (Secondary Objective 5, Table 9).

$$ICC = \frac{\text{Between cluster variability}}{(\text{Within cluster variability} + \text{Between cluster variability})}$$

To determine the most appropriate primary outcome for a definitive trial, completion rates and missing data were summarised for all outcome measures, along with estimates and variances.

3.10 The Broader Methodological Framework of the trial

To fully address the research question and trial objectives, a sequential, explanatory mixed method design was chosen (Cresswell, 2009) (Figure 5), but due to time constraints, it was not realistic to transcribe and analyse the qualitative data within the scope of this MRes. A mixed methods framework was felt to be necessary, to provide a comprehensive analysis of the feasibility and acceptability issues

associated with delivering and evaluating nutritional interventions in the care home setting.

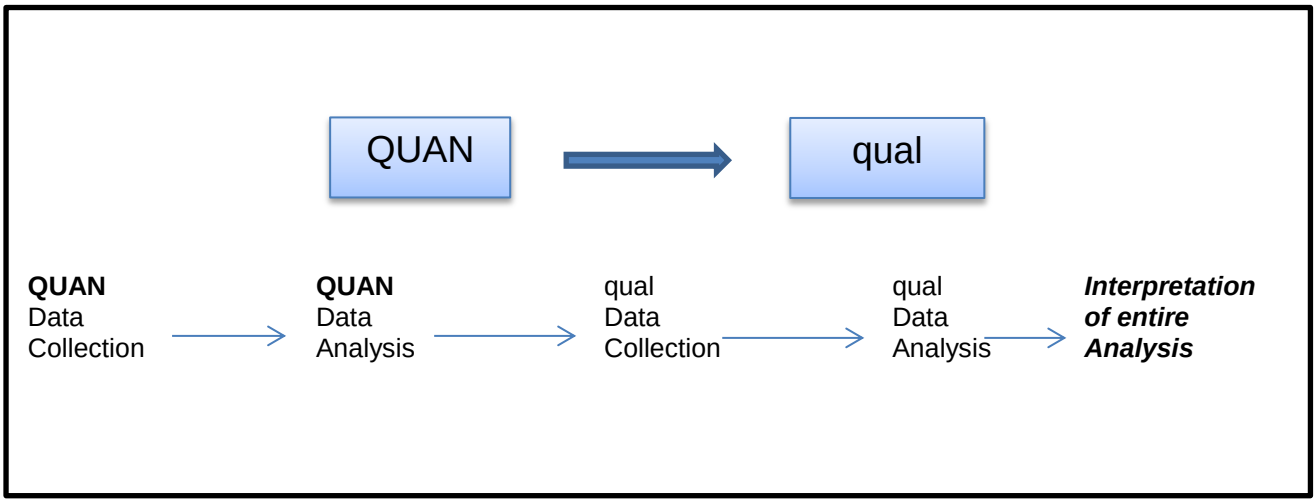


Figure 5: The sequential trial design (Adapted from, Cresswell, 2009)
'Quan' and 'qual' stand for quantitative and qualitative respectively; Capitalisation indicates an emphasis or priority on an approach or method

Existing studies of malnutrition interventions have used a quantitative approach, which whilst useful for determining quantitative outcomes such as nutrient intake and weight change, have provided limited information on, resident and staff perspectives and, the reasons why the care home environment poses challenges to the researcher. During the last 20 years, researchers have identified the need for employing a range of methodologies to enhance understanding of healthcare complexities and to ensure that disempowered groups are heard (O'Cathain et al., 2007). It was felt that the use of interviews and focus groups in a qualitative phase would enable the feasibility outcomes to be further explored with the trial participants, ensuring that resident and staff perspectives can be used to inform design and conduct for a definitive trial. The qualitative methodology has not been reported on in this chapter, but further information can be found within the trial protocol (Appendix 8, p156, 166-167, 173) and Appendix 18.

CHAPTER FOUR: RESULTS[5]

4.1 Recruitment to the trial: care homes and residents

All 6 care homes approached, consented to participate in the trial within the 3-month care home recruitment period (Sept 2013- Dec 2013). Table 17 shows the characteristics of the care homes. There were some identified differences in access to healthcare professionals (GP's and Nurses) between care home types (nursing and/or residential).

Table 17: Characteristics of the included care homes

Characteristics	Care Home					
	CH01	**CH02**	**CH03**	**CH04**	**CH05**	**CH06**
Care home type	N and R	R	N	N and R	R	R
Nursing staff onsite (Yes/No)	Yes	No	Yes	Yes	No	No
Weekly GP rounds (Yes/No)	Yes	No*	Yes	Yes	Yes	No*
Food record chart/Fluid chart for all residents	No**	No**	No**	Yes	Yes	Yes

N=nursing, R=residential

*GP called out as needed; **Charts only completed for those residents identified as eating or drinking poorly

All 280 residents living across the 6 care homes were screened using 'MUST' and 110 (39%) were at medium or high risk of malnutrition. 93 (84.5%) of these 110 residents were eligible to enter the trial and receive the intervention (Figure 6). Reasons for the remaining 17 residents not entering the trial are detailed in Table 18.

[5] **All of the trial data is stored in a Microsoft Access database, available on request.**

Table 18: Reasons for residents not being eligible to participate (n = 17)

Reasons given	Residents not eligible to enter the trial
	n (%)
Already receiving dietetic-led nutrition support	13(76)
In hospital	2(12)
Not registered with a Solihull GP	1(6)
Non-English speaking	1(6)

Data are numbers (%).

Of the 32 residents within the care homes assigned to SC (CH03, CH05), 2 moved out and 11 died by 6-months. Of the 32 residents within the care homes assigned to FB intervention (CH04, CH06), 2 entered end of life care, 1 moved out and 6 died. Of the 29 residents within the care homes assigned to ONS intervention (CH01, CH02), 1 moved out, 1 was admitted to hospital and 6 died. 63 residents completed the trial and were included in the analyses (Figure 6).

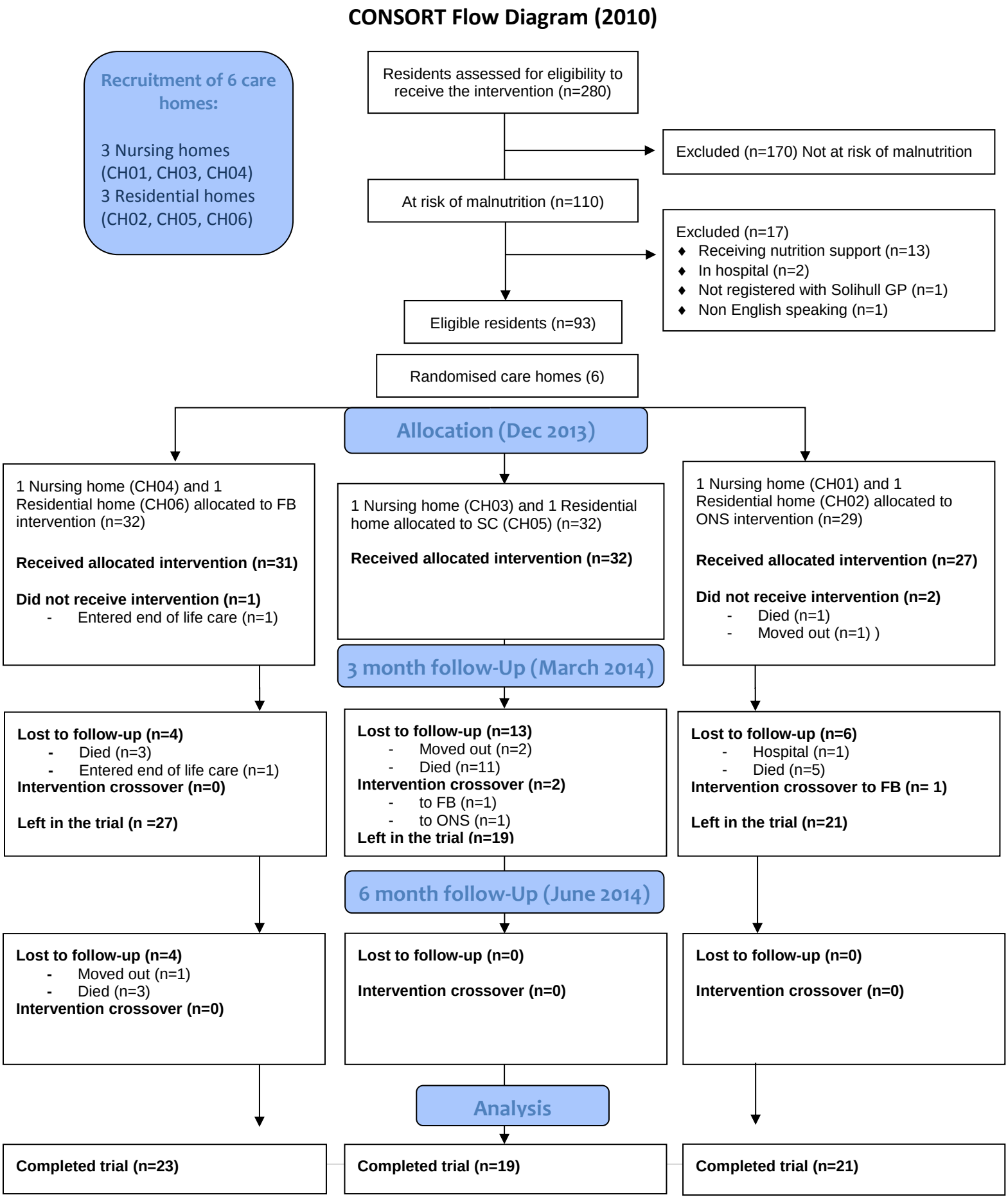


Figure 6: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the conduct of the trial, including the outcome for all residents (Schulz et al., 2010)

4.1.1 Baseline characteristics of residents

Included residents were mostly female (82%), with dementia the most prominent primary diagnosis (75%). Table 19 summarises the resident characteristics (variables) at baseline. It is acknowledged that testing for baseline differences between intervention arms in RCTs is usually not appropriate, given that any identified differences are caused by chance (Grobbee and Hoes, 2009; CONSORT statement, 2010). However, it was considered useful to assess for imbalances at baseline within this feasibility trial of few clusters (6), to inform the sample size for a definitive trial. All variables were statistically homogeneous according to chi-squared (χ^2) test for independent samples of categorical data (all p> 0.05), with the exception of the proportion of residents at medium and high risk of malnutrition in the care home assigned to FB intervention (34% high risk compared to >60% for the other 2 arms).

Table 19: Characteristics of residents at baseline (n = 93)

Variables	SC (n=32)	FB (n=32)	ONS (n=29)	*P*	
	n (%)	n (%)	n (%)		
Gender	F: 27(84.4), M: 5(15.6)	F: 26(81.3) M: 6(18.8)	F: 23(79) M: 6(21)	0.9	
Capacity	5 (15.6)	4 (12.5)	7(24.1)	0.5[a]	
Diagnosed dementia	25 (78.1)	25 (78.1)	20 (69)	0.6	
Diagnosed dysphagia	7 (21.9)	4 (12.5)	7 (24.1)	0.5	
Risk of re-feeding	3 (9.4)	0 (0)	4(13.8)	0.1[a]	
Malnutrition risk	High risk: 20(62.5) Med risk: 12(38)	High risk:11(34.4) Med risk: 20(63)	High risk:19(65.5) Med risk: 9(31)	SC vs FB	<0.05
				SC vs ONS	0.6
				FB vs ONS	0.01

SC= Standard Care; FB= Food-based intervention; ONS= Oral nutritional supplement intervention. F= female, M = Male.

Data are presented as numbers (%). Comparisons between intervention arms has been conducted using chi-squared for categorical data, or [a]Fisher's Exact text where 1 or more cells has an expected frequency of <5,

Table 20 summarises the clinical and nutritional characteristics of residents at baseline.

Table 20: Clinical and nutritional characteristics of residents at baseline

Characteristic	SC (n=32)	FB (n=32)	ONS (n=29)	*P*
Weight (kg)	Weighed (n=31) 48.6 (9.1)	Weighed (n=32) 55.9 (1.8)	Weighed (n=29) 48.2 (10.9)	<0.01
BMI (kg/m^2)	n=31 19 (17.0-20.5)*	n=32 20.1 (18.7-24.8)*	n=29 18.4 (17.6-21.6)*	<0.01**
MAC (cm)	Measured (n=27) 21.9 (2.7)	Measured (n=28) 23 (2.5)	Measured (n=25) 22 (3.0)	0.1
TSF (mm)	Measured (n=24) 9.3 (2.8)	Measured (n=22) 13.2 (5.6)	Measured (n=23) 8.4 (3.1)	<0.001
MAMC (cm)	n=24 18.9 (2.5)	n=22 18.9 (1.7)	n=23 18.5 (2.5)	0.7
HgD (kg)	Measured (n=14) 5.65 (3.9-8.3)*	Measured (n=22) 6.9 (4.0-11.5)*	Measured (n=13) 5.6 (3.2-10.3)*	0.8**
Energy Intake (kcal)	Available (n=29) 1553 (470)	Available (n=31) 1916 (496)	Available (n=27) 1535 (562)	<0.01
Protein Intake (g)	Available (n=29) 41 (14.6)	Available (n=31) 78 (22)	Available (n=27) 54 (20)	<0.001
Fluid Intake (ml)	Available (n=27) 1109 (237)	Available (n=31) 1332 (310)	Available (n=27) 1037 (260)	<0.001

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index; MAM= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; MAMC= Mid Arm Muscle Circumference; HGD= Handgrip Dynamometer.

The number of residents included is indicated for each characteristic. Normal data is presented as Mean (Standard Deviation), otherwise is Median (Interquartile Range) (indicated by *). Comparisons between intervention arms has been conducted using one-way ANOVA for normal data, otherwise Kruskall Wallis (indicated by **) has been used.

There was a significant difference in mean, weight (kg), TSF (mm), energy intake (kcal) and fluid intake (ml) ($p \leq 0.05$) between the residents within the care homes allocated to FB intervention (higher weight, BMI and intake values) and the residents within the care homes allocated to SC and ONS. There was a significant difference in mean BMI (kg/m^2) and protein intake (g) across all 3 arms ($p \leq 0.05$).

Of the 93 residents deemed eligible to receive the interventions at baseline, only 16 (17%) were determined by care home staff to have the capacity to consent to PROMs. Written informed consent was obtained from 11 residents, 3 residents declined, 1 resident was too unwell to be approached and 1 resident declined due to family influence. Table 21 summarises the PROM responses at baseline.

Table 21: Participant Reported Outcome Measure (PROM) responses at baseline

PROM	SC (n=3)	FB (n=2)	ONS (n=6)
COOP QoL score	5 (5-7)*	4 (2-6)*	5.5 (4-6)*
EQ5D VAS	53 (16)	70 (28)	61 (21)
EQ5D index value	-0.16 (0.4)	0.15 (0.3)	0.33 (0.3)
Hunger	4 (3)	5 (7)	4 (4)
Appetite	6 (4)	5.5 (6)	5 (4)
Dietary Satisfaction	9 (0.6)	8.5 (2)	8.5 (2)
Pleasantness of meals	9 (1)	6 (4)	6 (3)
Pleasantness of snacks	7 (1.5)	8 (1.4)	6 (4)
Pleasantness of drinks	9(8-10)*	9(9-9)*	10(8-10)*

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; QoL= Quality of Life; VAS= Visual Analogue Scale

Normal continuous data is presented as Mean (Standard Deviation), otherwise is Median (Interquartile Range) (indicated by *). Ordinal data (COOP) is presented as Median (Interquartile Range). EQ-5D index value ranges from -0.59 to 1, with higher scores corresponding to a better health state. COOP score ranges from 1 to 10, with higher scores corresponding to a better QoL

4.2 Retention in the trial

4.2.1 Mortality and termination of involvement

All 6 care homes completed the trial. Of the 93 residents deemed eligible to receive a nutritional intervention, 67 (72%) remained at month-3 and 63 (68%) completed the 6-month intervention. Table 22 summarises resident mortality and other loss to follow-up recorded throughout the trial.

Table 22 Resident mortality and other loss to follow up by 3-months (T1) and 6-months (T2)

	SC		FB		ONS	
	T1(n=32)	T2(n=19)	T1(n=32)	T2(n=27)	T1(n=29)	T2(n=21)
	n(%)		n(%)		n(%)	
Mortality	11 (34)	0	3 (9.4)	3 (11)	6 (21)	0
Other loss to follow up	2 (6)	0	2 (6)*	1 (4)	2 (7)*	0

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; T1= Month-3; T2= Month-6

Data are numbers (%). Other reasons for loss to follow up included residents moving out (n=4), entering end of life care (n=2), and being admitted to hospital with no planned return (n=1). *The figures include those residents that left prior to receiving the allocated intervention

In total, 23 residents died during the trial (25% mortality), 17 (74%) of whom were at high risk of malnutrition and 6 (26%) at medium risk of malnutrition. Of those 23, 87% died during T1. The 1 care home providing solely nursing care (SC arm) experienced the highest mortality rate during this interval. It is likely that the residents at risk of malnutrition in this care home would have had a condition or illness requiring medical care, compared to the residents within the homes providing both nursing and residential, or solely residential care.

4.3 Acceptability of the allocated interventions

4.3.1 Compliance

Compliance with the dietetic-led interventions (FB and ONS) was determined at 3- and 6-months (Table 23).

Table 23: Resident compliance with dietetic interventions at T1 and at T2

	FB		ONS	
	T1(n=27)	T2(n=23)	T1(n=21)	T2(n=19)*
	n(%)		n(%)	
Compliance with intervention (≥75% / 450-600kcal consumed daily)	21 (78)	16 (70)	14 (67)	12 (63)

FB= Food-Based; ONS= Oral Nutritional Supplements; T1= Baseline- 3months; T2= 3months- 6months

Data are numbers (%). 3 of the residents deemed compliant with the FB intervention at T1 were being given a different fortified drink or snack to that initially agreed at baseline, however the nutritional content was approximately equivalent.
*n=2 not included as 1 resident switched to FB intervention before month-3 and 1 resident was not provided with the intervention dose by staff

The proportion of fully compliant residents reduced from 74% at T1 to 67% by T2, although 86% of residents during both T1 and T2 consumed at least half of the provided amount (≥300kcal) of either FB or ONS intervention. Residents assigned to FB intervention had greater compliance compared with ONS at both T1 (78% versus 67%) and T2 (70% versus 63%). Reasons for non-compliance were given (Table 24)

Table 24: Reasons given by care home staff for resident non-compliance with dietetic-led intervention

Reason for non-compliance	FB intervention		ONS intervention	
	T1 (n=6)	T2 (n=7)	T1 (n=7)	T2 (n=7)
	n(%)		n(%)	
Consumed 50-75% of intervention dose (~300-444kcal)	4 (67)	2 (29)	4 (57)	6 (86)
Refused intervention	2 (33)		1 (14)	1 (14)
Poor overall intake, including intervention		5 (71)	1 (14)	
Change to different intervention			1 (14)	

FB= Food-Based; ONS= Oral Nutritional Supplements
Data are numbers (%).

Non-compliance in the ONS arm was largely associated with low intake of the intervention (50-75%). In the FB arm, reasons for non-compliance during T1 were low intake or refusal. Where a dislike of a FB intervention was identified at three-months, the choice of fortified snacks and/or drinks was adjusted to accommodate the changing preferences of the individual, whilst continuing to provide the additional 600kcal and 20-25g protein (Appendix 12). During T2, the majority (71%) of non-compliance was less specific to the intervention and instead due to a decline in appetite and overall intake.

4.3.2 Staff adherence to intervention schedule

4.3.2.1 ONS intervention

At T1, staff adherence to the intervention schedule was 100%. The ONS provided and the ONS consumed was documented on each resident's drugs chart. At T2, staff adherence was 95%. Drug chart documentation and discussions with staff, revealed that 1 resident in CH01 was not consistently provided with the agreed dose.

4.3.2.2 Food-based intervention

At T1, the staff demonstrated 100% adherence to the intervention schedule, but there were some deviations from the documented FB snacks/drinks for 3 residents within CH04. Following initial discussions, the staff had decided that a different combination (Appendix 12) may suit these residents better and had provided these revised options daily. The nutritional content was approximately equivalent to the plan initially discussed. At T2, staff adherence with the intervention schedule was 100% and there were no deviations from the agreed plans.

4.3.3 Adverse events (AEs)

Three adverse events were recorded by care home staff throughout the trial, 1 in each intervention arm. Details are shown in Table 25.

Table 25: Details of the reported adverse events (n=3) and how these were addressed

Adverse Event	Data collection Interval	Was the event expected?	Intervention Arm	How the event was addressed
Reduced BMI, placing resident at re-feeding risk	Baseline-3months	Yes	SC	Changed to FB intervention (Table 26 and 27) and followed NICE guidance (2006)
Reduced BMI, placing resident at re-feeding risk	Baseline-3months	Yes	FB	GP was investigating an underlying clinical cause. No changes to intervention.
Poorly controlled blood glucose levels, reportedly exacerbated by ONS intake	Baseline-3months	No	ONS	Changed to FB intervention (Table 26 and 27). Care home staff monitored blood glucose levels daily.

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index

4.3.4 Change of intervention

Intervention change is summarised in Table 26.

Table 26: Change of interventions recorded throughout the trial

	SC	FB	ONS
	T1 (n=32)	**T1 (n=32)**	**T1 (n=29)**
	n(%)	n(%)	n(%)
Changed intervention	2 (6)	0	1 (3)
Intervention not started	0	1 (3)	2 (10)

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements
Data are numbers (%).

Three residents never received their initial intervention, 1 (allocated to FB intervention) entered end-of-life care, 1 died (allocated to ONS) and 1 moved out (allocated to ONS). No residents within the care homes allocated to FB intervention, 2 residents within the care homes allocated to SC and 1 resident within the care homes allocated to ONS were required to change following intervention commencement. The details are shown in Table 27.

Table 27: Details of the intervention changes (n=3)

Reason	Data collection Interval	Intervention Arm	Intervention switched to
Poor blood sugar control exacerbated by intervention (Table 25)	Baseline- 3months	ONS	FB
Decline in nutritional status and ACBS criteria met	Baseline- 3months	SC	ONS
Decline in nutritional status, at risk of re-feeding syndrome (Table 25)	Baseline- 3months	SC	FB

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; ACBS= Advisory Committee on Borderline Substances

4.4 Completion of tools and questionnaires by care home staff

4.4.1 'MUST'

Malnutrition risk category (low, medium or high) was available in the care home records for 100% of the residents remaining in the trial at T1 and T2. The primary researcher calculated a repeat 'MUST' score for 2 randomly selected residents per care home (n=12). At T1, 11 'MUST' scores had been calculated correctly (92%). Step 2 (unintentional weight loss) had been calculated over 1 month, rather than 3-to-6 months for 1 resident. At T2, all 12 records (100%) detailed a correctly calculated score.

4.4.2 Healthcare resource usage

Staff were asked to complete the relevant healthcare resource usage information from the care records. The questionnaires were completed in full for 100% of the residents in the trial at T1 and at T2.

4.5 Acceptability and feasibility of the outcome measurements

4.5.1 Physical measurement data collection

4.5.1.1 Measured by care home staff

Height

Height, and the measurement technique used, was documented in the care home records for all 93 residents in receipt of an intervention. 61 residents (66%) had been measured using a freestanding stadiometer, 29 (31%) had their height estimated from ulna length and 2 (2%) had self-reported their height.

Weight

At baseline, only 1 resident, across all 6 sites was unable to be weighed by the care home staff, due to a decline in clinical condition. Of the remaining 92 residents, 7 (8%) were weighed with standing scales, 63 (70%) with chair scales and 19 (21%) with hoist scales. At T1, all 67 remaining residents were able to be weighed, but 1 resident, weighed by chair scales at baseline, was weighed using hoist scales, because of reduced mobility. At T2, this resident was again weighed using chair scales. All other residents in the trial at T1 (n=66) and T2 (n=62) were weighed using the same weighing scales as at baseline.

4.5.1.2 Measured by the primary researcher

Mid Upper Arm Circumference (MAC), Tricep Skinfold Thickness (TSF) and Handgrip strength (HGD)

Table 28 shows the number and percentage of residents at each data collection interval that either, consented, refused, or were unable to be measured.

Table 28: Resident acceptability of physical outcome measurement at baseline (B), 3-months (T1) and 6-months (T2)

	MAC			TSF			HGD		
	B (n=90)	**T1 (n=67)**	**T2 (n=63)**	**B (n=90)**	**T1 (n=67)**	**T2 (n=63)**	**B (n=90)**	**T1 (n=67)**	**T2 (n=63)**
	n(%)			n(%)			n(%)		
Measured	80(89)	59(88)	55(87)	69(77)	49(73)	50(79)	49(54)	39(58)	31(49)
Mean	**88**			**76**			**54**		
Refused	8(9)	7(10)	6(9.5)	12(13)	12(18)	10(16)	10(11)	9(13)	9(14)
Mean	**9.5**			**16**			**13**		
Unable to measure	2(2)	1(1.5)	2(3)	9(10)	6(9)	3(5)	31(34)	19(28)	23(37)
Mean	**2.2**			**8**			**33**		

MAC= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; HGD= Handgrip Dynamometer; B= Baseline; T1 = Month-3; T2= Month-6

In the time between randomisation and baseline measurement, three residents had already left the trial, hence n=90 at B

Over the 3 data collection intervals, 88% of residents had MAC measured, 76% had TSF measured and 54% had HGD measured. The lower percentage for HGD was largely attributable to difficulties in understanding the instruction, or to physical difficulties when attempting to grip the dynamometer. It was not always the same residents that declined or were unable to take part in the measurements. This fluctuation in ability and willingness to participate may be a consequence of the high number of residents with cognitive impairment.

4.5.2 Nutritional intake data collection

Food record charts (FRC) and Fluid charts (FC) were collected from care home records, at baseline, T1, and T2, to enable average energy, protein and fluid intake to be determined. Table 29 shows the number and percentage of FRCs and FCs that were either, available and complete, available but incomplete, or unavailable at each data collection interval.

Table 29: The availability of FRCs and FC's at baseline (B), 3-months (T1) and 6-months (T2)

	FRC			FC		
	B (n=90)	T1 (n=67)	T2 (n=63)	B (n=90)	T1 (n=67)	T2 (n=63)
	n(%)			n(%)		
Available and complete	71(79)	55(82)	52(83)	76(84)	60(90)	54(86)
Mean	**81**			**87**		
Available but incomplete	15(17)	12(18)	8(13)	9(10)	7(10)	7(11)
Mean	**16**			**10**		
Unavailable	4(4)	0	3(5)	5(5.5)	0	2(3)
Mean	**3**			**3**		

FRC= Food Record Chart; FC= Fluid Chart; B= Baseline; T1= Month-3; T2= Month-6

Over the 3 data collection intervals, 81% of FRCs and 87% of FCs were available and complete, but there were some limitations to this method of information collection. Whilst the care home staff indicated how much of a meal or snack had been consumed by the resident as a proportion (All, ¾, ½, ¼, refused), there was little to no information on what part of the meal had been eaten. There was also minimal information on the recipes used or on specifying whether ingredients had been added to enrich the calorie content. This lack of information may have reduced the accuracy of the subsequent dietary analysis and estimation of daily energy, protein and fluid intake.

4.5.3 Participant-reported outcome measures: PROMs

At each data collection interval, the EQ5D-5L questionnaire, the COOP quality of life chart and the VAS tool were provided to the residents by the care home staff. All eligible residents received the questionnaires at baseline (n=11), at 3-months (n=8) and at 6-months (n=7) and 100% of the questionnaires were completed in full. All residents required the care home staff to read the questionnaires to them (due to poor eyesight) and to mark on their responses (due to poor dexterity).

The number of eligible residents reduced from 11, to 7 over the course of the trial, with 5 of the residents remaining at T2 allocated to ONS intervention. Due to the lack of available data, there will be no further analysis here, but the data recorded has been summarised descriptively (Appendix 20). Resident and staff perceptions of the questionnaires and the perceived ease or difficulty of taking part in PROMs will be explored further within the qualitative phase.

4.5.4 Healthcare resource usage (HCRU): Piloting of a questionnaire

The HCRU questionnaire completed at T1 and T2 collected information on all hospital admissions, GP call-outs (not routine) and visits from, district nurses, tissue viability nurses, consultants, dietitians and speech and language therapists (SaLT). Table 30 summarises hospital admissions and professional visits recorded across the care home sites.

Table 30: Hospital admissions and Healthcare professional visits recorded throughout the trial

	CH01	CH02	CH03	CH04	CH05	CH06
	(n=12)	(n=9)	(n=8)	(n=18)	(n=11)	(n=9)
Hospital admissions	2 for 1 resident	2 for 2 residents	2 for 1 resident	9 for 5 residents	2 for 2 residents	7 for 5 residents
GP call-outs	22 for 10 residents	14 for 7 residents	28 for 9 residents	18 for 11 residents	24 for 10 residents	11 for 7 residents
District Nurse	0	3 for 1 resident	0	0	8 for 7 residents	52 for 8 residents
Dietitian	0	0	1 for 1 resident	0	4 for 3 residents	1 for 1 resident
SaLT	0	1 for 1 resident	1 for 1 resident	0	0	2 for 2 residents
Consultant	2 for 2 residents	0	3 for 3 residents	0	0	2 for 2 residents
Tissue Viability Nurse	3 for 2 resident	0	2 for 2 residents	0	0	0

CH= Care Home; SaLT= Speech and Language Therapist
*Data are shown as the number of admissions or visits, for the number of residents

24 hospital admissions were recorded for 16 residents during the trial. Admissions to Accident and Emergency (A&E) accounted for 46% of the recorded admissions, followed by outpatient appointments (37.5%) and inpatient admissions (17%). The majority of A&E admissions were for falls (82%) (Appendix 21). The staff did not indicate that nutritional status was a factor in falling, nor did they directly attribute any of the outpatient appointments (Appendix 21) or inpatient admissions to nutritional status or an allocated intervention.

117 GP call-outs were recorded for 54 residents throughout the trial. The fewest number were recorded for CH02 and CH06, the only 2 care homes that do not receive weekly GP rounds (Table 17). Although routine check-ups were not recorded (Appendix 22), it is possible that more frequent, scheduled visitations, resulted in more documented GP assessments in the other 4 homes. The most frequently recorded reasons for call-outs were, chest examinations (suspected chest infection) (26%), medication reviews (19%) and urinary tract infections (15.4%) (Appendix 22). The staff did not directly attribute any of the call-outs to nutritional status.

District Nurse Visits were usually scheduled to deliver wound care (37%) and to check pressure areas (49%) (Appendix 22). The number of recorded visits differed substantially between CH06, the smallest home in the trial, and the other 5 care homes. CH06 is a residential home, which arranges regular District Nurse visits to replace the nursing duties conducted by staff in the care homes providing nursing care (Table 17). The other recorded visits were also for residential homes (CH02 and CH05); although less reliance appeared to be placed on District Nurses by these 2 care homes. The staff within the 3 care homes did not directly attribute any visits to a decline in a resident's nutritional status or to the allocated intervention.

The 5 recorded dietitian appointments were arranged in response to a decline in nutritional status. Two residents subsequently switched intervention arms (section 4.3.4). The remaining 3 residents were referred late during T2 and continued to be followed up after trial completion. The care home staff requested SaLT visits, because of concerns relating to swallowing function. Two visits during T2 resulted in recommendations to modify food texture (normal to fork-mashable).

4.6 Change in outcomes

4.6.1 Change in anthropometric indicators and nutrient intake

Table 31 shows the intervention effects on physical outcome measures and nutrient intake by T1 (see Table 20 for baseline data and Appendix 23 for data at 3-months). Where the 95% confidence interval (CI) of the mean difference (MD) does not cross zero, this suggests sensitivity to change and a difference between the trial arms. This was observed for weight change, BMI change and change in energy intake for the comparison between each of the dietetic-led intervention arms (net increase) and the SC arm (net decrease) during T1, but was not observed when the 2 dietetic-led intervention arms were compared. The 95% CI also implied a difference between the ONS arm and the SC arm for change in protein intake and fluid intake and although there was a decline in MAMC in all 3 arms, this was minimised in the FB arm, when compared to the SC arm.

Table 31: Intervention effects on anthropometric indicators and nutrient intake from baseline to 3-months (n = 67)

Outcome	SC (n=19)	FB (n=27)	ONS (n=21)	SC vs. FB		SC vs. ONS		FB vs. ONS	
				Mean Difference (MD)	[95% CI]	Mean Difference (MD)	[95% CI]	Mean Difference (MD)	[95% CI]
Weight change (kg)	Weighed (n=19) -1.5 (3.3)	Weighed (n=27) 0.42 (2.4)	Weighed (n=21) 0.82 (2.7)	-1.9	[-3.6, -0.23]	-2.3	[-4.3, -0.40]	-0.4	[-1.9, 1.1]
BMI change (kg/m^2)	n=19 -0.55 (1.2)	n=27 0.16 (1.0)	n=21 0.33 (1.2)	-0.7	[-1.4, -0.06]	-0.88	[-1.65, -0.11]	-0.17	[-0.79, 0.44]
MAC change (cm)	Measured (n=13) -1.06 (1.5)	Measured (n=24) -0.29 (1.2)	Measured (n=18) -0.39 (1.8)	-0.77	[-1.7, 0.14]	-0.67	[-1.9, 0.57]		
TSF change (mm)	Measured (n=11) 0.86 (1.5)	Measured (n=19) -0.29 (2.0)	Measured (n=15) 1.6 (3.6)	1.15	[-0.26, 2.6]	-0.77	[-2.9, 1.38]		
MAMC change	n=10 -1.36 (0.8)	n=19 -0.18 (1.5)	n=16 -0.65 (0.9)	-1.17	[-2.2, -0.14]	-0.71	[-1.44, 0.02]		
HgD change (kg)	Measured (n=7) 0.16 (2.4)	Measured (n=17) -0.82 (3.4)	Measured (n=6) -1.5 (2.5)	0.97	[-1.9, 3.9]	1.62	[-1.34, 4.65]		
Change in energy intake (kcal)	Available (n=18) -103 (275)	Available (n=27) 277 (250)	Available (n=21) 376 (375)	-380	[-550, -226]	-479	[-697, -263]	-99	[-281, 83]

Change in protein intake (g)	Available (n=18) 0.72 (6.5)	Available (n=27) 3 (12.9)	Available (n=21) 16.7 (12.5)	-2.3	[-8.9, 4.3]	-16	[-226, -9.4]		
Change in fluid intake (ml)	Available (n=18) 400 (100 - 500)*	Available (n=27) 100 (-20 - 400)*	Available (n=21) 250 (112.5 -250)*		Mann-Whitney U = 164**		Mann-Whitney U = 110**		

MD = Mean Difference; SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index; MAC= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; MAMC= Mid Arm Muscle Circumference; HgD= Handgrip Dynamometer

Normal data is presented as Mean change (Standard Deviation), otherwise is Median change (Interquartile Range) (indicated by *). The mean difference (MD) between each dietetic-led intervention arm (FB and ONS) and the SC arm has been calculated for normal data alongside 95% confidence intervals (CIs), otherwise the Mann-Whitney U Test (indicated by **) has been used. Where sensitivity to change is suggested by the CI, the MD between the FB and ONS arms has then been calculated (final column).

Table 32 shows the intervention effects on physical outcome measures and nutrient intake by T2 (see Appendix 23 for absolute data at 3-months and at 6-months). There remained a suggested difference in the change in energy intake between each of the dietetic-led intervention arms (net increase) and the SC arm (net decrease) from baseline to 6-months (T2). As at T1, this was not observed when the 2 dietetic-led intervention arms were compared. The mean change in kcal from baseline to 6-months was less than the added intervention for both of the dietetic-led intervention arms, suggesting that not all residents were compliant with the interventions (Table 23) and some may have reduced their intake of other foods and drinks (Table 24).

The mean change in weight and in BMI over the full 6-month intervention was negative in the SC arm, compared with positive change in each of the dietetic-led intervention arms. However, the 95% CI crossed zero for each comparison, which suggests these outcomes were less sensitive to change at T2 compared to T1.

Table 32: Intervention effects on anthropometric indicators and nutrient intake from baseline to 6-months (n = 63)

Outcome	SC (n=19)	FB (n=23)	ONS (n=21)	SC vs. FB		SC vs. ONS		FB vs. ONS	
				Mean Difference (MD)	[95% CI]	Mean Difference (MD)	[95% CI]	Mean Difference (MD)	[95% CI]
Weight change (kg)	Weighed (n=19) -0.57 (3.5)	Weighed (n=23) 0.87 (3.4)	Weighed (n=21) 0.84 (2.5)	-1.4	[-3.6, 0.73]	-1.4	[-3.3, 0.51]		
BMI change (kg/m^2)	n=19 -0.16 (1.3)	n=23 0.33 (1.3)	n=21 0.34 (1.1)	-0.49	[-1.3, 0.35]	-0.50	[-1.3, 0.27]		
MAC change (cm)	Measured (n=13) -0.96 (1.6)	Measured (n=19) -0.29 (1.2)	Measured (n=18) -0.14 (2.1)	-0.67	[-1.68, 0.34]	-0.82	[-2.2, 0.59]		
TSF change (mm)	Measured (n=11) 0.68 (2.6)	Measured (n=16) 0.66 (2.9)	Measured (n=13) 1.65 (4.0)	0.03	[-2.2, 2.26]	-0.97	[-3.8, 1.86]		
MAMC change	n=11 -1.08 (1.1)	n=15 -0.40 (1.1)	n=14 -0.29 (1.5)	-0.68	[-1.58, 0.22]	-0.71	[-1.90, 0.33]		
HgD change (kg)	Measured (n=6) 1.8 (2.2)	Measured (n=11) -0.42 (2.6)	Measured (n=6) -0.35 (2.1)	2.2	[-0.50, 4.9]	2.2	[-0.61, 4.9]		
Change in energy	Available (n=17)	Available (n=23)	Available (n=21)	-255	[-401, -109]	-400	[-577, -223]	-145	[-319,29.1]

intake (kcal)	-50.9 (183)	204 (251)	349 (319)						
Change in protein intake (g)	Available (n=17) 1.0 (-3.5 -4.5)*	Available (n=23) 3.0 (-10 - 6)*	Available (n=21) 9.0 (2 - 26.5)*		Mann-Whitney U = 175**		Mann-Whitney U = 68.5**		
Change in fluid intake (ml)	Available (n=17) 120 (223)	Available (n=23) 199 (210)	Available (n=21) 224 (196)	-79	[-219, 60.9]	-104	[-242, 34.5]		

MD= Mean Difference; SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index; MAC= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; MAMC= Mid Arm Muscle Circumference; HgD= Handgrip Dynamometer

Normal data is presented as Mean change (Standard Deviation), otherwise is Median change (Interquartile Range) (indicated by *). The mean difference (MD) between each dietetic-led intervention arm (FB and ONS) and the SC arm has been calculated for normal data alongside 95% confidence intervals (CIs), otherwise the Mann-Whitney U Test (indicated by **) has been used. Where sensitivity to change is suggested by the CI, the MD between the FB and ONS arms has then been calculated (final column).

4.7 Assessing feasibility and acceptability

Table 33: Assessment of feasibility and acceptability criteria

Primary objectives	Success criteria	Met or not met
Recruitment of care homes:		**Met**
	Recruitment target of 6 met in the time available (3 months).	6 care homes recruited within 3 months
Resident eligibility criteria and recruitment		**Met**
	Favourable difference in number at risk of malnutrition and number that were deemed eligible (≤20% difference)	84.5% of those at risk of malnutrition were eligible for the intervention
	Estimated resident recruitment target of n≥50 met (Section 3.6)	93 residents recruited
Retention of care homes and residents		**Met**
	Retention of 100% for care home sites	100% care homes retained
	Retention of ≥65% for residents at 6-months follow up, accounting for expected high mortality (Shah et al, 2012) and attrition rate (Manders et al., 2009; Parsons et al., 2011; Leslie et al, 2012).	68% of residents retained at 6-months
Intervention acceptability to residents and staff		**Met**
	Intervention change of ≤10% for each trial arm	Intervention change of 7.4% for SC arm, 4.3% for ONS arm and 0% for FB arm
	Given that the clinical benefits of ONS (unknown for food-based) are seen with 1-3 servings (300-900kcal) daily (NICE, 2006; Stratton and Elia, 2007) :	
	- ≥80% of residents to be compliant with ≥50% dietetic-led intervention dose (≥300-450kcal)	86% of residents compliant with ≥50% of dietetic-led intervention dose at T1 and T2
	- ≥60% of residents to be compliant with ≥75% of the dietetic-led intervention dose (≥450-600kcal)	Resident compliance with ≥75% of the dietetic-led intervention dose at T1 and T2: FB: 78% and 70%; ONS: 67% and 63%
	≥85% staff adherence to intervention schedule	Staff adherence: 100% for FB at T1 and T2. 100% for ONS at T1 and 95% at T2

Feasibility and acceptability of the outcomes piloted		**Met for**
	Data completeness of ≥ 80% (see section 3.5.3)	Weight, BMI, MAC, Energy, protein, fluid intake (>80% data completeness)
	Reported and recorded values considered complete. Unknown and blank values (due to lack of recording, resident refusal, inability to measure) considered missing values.	**Not met for**
		HgD and TSF (completeness of 54% and 78% respectively)

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index; MAC= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; HgD= Handgrip Dynamometer; T1= Baseline- 3months; T2= 3months- 6 months

CHAPTER FIVE: DISCUSSION

This chapter reviews the key findings of the trial, in terms of the feasibility and acceptability objectives and considers how these may inform future clinical practice and a definitive trial in the care home setting.

5.1 Recruitment and retention

5.1.1 Recruitment of care homes and participating residents (Primary objectives 1 and 2)

All 6 care homes provided written consent and remained in the trial until completion. Prior to trial commencement, the primary researcher had established good working relationships with the care home managers and staff, within a clinical role. This existing rapport may have been central to successful recruitment and in enabling specific roles to be allocated to staff during the trial process. The importance of taking a personal approach when seeking consent from care home managers has been demonstrated within previous research in this setting (Zermansky, 2007; Luff et al., 2011). In a definitive trial, it may be necessary to build-in time for researcher visits to potential care homes, to establish trust and good communication prior to starting recruitment.

'MUST' screening across the 6 care homes, identified 110 residents (39%) at risk of malnutrition, a similar percentage to that reported within another care home nutritional intervention trial conducted in Hampshire (37%) (Parsons et al., 2011). 84.5% of those at risk met the eligibility criteria to enter the trial, enabling the recruitment target to be met (Table 33) and supporting the case for a definitive trial in

this setting. A large proportion (75%) of the eligible population presented with a primary diagnosis of dementia. An ONS intervention RCT conducted in German Nursing homes, which also included residents with cognitive impairment, reported a comparable percentage (71.4%) (Stange et al., 2013). The decision was made to include residents with dementia, in order to assess feasibility and acceptability of the trial design with a representative care home population (Gillette-Guyonnet et al., 2007; Johansson et al., 2009; Wirth et al., 2011).

Assessment of resident characteristics at baseline, highlighted imbalances between the intervention arms and indicates a need to recruit a large number of care homes within a definitive trial (secondary objective 5), to increase the likelihood of producing balance across cluster-level covariates. The minimum number of clusters recommended per arm to ensure statistical validity, is at least 4 (Campbell et al., 2012). With fewer units per arm, parametric tests may be unreliable and it becomes impossible to achieve statistical significance at $p<0.05$ using a non-parametric test (Donner and Klar, 1994).

5.1.2 Retention of participating residents **(Primary objective 3)**

Despite the fragility of the participating population, it was possible to complete follow-up on 68% of residents, achieving the retention target at 6-months (Table 33). Mortality was the primary reason for residents leaving the trial (23, from 93 in six-months, 25%) and appeared to be associated with 'MUST' risk category (17, from 23 were high risk, 74%), a relationship demonstrated previously in the acute setting (Stratton et al., 2006). Mortality was expected to be high, on consideration of other care

home nutritional intervention trials (17%, in 3-months (Leslie et al., 2012; Stange et al., 2013)) and a cohort study describing 1 year mortality in UK care home residents (26% (Shah et al., 2012)). The attrition data from this feasibility trial could be used to estimate expected mortality and loss to follow-up in a definitive trial, informing the sample size calculation (secondary objective 5) and preventing statistical validity being compromised (Whitley and Ball, 2002).

Of the 23 residents that passed away, 20 (87%) had died by month-3, suggesting that at least a proportion may have been nearing end-of-life, at recruitment. Being on an end-of-life care pathway was defined as an exclusion criteria, however it is acknowledged that a significant proportion of care home residents are either palliative or have reached an end-of-life stage, which can sometimes last for many months. The restrictions imposed by the approving REC required care home staff to assess resident eligibility. Those responsible may have found it challenging to distinguish between residents that may benefit from nutritional intervention and those that were end-stage palliative. In clinical practice, when a resident is referred following 'MUST' screening, the dietitian undertakes a comprehensive nutritional assessment prior to the initiation of nutrition support, which includes assessment of medical and surgical history. In a definitive trial, not subject to the same ethical restrictions, dietetic assessment using a validated method, such as, The Subjective Global Assessment (SGA) (Detsky et al., 1987) could be considered following 'MUST' screening to identify where malnutrition is an indication of end-stage disease, as opposed to an indication of inadequate nutritional intake that may respond to intervention.

The highest mortality rate was observed within the 1 care home providing solely nursing care. This is perhaps reflective of the greater severity of condition and level of dependency of the nursing residents in the trial. The last large scale study investigating survival rates in UK care homes was commissioned by BUPA, 1 of the UK's largest care home providers (Forder and Fernandez, 2011). Analysis of a large sample (>10,000) suggested that survival was 25% shorter for residents in nursing beds, compared to those in residential beds. This again highlights the need to sample a large number of care homes within a definitive trial (secondary objective 5), to achieve a representative population of care home types.

5.2 Acceptability of the interventions (Primary objective 4)

5.2.1 Acceptability to residents

In assessing intervention acceptability to residents; compliance, crossover and intervention-related adverse events were considered. The feasibility success criteria for compliance were met, with over 60% of the residents assigned to FB and to ONS compliant with 450-600kcal/day and over 80% compliant with at least 300-450kcal/day (Table 33). Compliance with FB was higher than ONS at 3- and 6-months, perhaps due to the greater variety and flexibility offered by this intervention.

A systematic review conducted in 2012, identified 46 studies of ONS intervention (9 in the care home setting), which included compliance data. The review reported mean compliance of 78% (37%-100%) and mean intake of 433kcal/day. Greater compliance was noted with reduced volume, energy-dense ONS (1.5-2kcal/ml) and

when a variety of flavours was offered (Hubbard et al., 2012), both of which are reported in clinical practice. In this feasibility trial, 3 nutritionally equivalent ONS were used, 2 of which were 1.5kcal/ml varieties. The ONS were supplied free of charge by 2 medical nutrition companies and the bottle size and flavours delivered were dictated by availability. In a fully-funded definitive trial, ONS compliance may be improved by specifying use of the 1.5kcal/ml ONS bottles and by offering residents a choice of flavours.

The FB options included both snacks and drinks and could be adjusted at the 3-month review to take account of any change in preferences. There is considerably less in the literature on the compliance to FB intervention, but the information available suggests compliance is generally good. Two trials included in the systematic review (Chapter 2) reported mean compliance of 99% (380kcal) (Beck et al., 2002) and 98.5% (Kwok et al., 2001) respectively. Further qualitative work being undertaken aims to explore the influence of resident and care staff attitudes to FB and ONS intervention, on compliance.

Only 3 residents were required to change interventions during the trial. Two residents allocated to SC experienced a decline in their nutritional status, which necessitated a move onto dietetic-led intervention. Consumption of ONS was reportedly found to affect the blood sugar control of the third resident, who was subsequently moved onto FB intervention. Three adverse events were recorded, 2 of which, were associated with a decline in nutritional status. Both residents were assessed as being at risk of refeeding syndrome (Section 3.4.4.2) on the basis of low

BMI (Table 14). National guidelines advise staged hypocaloric nutritional support and electrolyte supplementation for those at risk (NICE, 2006). However, not all individuals that meet the criteria develop symptoms during nutritional repletion (Zeki et al., 2011) and guideline adherence may delay adequate nutrition. In this trial, the 2 residents had been eating reasonably well, but were continuing to lose weight, possibly due to undiagnosed disease. Although the guidelines were adhered to, further research is required in this setting, to determine whether individuals are still at risk of the physiological consequences of refeeding without having undergone a period of starvation. The small percentage of intervention changes and adverse events overall (<10%), suggests that all 3 interventions were largely acceptable to residents and to staff monitoring nutritional status and could therefore be considered within a definitive trial.

5.2.2 Staff acceptability of the intervention schedule

Staff adherence with the intervention schedules was found to be high, with 100% of residents receiving the interventions during the first 3-months and 100% of residents allocated to FB and 95% of residents allocated to ONS receiving the interventions during the second 3-months. The primary researcher was able to find documented evidence of intervention intake on FRCs and drugs charts. By contrast, studies within the published literature that have relied on care home staff to provide ONS have found that the intervention is not provided in accordance with instructions and documentation of consumption is poor (Johnson et al., 1993; Kayser-Jones et al., 1998; Simmons and Patel, 2006). It is possible that the established relationships with the participating care

homes improved the willingness of staff to adhere to the trial protocol. This topic will be further explored with staff during the qualitative phase.

5.3 Acceptability and feasibility of the outcome measures and data collection methods (Primary objective 5)

5.3.1 Care home staff measured

The available literature suggests that recording of nutritional care processes in the care home setting lacks uniformity and accuracy, particularly when compared to independent assessments by researchers using standardised protocols (Zermansky, 2007; Simmons et al., 2009). However, in order to ensure clinical applicability, it was decided that as much data as possible should be collected using methods consistent with usual procedures (Maas et al., 2002). The following assessments were made by staff and collected retrospectively by the primary researcher.

5.3.1.1 'MUST' Screening

National guidance recommends malnutrition screening on admission to care homes, followed by ongoing monitoring according to risk category (NICE, 2006). The literature suggests that recording and accuracy of screening is variable, compromising care for those at risk (Woodcock et al., 2011). The high level of accuracy in this trial (section 4.4), suggests that the staff are competent in undertaking screening, which may be attributed to the 'MUST' training provided by the dietetic service prior to trial commencement. Self-perceived confidence and competence with screening will be further explored with staff during the qualitative phase. Other dietetic-led projects have

demonstrated improvements in ‘MUST’ documentation and accuracy following tailored staff training (Cawood et al., 2008; Woodcock et al., 2011), suggesting that training would need to be a requirement for all care homes recruited to a definitive trial.

5.3.1.2 Height, weight and BMI

Height was collected from ‘MUST’ records for 100% of residents at baseline. The measurement techniques used had been clearly documented. The majority had been measured using a freestanding stadiometer (66%), but where this was not possible, estimation by ulna length was the most frequently used alternative measure (31%). Surrogate methods of height estimation are required for those who are bedridden, confined to a wheelchair, or unable to stand straight (Hickson and Frost, 2003). A recent study concluded that ulna length appears to be the most appropriate surrogate measure for height in females over 65 years and for those unable to self-report (Reidlinger et al., 2014). Staff training on the measurement of ulna length had been provided within all participating homes. The documented use of the technique highlights the importance of training on nutritional assessment prior to research or within clinical practice, to increase the efficiency and completeness of documentation.

Measured body weight and calculated BMI were collected from ‘MUST’ documentation at the 3 data collection intervals. Just 1 resident had not been weighed at baseline, following a decline in clinical condition and a decision by staff that weighing would be an unnecessary burden. It was possible to retrieve the required information for the remaining 92 residents at baseline and 100% of the residents remaining at 3- and 6-months. Inconsistencies in the weighing equipment used can increase the risk of

errors in malnutrition risk assessment and subsequently impact on patient care (Department of Health, 2010; Clarkson, 2012). Throughout the trial, only one resident was weighed using different types of scale, justified by the staff, in terms of reduced mobility at the 3-month interval. The success criteria for weight and BMI were achieved (Table 33), indicating that assessment is acceptable to the majority of residents and is feasible for staff to undertake.

5.3.1.3 Nutritional Intake

Studies that have evaluated the accuracy of staff documentation of dietary intake have shown it to be erroneous when compared to independent assessments made by research staff (Simmons and Reuben, 2000; Castellanos and Andrews, 2002). In this trial, the primary researcher did not have capacity to observe resident food and fluid intake and in a definitive trial, intake assessment by research staff would risk losing an important element of testing interventions in the 'real world' setting. The majority of FRCs and FCs were available and complete, meeting the success criteria for data completeness (Table 33). However, limitations relating to the usefulness of the data were observed (section 4.5.1.2).

The most widely used method of estimating resident food intake was used in all 6 homes; the assessment of mealtime servings as a whole, following which a proportion consumed is assigned (Kayser-Jones et al., 1997). A study, which compared this method with weighed food intake, discovered that staff were correct less than 45% of the time (Castellanos and Andrews, 2002). Improvements in the accuracy of recording could be made through greater emphasis on recording exactly what food was

eaten, or by taking photographs of the plate before and after mealtimes (Heath and Sturdy, 2009). A validation study, which compared three methods of assessing intake (Simmons and Reuben, 2000), found the photographic method to be reliable and time-efficient and a possible solution for increasing the accuracy of estimation. In a definitive trial, a member of staff could be assigned to photograph each resident's plate before and after a meal, enabling comparisons to be made in a more accurate manner that does not rely on staff memory. In routine care, photographs could be used to estimate nutritional intake and to form important evidence during a CQC inspection.

5.3.2 Measured by the primary researcher

5.3.2.1 Mid-Upper arm circumference (MAC)

MAC is included in the 'MUST' as an alternative measure for BMI (BAPEN, 2003) and because of its relatively simplistic assessment, has been deemed suitable for use in the care home setting (Wijnhoven et al., 2013). The MAC assessment was found to be acceptable to the majority of residents (88%), enabling the success criteria to be met (Table 33). However if MAC is to be used as a determinant of undernutrition within a definitive trial, more than 1 researcher may become responsible for the assessments. A recent cross-sectional care home study compared 2 observers independently assessing MAC on 3 occasions over an 8-day period. The study found no systematic differences between observers and concluded that MAC is acceptable for clinical use in a care home setting (Wijnhoven et al., 2013). Training and use of a standardised protocol is however essential to ensure accurate and appropriate measurements are undertaken.

5.3.2.2 Tricep Skinfold thickness (TSF)

An average of 76% of residents in the trial had TSF measured, narrowly missing the success criteria for data completeness (Table 33). A number of challenges were encountered during measuring, including difficulties encouraging residents to be still, inappropriate positioning of bedridden residents and anxiety in relation to the visual perception of the calliper. This experience is similar to that described in a feasibility trial conducted with persons with severe or profound intellectual and sensory disabilities (SIMD) (Waninge et al., 2009) and suggests that it may prove challenging to accurately perform the measurement in a population with fluctuating capacity and challenging behaviours. Other studies have demonstrated the successful use of TSF assessment in care home residents with dementia (Wouters-Wesseling et al., 2006; Aukner et al., 2013), however, the study by Aukner et al (2013), excluded residents that exhibited aggressive and volatile behaviour, on the basis that the measurements would not be possible. No such exclusion criteria were applied in this trial, to enable assessment of feasibility in the general care home population.

Primary problems associated with the TSF measurement include measurement error due to poor technique and substantial differences when measurements are made on the same individual by different observers (Ulijaszek and Kerr, 1999). The challenges encountered within this trial suggest that these sources of error are likely to be emphasised within the care home population, limiting potential use within a definitive trial.

5.3.2.3 Handgrip strength

Handgrip strength is the technique most often recommended for measurement of muscle strength and assessment of muscle function in clinical practice (Cruz-Jentoft et al., 2010). Only 54% of residents in this trial were able to undertake the test and therefore the success criteria for data completeness was not met (Table 33). Cognitive impairments made it difficult for residents to understand and follow the instructions and physical limitations meant some residents were unable to attempt the measure. This is a similar outcome to that noted within other trials conducted in the care home setting where no residents were excluded on the basis of cognitive or physical impairment. In a cluster randomised feasibility trial investigating the efficacy of a rehabilitation intervention in UK care home residents, percentage-missing values for handgrip strength ranged from 36 to 53% (Hoppitt et al., 2010). Similarly, Stange et al (2013) were unable to measure handgrip strength in 38% of the residents recruited to their nutritional intervention trial. These findings suggest that handgrip strength, in its current form does not enable assessment of muscle strength in the general care home population. The observed lack of acceptability suggests there is a requirement for new measurement outcomes for use in a UK care home setting, for elderly with functional impairments.

5.4 Participant reported outcome measures (PROMs) (Primary objective 5, Secondary objective 2)

There is a lack of literature investigating the relationship between nutrition support and PROMs in the care home population (Stange et al., 2013). In the absence of any nutrition specific measures of quality of life or health state, this trial assessed the feasibility and acceptability of existing generic tools (EQ5D and COOP), alongside piloting of a VAS to assess appetite and dietary satisfaction. Adults lacking capacity could not be included (Section 3.2) on the basis that their involvement would not benefit other people with the same or similar impairing condition (Mental Capacity Act, 2005). Only 17% of the residents that entered the trial had capacity and of those, 11 (65%) consented to participate. At each data collection interval, all questionnaires were provided by staff to the participating residents and all of the tools were returned, completed, to the primary researcher. The residents were able to understand the tools, but all had poor hearing and vision, together with poor dexterity, which led to a requirement for staff to read out the questions and mark on responses. The low numbers recruited, significantly reduced the data available to assess feasibility and acceptability and as the tools were not evaluated with those lacking capacity, the proportion of residents that may be able to respond in a definitive trial remains unknown.

The inclusion of PROMs is important to assess the impact of interventions on resident-reported outcomes and to determine Quality Adjusted Life years (QALYs), which form an important part of the economic evaluation of interventions (Table 15). Some care home studies have used proxy respondent, by a family member or

caregiver familiar with the status of the resident (Stange et al., 2013), however problems may arise if caregivers report on different aspects than residents and the perspectives become complementary rather than interchangeable (Arons et al., 2013). At the risk of overestimating participant-centred outcome measures for the resident cohort, because the most severely cognitively impaired cannot respond, data from proxy respondents could be collected and analysed separately within a definitive trial. As it is unlikely that all residents would be able to complete the tools, PROMs would not be considered as primary outcome measures within a definitive trial. The perceived importance and burden of taking part in PROMs, alongside the opinions of staff and residents in relation to whether others could have taken part will be explored within the qualitative phase.

5.5 Piloting of a Healthcare resource usage (HCRU) questionnaire (Secondary objective 1 and 3)

5.5.1 Acceptability, feasibility and usefulness

Few studies have analysed the large-scale economic consequences of malnutrition, but the cost is estimated to be high; £5 billion for direct health care (Guest et al., 2011; Wilson, 2013) and £13 billion for associated health and social care (Elia and Russell, 2009). The extent by which nutritional interventions can improve outcomes in a cost effective manner is currently unknown. In the absence of a standardised HCRU questionnaire for malnutrition, the questionnaire piloted in this trial was designed to collect information on healthcare professional visits and hospital admissions. Care

home staff completed 100% of the questionnaires at 3- and 6-months, obtaining all of the required data from resident care records and GP visit logs.

The greatest limitation was that the type of care provided and the baseline provision of healthcare resources (Table 17) influenced the number of outside healthcare professional visits. Residents requiring personal care only, had their nursing needs met by the NHS through district nurse and GP visits. If, on the other hand, a resident required full-time nursing care and was placed within a nursing or dual care home, the nursing staff within the home would meet some or all of these needs. The questionnaire was able to collect useful data on hospital admissions, visits by consultants and professional visits not delivered in-house (dietitian, speech and language therapist), but the data on district nurse and GP visits was likely influenced by the type of care being funded. To enable the questionnaire to be used within a definitive trial, to inform an economic evaluation of the interventions (Table 15), the usefulness of data on GP visits could be improved by providing thorough staff training regarding the need to document GP call-outs only. The limitations with the collection of data on nursing visits could possibly be addressed by focusing instead on the reasons for residents requiring nursing care (5.5.2.3).

5.5.2 Reasons for healthcare resource usage

The majority of hospital admissions were due to falls, a high proportion of GP call-outs were for assessment or treatment of suspected infections and the majority of district nurse visits were related to pressure sore care. Although previous research has suggested that poor nutritional status is associated with these outcomes (Table 34),

neither the care home staff nor the GP attributed any admissions or visits to a resident's malnourished status, perhaps indicating that awareness of the wide-ranging consequences of malnutrition (BAPEN, 2009) is limited. It is proposed that the incidence of falls, infections and pressure sores could be collected as independent secondary outcome measures within a definitive trial. The average cost of treating an infection (chest or urinary tract) or a pressure sore could be used alongside the frequency of occurrence to inform the economic evaluation of the interventions, reducing the reliance on GP or district nurse visit data. Further piloting would be required initially to establish the accessibility and reliability of the necessary data in the care home setting.

Table 34: The primary reasons for HCRU in this trial and their possible association with nutritional status

Reason for HCRU identified	Association with PEM
Falls	• PEM leads to reduced muscle mass and strength (Chevalier et al., 2008; Smoliner et al., 2008; Suzana et al., 2013), both of which are identified risk factors for falls (Kim et al., 2010; Johnson, 2003; Neyens et al., 2013).
Infections (Chest and Urinary Tract)	• Malnutrition is a major factor in the age-related reduction of the immune defence system (Strausbaugh, 2001; Koch et al., 2009) referred to as immunosenescence (Fulop et al., 2005). • Previous research has shown that a 10% loss of lean tissue, even in previously healthy older adults, impairs immunity and increases infection risk (Broadwin et al, 2001; Landers et al, 2001).
Pressure sores	• PEM has been shown to increase the risk of pressure ulcer development (Thomas, 2001; Mathus-Vliegen, 2004) and impair healing and recovery (Williams and Barbul, 2003; Harris and Fraser, 2004).

PEM= Protein Energy Malnutrition; HCRU= Healthcare Resource Usage

5.6 Change in outcomes (Secondary objective 4)

Whilst the feasibility and acceptability of outcome measures was a primary objective for the trial, sensitivity to change was also assessed, by comparing mean change in outcomes between the intervention arms at 3- and 6-months. Due to the lack of data for handgrip strength and PROMs, sensitivity to change in those outcome measures will not be discussed further.

5.6.1 Energy intake

For estimated energy (kcal) intake, positive changes favouring the dietetic-led intervention arms were observed at 3- and 6-months, but there was no difference noted between the FB and ONS intervention arms. Increase in total energy intake has been demonstrated in a number of care home malnutrition intervention trials using both FB (Turic et al., 1998; Odlund et al., 2003; Iuliano et al., 2013) and ONS (Turic et al., 1998; Manders et al., 2009; Parsons et al., 2011) intervention, which suggests that residents increase their overall energy intake when specific calorie-dense interventions are provided to them on a daily basis.

Improved nutritional intake is understood to be a key component in the causal pathway leading to improved clinical outcomes. Change in energy and protein intake should be included within a definitive trial as secondary outcome measures, to examine this relationship further. More accurate means of reporting intake (section 5.3.1.3) would enable use alongside compliance data, to determine whether habitual intake changes to compensate for the introduction of an intervention. Several care home ONS

intervention studies observed a reduction in energy intake from ‘normal’ food, when ONS was introduced into the diet (Fiatarone et al., 2000; Manders et al., 2009), but no comparison has been made with FB intervention. This evaluation may have important implications for clinical practice.

5.6.2 Weight and BMI

For recorded weight and BMI, positive changes favouring the dietetic-led interventions were observed when each intervention was compared with SC at 3- and 6-months. Again, there was no observed difference between the FB and ONS arms. An increase in weight and BMI has been reported in a number of care home malnutrition intervention trials using both FB (Kwok, 2001; Leslie et al., 2012) and ONS (Lauque et al., 2000; Wouters-Wesseling et al., 2002; Manders et al., 2009; Lee et al., 2013; Stange et al., 2013) intervention. Whilst such findings suggest these outcomes are sensitive to positive changes in dietary intake, the composition of weight gain is unknown. In terms of delivering functional benefit, a gain of fat mass will not result in improved muscle strength (Milne et al., 2009) and given that assessment was undertaken by care home staff, confounding factors such as oedema or ascites (Campillo et al., 2002; McKinlay, 2004) may not have been accounted for. The limitations associated with weight and BMI as outcomes of clinical relevance has led to calls for more focus on improvement in functional status or quality of life as primary trial outcomes. However, weight and BMI continue to be used in clinical practice as the primary outcome measures for nutrition support interventions.

The effect of nutrition support on weight gain is unlikely to be universal, given the diverse aetiology of unintentional weight loss. Sarcopenia, associated with loss of strength and increased frailty, is believed to occur regardless of energy balance (Rolland et al., 2011a) and evidence to date suggests the most effective intervention is a combination of adequate nutrition and resistance training (Rolland et al., 2011b). As there are no screening tools for the identification of sarcopenia, diagnosis is usually made through clinical judgement, adding weight to the case for dietetic assessment following 'MUST' screening in a definitive trial. A significant proportion of care home residents may be exhibiting signs of sarcopenia. Awareness may enable sub-group analysis and exploration of the impact of conventional nutritional support on PEM with or without age-related nutritional decline.

5.6.3 MAC, TSF and MAMC

Negative change was observed for MAC and MAMC over the 6-month intervention in all 3 arms, whilst positive change was observed for TSF. Whilst this suggests that weight gain may have been primarily due to an increase in fat mass, observed trends should not be overemphasised due to the feasibility nature of the trial and the lack of complete data for these outcomes. Significant difference in MAC change was demonstrated in 2 of the ONS intervention trials (Lee et al., 2013; Stange et al., 2013) included in the systematic review (Chapter 2). There is evidence to suggest that a low MAC is a more feasible and valid determinant of undernutrition in older adults than a low BMI (Powell-Tuck and Hennessy, 2003; Wijnhoven et al., 2010), as it is not influenced by spinal deformities and is less affected by fluid changes (Harris

et al., 2008). In a definitive trial, change in MAC could be included as an outcome measure, alongside weight and BMI. It should be noted however, that as for weight, the presence of sarcopenia may reduce MAC, irrespective of nutrition support.

Body composition is important, because of the association between muscle mass and, physical function, strength and morbidity. In older adults, low MAMC, a measure of arm muscle area, has been shown to have greater association with mortality than low BMI (Miller et al., 2002). Unfortunately, determining MAMC requires TSF measurement and additional calculation, which can hamper practical implementation. A systematic review (Allen et al., 2013), which analysed the impact of ONS consumption on skinfold thickness and MAMC in those with long-term cognitive impairment, found no overall statistically significant difference between ONS and control groups in the 6 reviewed studies. The challenges faced within this feasibility trial when attempting to accurately measure TSF, alongside the results of this systematic review (Allen et al., 2013), suggests that skinfold measurement, and therefore, also MAMC, are not appropriate for monitoring short-term changes in body composition, particularly with a population where accurate measurement may be hampered.

5.7 Data to inform calculation of the Intraclass Correlation Coefficient (ICC) for a definitive trial (Secondary objective 5)

In order to conduct a well-designed definitive trial with the aim of comparing efficacy of nutritional interventions, the ICC should be known beforehand to estimate required sample size and statistical power to reduce the chances of type II error (Murray et al., 2004).The ICC can be selected from previous work with a similar

population, it can be calculated from preliminary trial data and/or it can be estimated from the literature. Whilst the data collected in this trial could be used to inform the calculation, further literature searching and piloting is required first, to identify the most appropriate primary outcome measure with clinical relevance for an older care home population and to estimate the key population parameters needed to calculate sample size. The method of calculating the ICC is outlined in Appendix 24.

5.8 Trial Limitations

The care homes recruited into this trial do not necessarily represent the national care home population. All 6 had received long-term, regular input from the local dietetic team and were enrolled on a rolling program of staff training. The primary researcher had an excellent rapport established with the managers and staff, which may have made it easier to recruit all of the approached sites, to conduct the trial within the required timeframes and to encourage staff to adhere to the protocol. Evaluation of feasibility was undertaken in interested and motivated care homes, thus the transferability of the findings would be dependent upon tailoring to the local context.

The restrictions imposed by the approving REC led to limitations within the conduct of the trial. The absence of clinical dietetic assessment following 'MUST' screening, may have resulted in a number of end-stage palliative care home residents entering the trial and receiving interventions, which were unlikely to deliver nutritional benefit. This lack of expert assessment may have contributed to the high mortality rate during the first 3-months of the trial, reducing the observed effectiveness of the interventions and increasing the risk of attrition bias. Limitations in the design of the trial

also increased the risk of performance and detection bias through a lack of double blinding. Whilst the nature of the nutritional interventions under investigation makes it impossible to blind the care home staff to treatment allocation, it should be possible in a fully-funded definitive trial, for research staff measuring outcomes and collecting data to be blinded to the allocated intervention.

5.9 Implications for future research

Qualitative trial designs are particularly needed within care homes, to better understand the setting and the opinions and experiences of the residents, relatives and staff involved (Maas et al., 2002). It is likely that the perceived value of nutritional interventions by key stakeholders such as managers, care staff, residents, relatives and GPs, affects intervention compliance. One study, which used Normalisation Process Theory (NPT) to explore facilitators and barriers to the use of nutrition guidelines in care homes, reported a number of barriers to implementation, which were strongly associated with staff views (Bamford et al., 2012). Beyond the scope of the qualitative work being conducted following this trial, further qualitative research may be required to explore the nutritional and clinical priorities of those working and residing in the care home setting, alongside the perceived value of nutritional interventions. The results could be interpreted alongside the feasibility outcomes, to provide an enhanced understanding of nutritional care complexities (Cresswell, 2009) within care homes, and to further inform the design of a definitive trial and choice of primary outcome measure.

5.10 Conclusions and summary

The data presented in this thesis enable several conclusions to be drawn, which address the research question and trial objectives. The trial design was feasible to undertake within the care home setting. With commitment from staff and management, it was possible to obtain consent from 6 care homes and to identify 93 residents who were eligible to receive the allocated interventions, meeting the recruitment targets for homes and residents. The success criteria for the retention of care homes and residents throughout the trial were also met; however resident mortality was high, particularly during the initial 3-months. In a definitive trial it is proposed that dietetic assessment using a validated method could be used following 'MUST' screening, to identify where malnutrition is an indication of end-stage disease and intervention may not be appropriate.

The 3 nutritional interventions were considered acceptable to care home residents and staff, on the basis of low crossover rates, satisfaction of the success criteria for resident compliance and, high staff adherence to the intervention schedules. The established relationships between the primary researcher and each of the care home sites may have improved the willingness of staff to follow the trial protocol. Whilst this will be explored further during the qualitative phase, it is likely that researcher visits to establish trust and to deliver training will need to be accounted for within the timeframe of a definitive trial, to aid with successful recruitment of care homes and residents and to culture good relationships with staff teams.

Of the outcome measures piloted, weight, BMI, MAC and nutritional intake were found to be feasible and acceptable measurements to undertake in this population, meeting the success criteria for data completeness and consideration for use within a definitive trial. Although the trial was not powered to examine intervention outcomes, the direction of effect for weight, BMI and energy intake was in favour of the FB and ONS interventions, highlighting sensitivity to change for these outcome measures. In the care home setting, weight and BMI are frequently used as outcome measures of nutrition support within routine practice. This trial has demonstrated that a definitive trial comparing the efficacy of FB, ONS and SC interventions in increasing weight and BMI in malnourished care home residents is both feasible and acceptable to undertake. Such a trial could provide useful information as to whether continued NHS expenditure on prescribed ONS is warranted in this setting.

Whilst the design was feasible to undertake, this trial has highlighted a lack of clinically relevant outcome measures, appropriate to this setting, for both research and clinical practice. Many older adults consider functional independence to be more important than the prevention of disease (Warburton et al., 2001; Paterson et al., 2004), which supports the use of a measure of functional effects as a primary outcome for a future malnutrition intervention trial. This trial identified a need for a more simple measure of functional status, which considers the impediments of functional tests in the care home population. Development of such a test or measure may be a goal for future research, to enable nutrition support interventions to be compared within the care home setting using primary outcomes of greater clinical and patient relevance.

APPENDIX 1:
RESEARCH ETHICS COMMITTEE APPROVAL

APPENDIX 2:
R&D APPROVAL

APPENDIX 3:
CARE HOME INVITATION LETTER

Care Home
Care Home address
Postcode

Date

TRIAL INVITATION

A cluster randomised feasibility study evaluating current dietary interventions in the treatment of malnutrition in care home-dwelling adults

Dear (*insert name of Manager)*

We are carrying out a pilot study, managed by the Heart of England NHS Foundation Trust, to assess the feasibility and acceptability of running a full-scale study, comparing and evaluating three existing dietary interventions for malnutrition, within the care home setting.
Further to the delivery of nutrition support training and the establishment of nutrition focus groups within your care home, we would like to invite you to take part in this pilot malnutrition research.

There is limited evidence to guide the appropriate use of nutritional treatment for malnutrition, particularly in the care home setting. Commonly used interventions, include, dietetic-led food-based intervention, dietetic-led oral nutritional supplement (ONS) intervention and the standard care home diet for malnutrition. It is important that we compare and evaluate the effectiveness of these already established and widely used dietary interventions.
In this pilot, we will assess the feasibility and acceptability of the three dietary plans and the study design to both care home residents and staff.
Each care home that agrees to participate will be allocated at random to either one of the dietetic-led intervention arms or will be asked to continue to provide the standard care home dietary intervention plan for malnutrition. Residents within each care home will be deemed eligible to receive the dietary intervention on the basis that they require it to address malnutrition or risk of malnutrition. They will be identified using routine malnutrition ('MUST') screening and a review of care records, as per usual, standard practice.

Within the care homes allocated to one of the dietetic-led intervention arms, a registered dietitian will deliver either the food-based or the ONS intervention, in accordance with local and national nutrition support guidelines. Within the care homes allocated to standard care without added dietetic intervention, residents with, or at risk of malnutrition will continue to receive a high-energy diet, in line with the training already provided by the local dietetic service.

Nutritional status, change in anthropometry measures and compliance will be monitored for each resident in receipt of a dietary intervention plan, in line with usual, standard practice.
Additional outcome measures, such as resident rated quality of life, health state and satisfaction with the dietary intervention plan will only be collected for those residents that have capacity and have consented to provide this additional information.

Outcomes will be assessed at baseline and at 3 and 6 months after entry to the study. All outcome measures will be anonymous to the dietitian researcher.

The findings from this feasibility study will be used to inform the development and design of a future large-scale trial to compare dietetic-led food-based intervention, dietetic-led ONS intervention and the standard care home dietary intervention, in the treatment of malnutrition within care homes. The results of this future trial will inform decisions by dietitians, General practitioners, care home providers and commissioners, regarding the appropriate use of nutritional treatment for malnutrition in care homes.

This study is designed to fit in with routine care home practice as far as possible and to impose minimal additional workload. We enclose a care home information sheet for you, which describes the study in further detail.
If you would you like to take part in this pilot study, would like to learn more about this pilot study or if you have any questions, please contact us using the address or telephone number detailed at the top of this letter. Alternatively, please complete and return the reply slip enclosed and we will contact you to discuss the study further

If you would like to take part in the study, we can arrange a meeting with you to answer any questions that you may have

Yours Sincerely

Ruth Stow
Nutrition Support Dietitian and Dietitian Researcher

APPENDIX 4:
CARE HOME INFORMATION SHEET

A cluster randomised feasibility study evaluating current dietary interventions in the treatment of malnutrition in care home-dwelling adults

Care Home Information Sheet

Researcher Contact Details:

Patient Services Department (formerly PALS):

Care Home Information Sheet

Your care home is being invited to take part in a feasibility research study.
Before you decide whether you would like to participate, it is important that you understand why the research is being done and what it involves. Please read the following information carefully and discuss it with your staff as appropriate. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We want to know how dietetic-led food-based intervention, dietetic-led oral nutritional supplement (ONS) intervention and the standard care home dietary intervention plan, compare, in improving the outcomes of malnourished care home-dwelling adults.
All three dietary interventions are widely used within the care home setting, but there is currently a lack of capacity within the dietetic service to deliver a dietetic-led intervention to each resident identified, with, or at risk of malnutrition. It is therefore important that the dietetic-led intervention plans and the standard care home dietary intervention plans are compared and evaluated.

The care home setting is under-represented within research and therefore, the evidence to guide best care practices and improve quality of life is lacking. Currently there is no agreement on the best nutritional treatment for malnutrition and there are no published clinical trials comparing nutritional treatments of equal nutrient composition within a care home population.

We hope to develop a large-scale trial, which will be used to inform decisions by dietitians, general practitioners, care home providers and commissioners, regarding the most appropriate nutritional treatment for malnutrition in care homes.
Before this future large trial can take place, we need to ensure that we are able to compare and evaluate the three existing dietary interventions, within the care home setting.
This pilot study will help us to assess the feasibility and acceptability of running the study on a larger scale and will inform the design of the future trial.

Why have we been asked?

The study will include six care homes located in Solihull. We are asking you to consider taking part, because you provide nutritional care for people with, or at risk

of malnutrition and you have already worked closely with the Nutrition Support Dietitian in improving screening and care planning practices.

Do we have to take part?

It is up to you and the staff at the home to decide whether you wish to take part in this study. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a care home consent form.

What will happen if we do decide to take part?

In this case, we do not know which way of providing dietary intervention is best and therefore, we need to make comparisons.

The six care homes that agree to take part in the study will each be allocated to one of the three existing dietary intervention plans.
This means that as a care home, you will be allocated at random to either dietetic led food-based intervention, dietetic-led ONS intervention or you will be asked to continue delivering your standard care home dietary intervention plan for malnutrition.
The allocated dietary intervention will be delivered within the care home for a period of 6 months.

Identification of eligible residents to receive the dietary plan

All residents with, or at risk of malnutrition, who do not already have a dietetic treatment plan in place, but require a dietary intervention to meet their nutritional needs, will be considered for receipt of the plan that is allocated to the care home. They will be identified, through malnutrition screening and a review of care records, as per usual, standard practice, prior to initiation of a diet plan for malnutrition.

The ‘Malnutrition Universal Screening Tool’ (‘MUST’) will be used to identify those at risk of malnutrition. You currently use ‘MUST’ within standard practice. We would ask that two of your staff are assigned the role of MUST screening within this study. A review training session will be delivered by the dietitian to ensure that the staff are competent with using the tool.
Following ‘MUST’ screening your care home staff will consider the suitability of each identified resident, for receipt of a dietary plan. There are eligibility criteria that each resident must meet, to ensure that it is safe and appropriate for him or her to receive a dietary intervention for malnutrition. The staff will be able to discuss these criteria on an anonymous basis with the Dietitian researcher as required.

Residents with, or at risk of malnutrition that are eligible to receive the dietary intervention, but are lacking the capacity to consent will only be included within those aspects of the study that reflect usual, standard practice. Outcomes that are

routinely measured within usual monitoring of nutritional status will continue to be conducted. This data will be collected, in an anonymised format.

Residents who have capacity to consent, will further be asked to consent individually to provide information on quality of life, health state and dietary satisfaction through completion of anonymised questionnaires and self-reported scales and charts, and to be contacted regarding interviews, following the 6-month dietary plan.
An information sheet will be provided to those residents that are eligible for involvement in this part of the trial.

Baseline assessments

Once the eligibility of your residents has been determined, baseline assessments will need to be undertaken.
These assessments will include a calculation of average daily energy and protein intake (from three consecutive food record charts) and measurement of anthropometric indicators. These assessments are conducted within usual, standard care and will be repeated at 3 months and 6 months following care home allocation to a dietary plan.

After 3 and 6 months of the dietary plan, the assigned care home staff will complete a resource usage questionnaire for each resident, answering questions concerning their use of health and social care resources. This information can be obtained from care records.

Those residents that have capacity and have consented to further participation, will be asked to complete 3 brief questionnaires, to measure quality of life (COOP Chart), health state (the EQ-5D) and to measure perceived appetite and dietary satisfaction (Visual Analogue Scale). These questionnaires will also be repeated at 3 months and 6 months following allocation to a dietary plan.

The dietetic-led intervention arms

If your care home is allocated to receive either food-based or ONS intervention, we will ask you to continue to provide eligible residents with a high-energy diet (current standard care) and the registered dietitian will put in place an intervention plan, which will provide an additional 600kcal of energy and 20-25g protein daily. The intervention will be tailored to meet the preferences of each resident.
The dietitian will visit again at 3 months to review the dietary intervention plan and at 6 months, when the collection of outcomes will terminate.

If a resident does not tolerate the intervention, the care home staff will be advised to return the resident to the standard care home dietary intervention for malnutrition.

This is in line with the usual, standard, dietetic service provided to the care home residents.

The Standard care arm

If your care home is allocated to continue to provide the standard dietary intervention for malnutrition, we will ask you to continue to provide the eligible residents with a high-energy diet plan, in line with local and national guidance for first line nutritional therapy for malnutrition.
If any resident receiving this dietary intervention, suffers a decline in their nutritional status, dietetic-led intervention (food-based or ONS) will be introduced after 6 weeks, as per local and national best practice guidelines and usual, standard practice.

Interviews and Focus Groups

Following the 6 months of dietary intervention plans, we will ask to interview some of the residents that have capacity, and to hold a focus group with 6-8 staff, to find out more about their experiences during the study. Interviews and Focus groups will take place with the dietitian.

Residents with capacity have the opportunity to opt out of being considered for the interview process on the consent form for participant-reported outcome measures.

If you do not want your staff to take part in the focus group sessions following the 6-month dietary plan, you have the opportunity to opt out on the consent form provided with this information sheet. This will not affect your participation in the other parts of the study.

What impact will the study have on staff time?

The study has been designed to fit in with routine care as far as possible. The study duration is for 6 months on an allocated dietary plan.

- It would be useful if you would assign two of your staff to undertake the initial screening (MUST) to ensure consistency of screening and to give staff an opportunity to choose to take on this role.
- Weight, BMI and MUST score will be required again by the dietitian at 3 months and 6 months. This information is collected as part of your usual practice and should not require additional workload.
- Staff will be required to monitor the dietary intake and/or ONS intake of all residents within the study. Again this is in line with usual practice concerning residents with/at risk of malnutrition.
- Additional responsibilities required of staff, will be to complete a resource usage questionnaire for each resident at 3 months and 6 months study duration. This questionnaire can be completed directly from the care records of the residents.

- The staff will also be asked to observe for any adverse side effects and to report these to the dietitian as soon as possible, as per usual practice on initiation of a prescribed ONS or a dietary change.
- If allocated to a dietetic-led intervention arm, the staff (including catering staff, for food-based intervention) will be responsible for providing the resident with the agreed food/beverage/ONS on a daily basis. Again, this follows usual practice when the dietitian puts a treatment plan in place following a referral.
- Following 6-months of delivering the allocated dietary intervention, we will ask to hold a focus group, to establish the collective opinions of the staff involved in the study. Alongside the resident interviews, this will ensure that the voice of your residents and their carers is used to design the future trial (optional).

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part.
All three dietary interventions are currently used within usual standard practice. The residents that are identified as eligible to receive the dietary plan within your home will be monitored as per usual practice. Individual dietary plans will be adjusted, or changed if they are not tolerated, or they are not meeting individual nutritional needs. This will ensure no change from usual, standard practice at the individual resident level.
There may be a small risk of mild side effects on initiating ONS or changing the diet; this can include diarrhoea, bloating, nausea and early satiety, but is rare and the dietitian will discuss monitoring with you.

What are the possible benefits of taking part?

Although there may not be a direct benefit from taking part in the study, the information we get from this study may help us to provide improved nutritional care for future care home residents with malnutrition. The findings from the study will be used to inform a future main trial and will be shared with the local care home community.
Your residents may benefit from receiving a dietary intervention plan for 6-months, if it is effective at improving nutrient intake and anthropometric indicators.

What if something goes wrong?

If any harm comes to residents or staff taking part in this research, there are no special compensation arrangements. If harm is caused due to someone's negligence, then you may have grounds to take legal action but you may have to pay for it. If you do wish to complain, or have any concerns about any aspect of the way your staff or residents have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms are available: ask to speak to the complaints manager of the Heart of England NHS Foundation Trust.

If you have a concern about any aspect of this study you should ask to speak to the dietitian who will do their best to answer your questions
. If you remain unhappy and wish to complain formally you can contact your local Patient Services Department (formerly PALS) on .

Will our taking part in this study be kept confidential?

All information collected in the study will be anonymous and will remain strictly confidential. The information will be put into a computer and analysed in an anonymous format. No personal, identifiable information will be collected by the dietitian.

We will be asking for your permission to tell the care home GP(s) that you are taking part in the study, to let them know that some of their patients may be in receipt of an allocated dietary intervention plan. The GP may ask you for further details of which residents are receiving the plan.

What will happen to the results of the research study?

The results of the study may be published in a nutrition and dietetics journal after the study has been completed but residents and care homes will not be identified in any report or publication.

Who is organising and funding the research?

The study is being conducted as part of a student project that the Dietitian is undertaking. It is self-funded and no payments will be made to the participants or clinical staff taking part in the study.

Who has looked at the research?

All research in the NHS is looked at by an independent group of people within a Research Ethics Committee to protect the safety, rights, well-being and dignity of participants. This study has been reviewed and approved by *insert committee and date*

Contact for Further Information

Should you want further information about the study please contact:

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

APPENDIX 5:
CARE HOME CONSENT FORM

A cluster randomised feasibility study evaluating current dietary interventions in the treatment of malnutrition in care home-dwelling adults

Care Home Name:	**Please Initial Box**
1. I confirm that I have read and understand the information sheet dated ***insert date*** for the above study and have had the opportunity to ask questions.	
2. I understand that the participation of the care home and the residents is voluntary and residents are free to withdraw from the participant-reported outcome measures or individual interviews at any time, without the quality of their nutritional care being affected.	
3. I understand that relevant aspects of the resident care home records may be looked at by regulatory authorities. I give permission for these individuals to have access to the care home records.	
4. I agree for the care home to take part in the above study	
5. I agree to care home staff being considered for focus groups with the dietitian following the trial to discuss their experiences (optional)	
6. I give consent to the GP being informed about our participation in this study	

Name of person representing care home:

Signature: **Date:**

Name of person providing information:

Signature: **Date:**

For further information about the study please contact:

APPENDIX 6:
CARE HOME SCREENING LOG

Care Home name:	
Care Home address:	
Telephone Number:	
Assigned care home staff:	

Part A: Malnutrition Screening

Total number of residents screened using 'MUST':

Number of residents at moderate risk of malnutrition

Number of residents at high risk of malnutrition

Part B: Care Home staff assessment

Total number of resident's staff assessed as 'not suitable' to receive dietary treatment plan

Please provide the main reasons for this assessment outcome:

-

-

-

-

-

Part C: Inclusion/Exclusion Criteria for receipt of dietary treatment plan

Number of eligible residents receiving tube or parenteral nutrition	Number of eligible residents unable to eat and drink
Number of eligible residents not registered with a Solihull GP	Number of eligible residents already receiving nutrition support (dietetic advice or prescribed ONS)
Number of eligible residents on an end of life care pathway	Number of eligible residents with a known eating disorder or illness, which requires a therapeutic diet incompatible with fortification and/or supplementation.

Part D: Inclusion/Exclusion Criteria for additional participant-centric outcome measures:

Number of eligible residents that are non-native English speaking

Total number of eligible residents that lack the capacity to consent to further involvement

Part E: Trial Details

Date of care home randomisation: / /

Care Home Trial Number:

Treatment Allocation

Number of residents eligible to receive dietary plan

Number of residents with capacity to consent to additional outcomes

Completed by (print name):

Signed: **Date** / /

APPENDIX 7:
MALNUTRITION UNIVERSAL SCREENING TOOL ('MUST')

To calculate a malnutrition risk score, follow the 5 steps detailed below:

STEP 1: **Body Mass Index (BMI) score:** Use height and weight (if possible) to get a BMI score.		STEP 2: **Unintentional weight loss score:** Score for percentage unplanned weight loss in the last 3-6 months		STEP 3: **Acute Disease effect Score**	
BMI >20	0	<5% weight loss	0	No problems with dietary intake	0
BMI: 18.5-20	1	5-10% weight loss	1	No or negligible dietary intake for >5 days in presence of acute disease	2
BMI <18.5	2	>10% weight loss	2		

STEP 4: Add the scores from steps 1, 2 and 3 together to obtain an **overall risk of malnutrition**.

- A score of 0 is classed as **'Low'** Risk (no further action required)
- A score of 1 indicates **'Moderate'** risk
- A score of 2 or more indicates a **'High'** risk of malnutrition

STEP 5: For patients identified as moderate or high risk of undernutrition, implement the relevant core care plan and dietary interventions, documenting as an individualised care plan

'MUST' Record

Participant trial number: **Care Home Trial number:**

Pre-assessment details	**Height (m):**		**Weight 3-6 months ago or usual weight (kg):**	

Date:	**Present Weight (Kg):**	**Step 1:** BMI Category Score (0,1,2)	**Step 2:** Weight loss category score (0,1,2)	**Step 3:** (if appropriate) Acute disease effect (0,1,2)	**Total risk undernutrition score** (add steps 1, 2 and 3):	**Risk category** (High, Moderate)

‘MUST’ score:

The 'MUST' materials are reproduced here with the kind permission of BAPEN. The tool has been adapted from the original BAPEN tool, to make it easier to score for BMI and for weight loss. This simplified version was developed by the ‘Focus on Undernutrition’ team at County Durham and Darlington Community Health services and has been approved by BAPEN. The tool layout has been adapted slightly for use within this guidance.

Copies of the 'MUST', an explanatory booklet for use in training and implementation and the 'MUST' report are available from the BAPEN Office. See www.bapen.org.uk for details.

APPENDIX 8:
TRIAL PROTOCOL

A cluster randomised feasibility trial evaluating current dietary interventions in the treatment of malnutrition in care home-dwelling adults

Short title: Malnutrition in care homes: A feasibility study

TRIAL PROTOCOL: VERSION 2.0

Chief Investigator: Dr Alison Rushton

Trial Sponsor: Heart of England NHS Foundation Trust

Student Project: National Institute for Health Research (NIHR) Clinical Academic Training Programme for AHP's (Masters in Research)

Contact Details:

Contents:

1. Trial Outline

Design:

A cluster randomised trial, assessing the feasibility and acceptability of comparing and evaluating existing dietary interventions in the treatment of malnutrition, within care homes for the elderly.

Randomisation will take place at the level of the care home, using a computer – generated random number list to allocate each home to either, dietetic-led food based intervention, dietetic-led oral nutritional supplement (ONS) intervention or the standard care home dietary intervention plan. The trial will need to be open-label due to the nature of the nutritional interventions under investigation.

Aim of study

To determine the feasibility and acceptability of running a full-scale cluster randomised trial comparing the efficacy of established dietary intervention plans for malnutrition, within care homes for the elderly.

Using questionnaires, self-reported scales, resident interviews and staff focus groups, we will assess the acceptability of the different dietary plans to both care home residents and staff, the willingness of care homes to randomise to the established dietary plans, recruitment and retention rates, data collection processes and data completeness.

Setting

Six care homes within the Solihull area, selected specifically to establish feasibility within different types of care homes

Target population to receive the dietary plans

Care home residents within the participating homes, with or at risk of malnutrition.

Dietetic-led intervention Arms

The Solihull Nutrition Support dietitians currently use both food-based intervention and ONS intervention as treatment options for malnutrition within the care home setting.

Dietetic led food-based intervention will increase the daily calorie content of the diet by 600kcal and the daily protein content by 20-25g, alongside the standard care home diet for malnutrition, continued for 6 months. The content of the dietary intervention plan will follow locally agreed Nutrition Support guidelines.

Dietetic led ONS intervention will increase the daily calorie content of the diet by 600kcal and daily protein content by 24g, alongside the standard care home diet for malnutrition, continued for 6 months. The ONS intervention will use standard liquid sip feeds, in accordance with the local prescribing formulary and enteral feeding contract.

Standard, care home intervention Arm

The current standard care home diet for malnutrition, without added dietetic intervention, will be delivered to residents for the 6-month period, in line with the training already provided to care home staff (including catering teams) by the Registered Dietitian. The purpose of the standard dietary intervention is to provide and encourage a calorie dense diet (Department of Health, 1992), which may be achieved through provision of small, frequent meals, recipe enrichment with additional calories and prompting and assistance from care home staff where required.

The three dietary intervention options will be allocated at the level of the care home and the suitability of provision to each care home resident with, or at risk of malnutrition, will be determined at baseline. To ensure that this study does not change usual, nutritional care at the individual level, the nutritional status of each care home resident will be monitored throughout the 6-month dietary plan, using usual outcome measures.

Should any of the residents not tolerate a dietetic-led intervention (food-based or ONS), the care home staff will be advised to return the resident to the standard care home dietary plan for malnutrition. This follows usual, standard practice.

Should any of the residents within the care homes that have been randomised to continue with the standard care home diet for malnutrition, experience a decline of nutritional status, dietetic-led intervention (food-based or ONS) will be introduced after 6 weeks of standard care. This follows local and national nutrition support guidelines and usual, standard practice within each of the care homes.

Measurement of outcomes

As this is a feasibility trial, there is no specified primary outcome measure.

Existing studies investigating malnutrition interventions have used a variety of outcome measures including mortality, morbidity and measures of nutritional status. There is a lack of good quality evidence for all reported outcomes, particularly within the care home setting.

This trial will collect and evaluate a range of outcome measures to use within the main trial. The outcome measures collected within usual monitoring, such as change in energy intake and anthropometric parameters (weight, BMI, handgrip strength and MAMC) will continue to be collected for all residents with, or at risk of malnutrition that are placed onto a dietary plan.

A healthcare resource-usage questionnaire will be trialled by care home staff within this trial to inform the development of a malnutrition specific instrument for the future trial. For residents who have the capacity to consent to join the trial, additional outcome measures will be collected, including: participant-reported quality of life (CO-OP Charts), health state (EQ-5D questionnaire), and participant rated appetite and dietary satisfaction (VAS tool).

Interviews with a sample of residents and focus groups with care home staff will complement the quantitative data collection by further exploring the feasibility and acceptability of the trial design.

Sample Size

As this is a feasibility trial, no formal sample size calculation is required.

Six local care homes will be recruited into the trial and will be randomised into the three dietary intervention arms of the trial.

It is estimated that 30 to 42% of care home residents are at risk of malnutrition (Russell and Elia, 2010). Based on the capacity of the selected care homes, which range in size from 26 to 70 beds, we estimate that between 8 and 30 residents will be identified as moderate or high risk of malnutrition within each participating care home and will be considered for receipt of the allocated dietary intervention plan for malnutrition.

Study Duration

12 months study duration, including delivery of a 6-month dietary intervention plan.

1. Background

1.1 *Rationale*

Often unrecognised and under-treated, malnutrition[6] predisposes individuals to disease, delays recovery from illness (McWilliams, 2008) and reduces quality of life (QoL) (Gaskill et al., 2008; Brotherton et al., 2010). Care home residents are especially vulnerable, with an estimated 30 to 42% at risk of malnutrition (Russell and Elia, 2010). In recent years, the NHS has focused attention on the increasing problem of malnutrition amongst hospitalised patients, where acute trusts have control over the dietary content of daily meal provision. In the community setting, tackling malnutrition can pose a greater challenge, particularly as independent providers run many of the care homes.

There is currently no internationally agreed nutritional treatment for malnutrition (Baldwin and Weekes, 2011). Current techniques include food-based intervention (recipe enrichment/fortification, nourishing snacks and fortified drinks) and/or the use of prescribed oral nutritional supplements (ONS) (NICE, 2006)**.** Although National recommendations by The British Dietetic Association (BDA) and The National Prescribing Centre (NPC) suggest improving nutritional intake first using conventional foods and secondly by prescribed means (Thomas, 2001; NPC, 2012), it is currently unclear whether food-based intervention is able to improve clinical and nutritional outcomes for malnourished individuals.

Conventional food is less expensive than ONS, which incurred a national spend of £105 million to the NHS from 2010 to 2011, a 10% increase from 2009/10 (NHSBSA,

[6] Within this proposal, 'malnutrition' refers to under nutrition, not over nutrition or obesity.

2011). At this time, many primary care trusts and GP practices identified a significant and increasing spend on ONS, prompting a move by Medicines Management teams to impose stricter prescribing guidance and encourage increased use of food-based intervention (Hobday, 2010). It is therefore becoming increasingly important to assess whether conventional food is able to improve the nutritional and clinical outcomes of those at risk of malnutrition within care homes.

In Solihull, the Heart of England NHS Foundation Trust, Community Nutrition Support Dietitians provide a monthly service to the local care homes, delivering advice, training and support to care home staff and facilitating good nutritional care for the care home residents. All of the local care homes conduct monthly nutritional screening and implement a standard dietary intervention plan for those residents with, or at risk of malnutrition.

If a resident remains at high risk of malnutrition for 2 months, the care home staff will make a formal referral to the dietitian for an individual resident assessment and implementation of a dietetic intervention plan, using a food-based or an ONS approach, in line with local and national nutrition support and prescribing guidance. There is currently a lack of capacity within the dietetic service to deliver a dietetic-led intervention for each resident identified with, or at risk of malnutrition. To enable the current dietetic service provision within care homes to be evaluated, it is important that the dietetic-led and standard care home intervention plans are compared and evaluated.

Undertaking a large-scale trial within a care home setting, will likely be met by a number of challenges. Care homes provide care to frail older people with high support needs and are arguably home to one of our most vulnerable populations

(Quince, 2013). Research is likely to challenge care homes and the staff that work there, as it adds an additional pressure on to what is already a heavily burdened care sector (Froggat et al, 2009).

There is also limited data upon which to design a substantive trial or on which to base a sample size calculation. We therefore propose to undertake a pilot study, randomised at the level of the care home, to evaluate the feasibility and acceptability of evaluating and comparing the three existing dietary intervention plans that are provided to those with, or at risk of, malnutrition within care homes for the elderly. These interventions are dietetic-led food-based intervention, dietetic-led ONS intervention and the standard care home intervention for malnutrition. They will be allocated to the care homes for a 6-month period.

In addition to an evaluation of existing dietary interventions and routinely collected outcome measures, participant-reported outcomes will be collected, using questionnaires, charts and scales, from those residents that have the capacity to provide informed consent. Individual interviews with a sample of these residents, alongside staff focus groups within each care home, will ensure that the voice of residents and their carers is embedded within the design of the future trial.

The results of the pilot study will inform the development and design of a future cluster randomised controlled trial to compare dietetic-led food-based intervention, dietetic-led ONS intervention and the standard care home dietary intervention, in the treatment of malnutrition within the care home population. The future trial will aim to consider and compare a number of outcomes, including nutrient intake, anthropometric parameters, patient reported outcomes and cost effectiveness. The results of the future trial will inform decisions by dietitians, General practitioners, care

home providers and commissioners, regarding the appropriate use of nutritional treatment for malnutrition in care homes.

1.2 Existing Research

2.2.1 Malnutrition Intervention

Systematic reviews of malnutrition interventions (Stratton et al. (2003), Milne et al. (2005 and 2009), NICE (2006), Koretz (2007)), have tended to scrutinise the evidence base for the use of ONS, in a variety of clinical conditions and within the acute setting. A meta-analysis of 24 trials on oral energy and protein supplementation showed a reduction in mortality with ONS use, which was consistently significant in undernourished older adults over 75 years (Milne et al, 2005). In 2006, NICE reviewed studies comparing groups in the acute setting receiving either ONS alongside dietary advice or no advice/intervention at all. The results demonstrated significant weight gain in the groups receiving the intervention and a meta-analysis indicated a significant reduction in complications and mortality rate (NICE, 2006). This study has formed the basis of national policy in the UK on the management of Disease Related Malnutrition (DRM), but due to considerable heterogeneity of the included studies, the effect size for ONS has not yet been determined.

A 2007 review, which summarised a number of systematic reviews, covering a variety of clinical conditions within the acute setting, concluded that there is strong evidence to support the use of ONS in acutely ill patients with a wide range of clinical conditions (Stratton and Elia, 2007).

In response to the increasing focus on prescribing practices in primary care, The Medical Nutrition International Industry (MNI) has recently released an ‘ONS Dossier’

detailing the growing evidence that is available to support the use of ONS as an effective solution to improve patient outcomes and treat malnutrition (Engfer and Green, 2012).

Impact of dietary advice/intervention on malnutrition:

A Cochrane review conducted in 2007 and updated in 2011 became the first review to address the impact of dietary intervention and advice on DRM (Baldwin and Weekes, 2007; 2011), identifying 45 randomised controlled trials (RCTs) in four different comparisons: dietary advice to no advice; to ONS; to dietary advice plus ONS; and dietary advice plus ONS to no advice.

Increasing nutritional intake through diet alone

12 studies were identified for this comparison, one of which was conducted in elderly individuals, but not in a care home setting (Rydwik 2008, in Baldwin and Weeks, 2011). Combined analysis suggested increased weight (9 studies with an average of 81 participants), mid-arm muscle circumference (MAMC; 2 studies with an average of 65 participants) and energy intake (7 studies with an average of 67 participants) for subjects that received dietary advice compared to routine care. The authors advise caution when interpreting the findings on weight improvement as they were obtained from just one trial with high risk of bias (Macia, 1991, in Baldwin and Weekes, 2011).

Dietary advice compared with ONS:

8 studies were identified for this comparison, with just one study focused on elderly participants, not in a care home setting (Gray-Donald 1995, in Baldwin and Weekes, 2011). Combined analysis demonstrated significantly greater weight gain (7 studies

with an average of 57 participants) in groups receiving ONS, but observed no statistically significant differences for any other outcomes.

Dietary advice compared with dietary advice plus ONS:

16 studies were identified for this comparison, but no studies specifically used elderly participants. Combined analysis of the studies, suggested that subjects receiving both dietary advice and ONS were less likely to be admitted to hospital (2 studies with an average of 54 participants). The analysis also indicated significantly increased MAMC (3 studies with an average of 164 participants), Tricep Skinfold Thickness (TSF; 6 studies with an average of 64 participants) and handgrip strength (4 studies with an average of 77 participants).

Dietary advice plus ONS compared with no advice:

14 studies were identified, 2 of which used a population of frail elderly participants (Chandra 1985; Persson 2007, in Baldwin and Weekes, 2011). Combined analysis indicated weight gain (9 studies with an average of 50 participants), improvements in TSF (1 study) and increased energy intake (6 studies with an average of 60 participants) for those receiving dietary advice and ONS. None of these outcomes was seen within either of the studies using a population of frail elderly participants.

Patient-reported outcome measures and cost effectiveness

The Cochrane study highlighted a complete lack of evidence for the effects of dietary intervention on patient-reported outcomes such as quality of life and a similar lack of evidence regarding cost benefits. This has subsequently been highlighted as an area requiring further research.

Limitations of the Cochrane review

As statistical and clinical heterogeneity existed across all groups of trials identified, it is not yet possible to evaluate the effects of dietary advice/intervention given with or without ONS in different practice settings, patient groups or clinical conditions. Of the 45 studies reviewed, four were conducted with elderly participants, but no studies were described within the care home setting.

The quality of evidence in the review has been described as low to moderate, with the majority of studies being small (average study size, n=75) and lacking in power. As such, there remains a lack of good quality evidence for all of the reported outcomes and the authors acknowledged a limited evidence base to indicate that dietary intervention and ONS have equal efficacy in managing DRM (Baldwin and Weekes, 2011). Almost no information was provided within the studies, concerning the specific intensity and content of the dietary intervention used (foods or combination of foods used), limiting the practical application of findings. It is essential that future studies detail the type, intensity and duration of dietary intervention used.

2.2.2 Malnutrition Intervention in the care home population

Despite a population of 400,000 residing in UK care homes (4% of the over 65 population and 20% of the over 85 population), the care home setting is largely under-represented within research and as a result, the evidence to guide best care practices to improve quality of life is lacking (Cochrane Editorial Unit, 2013).

Initial scoping has highlighted an insufficient literature base to conduct a systematic review of malnutrition intervention in the care home population. A systematic search, highlighted a complete lack of RCTs, investigating the effectiveness of dietary intervention alone in the treatment of malnutrition, although a case-control study demonstrated significantly increased energy intake following 15-weeks of energy-

fortified meals. However, as study participants were of a healthy body mass index (BMI) (median: 23kg/m^2), the results cannot be generalised to a malnourished population (Odlund et al., 2003).

The effectiveness of ONS within long-term care has received more attention. A prospective RCT of 88 nursing home residents randomised to ONS or usual diet, demonstrated significantly improved energy intakes, mini-nutritional assessment (MNA) scores and weight with ONS (Lauque et al., 2000). A double-blind placebo RCT investigating acceptance and effectiveness of ONS, demonstrated a 2.5% improvement in body weight (Wouters-Wesseling et al., 2003).

Few RCTs have compared the effectiveness of malnutrition interventions in the care home population. One study, which compared three energy-dense snacks/drinks daily to three 300kcal ONS daily, demonstrated increased energy intake of 26-30% with snacks/drinks and 46-50% with ONS (Turic et al, 1998), but it was not clear whether the nutrient content of the interventions was comparable.

A more recent trial conducted with elderly care home residents, compared ONS intervention with dietary advice, in the form of a standardised advice sheet. The study reported increased energy and protein intakes that were 32% and 25% higher respectively in the supplement group (Parsons et al., 2011). However, the comparison between a cognitive intervention (written advice) and a physical intervention (ONS) introduces study bias and ultimately limits practical application.

2.2.3 Summary of existing research

The analysis of systematic reviews of malnutrition intervention and an extended review focusing on the care home population has revealed a lack of published clinical trials comparing food-based interventions with ONS interventions of equal

nutrient composition. To enable the efficacy of food-based strategies to be compared with ONS provision within a care home population, an adequately powered RCT is required, using interventions that are homogenous in nutrient composition alongside a comparative standard care arm.

Although both food-based and ONS interventions are established dietetic-led treatment options for malnutrition within care homes, existing studies provide insufficient information to plan a substantive trial in this care setting. It is therefore essential to show supportive data that the comparison and evaluation of these existing dietary interventions is acceptable and possible to implement within this population. We propose to undertake a pilot study, cluster randomised at the level of the care home, to assess the feasibility and acceptability of running a large-scale trial comparing and evaluating dietetic-led food-based intervention, dietetic-led ONS intervention and the standard care home dietary intervention plan for malnutrition.

2.Trial Design and Procedures

Further to the Medical Research Council guidance (MRC, 2008), which describes the importance of piloting to investigate trial uncertainties, a feasibility trial is proposed, with the following objectives:

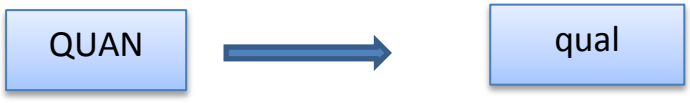
Process feasibility Objectives:	Objectives to inform future trial design:
Evaluation of the current dietary intervention plans for malnutrition: - Assess whether resident eligibility criteria for receipt of the dietary plans are too open or too restrictive - Assess recruitment and retention - Assess compliance and tolerance of each dietary plan - Assess whether assigned care home staff are able to complete the Malnutrition Universal Screening tool ('MUST')	- Assess whether the nutrient content of the dietetic- led interventions is optimal to deliver an effect - Collect data to inform sample size calculation and estimate Intracluster Correlation Coefficient (ICC) for the main trial - Pilot a method of collecting healthcare resource usage data
Research element: Resident and staff perspectives - Assess whether the dietary plans are acceptable to both residents and staff - Assess which outcome measures are most acceptable and feasible to use within the main trial, for both residents and care home staff - Assess whether residents are able to complete the study questionnaires - Assess whether assigned care home staff are able to complete the standardised mini mental state examination (sMMSE) and the healthcare resource usage questionnaire	- Review of the most appropriate participant-reported outcome measures to use within the main trial

The feasibility trial will recruit a variety of care home types, including nursing, residential and dementia focused, which will allow the evaluation of feasibility and acceptability of the trial design and methodologies across a range of long-term care settings. Randomisation will take place at the care home level. All residents with, or at risk of malnutrition, who do not already have a dietetic-led plan in place at baseline, but require dietary intervention to meet their nutritional needs, will be considered for receipt of the plan that is allocated to the care home. The dietary plan will be allocated for a 6-month period, but to ensure that this trial does not change usual, nutritional care at the individual level, the nutritional status of each care home resident will be monitored throughout the 6-month dietary plan, using usual outcome measures. Should a resident that is deemed suitable for the intervention at baseline,

not tolerate the plan, refuse to comply with the allocated plan, or require adjustments to meet their changing nutritional needs, the dietary intervention will be altered accordingly, to meet individual need.

In 2013, The Alzheimer's Society estimated that 80% of residents in care homes suffer with Dementia or severe memory problems (Quince, C, 2013). The population of residents identified with, or at risk of malnutrition in each care home, is therefore likely to include individuals that lack the capacity to consent for themselves. Residents with, or at risk of malnutrition that are eligible to receive the dietary intervention, but are lacking the capacity to consent will only be included to the level of usual care for malnutrition. Outcomes that are routinely measured to monitor nutritional status within usual care will continue to be collected and will be provided to the dietitian researcher, in a resident anonymous format. Residents who have capacity to consent, as determined by trained care home staff, will further be asked to consent individually to provide information on quality of life, health state and dietary satisfaction, and to be contacted regarding interviews, following the 6-month plan. Participant reported outcomes will be measured through completion of anonymous questionnaires and self-reported scales.

The feasibility trial will take the form of a sequential, explanatory mixed method design:



QUAN Data Collection *(usual, standard outcomes and participant reported outcomes)* → **QUAN** Data Analysis *(Descriptive Statistics)* → qual Data Collection *(Interviews /Focus Groups)* → qual Data Analysis *(Thematic)* → ***Interpretation of entire analysis***

'Quan' and 'qual' stand for quantitative and qualitative respectively.

Figure 1 (Adapted from Cresswell, 2009)

Following delivery of the 6-month dietary plan within each care home, the participant-reported outcomes, will be further explored with a sample of residents that have consented to take part in individual interviews. Upon receipt of management approval and staff consent, the acceptability and feasibility of the trial will also be discussed with care home staff using focus group techniques.

Semi structured interviews will explore the experiences and perspectives of the residents receiving the diet plans and providing self-reported outcomes, whilst focus groups will establish and provide reasoning for the 'collective' views of the staff delivering the plans and conducting the screening and outcome measures. The findings will complement, explore and explain the quantitative data collection and will ensure that resident and staff perspectives are used to inform the future trial design.

2.1 Entry Criteria

2.1.1 Inclusion Criteria

- Local Care Home that has received dietitian training

All care home residents that require dietary intervention for malnutrition will receive the randomly allocated dietary plan, provided they meet the following criteria

1. With/at risk of Disease related malnutrition using the Malnutrition Universal Screening tool ('MUST'; Elia, 2003)
2. Able to eat and drink
3. Registered with a Solihull GP and subsequently eligible for the provision of healthcare services provided by the Heart of England NHS foundation Trust (HEFT)

3.1.2 Exclusion Criteria

Residents will not receive the randomly allocated dietary plan if they,

1. Currently receive (or are likely to receive in the next 6 months) tube or parenteral nutrition
2. Currently receive nutrition support in the form of individualised dietetic advice or prescribed ONS.
3. Have a known eating disorder or illness, which requires a therapeutic diet incompatible with fortification and/or supplementation. This may include but is not limited to, Galactosemia or known lactose intolerance, chronic renal disease requiring dialysis, poorly controlled diabetes, in receipt of active cancer treatment, or liver failure.
4. Are on an end-of-life care pathway

The eligibility criteria listed, are those used within usual, standard assessment for those with, or at risk of malnutrition that are being considered for receipt of a dietary intervention plan.

Exclusion due to use/likelihood of parenteral nutrition or individualised nutritional support will be determined by the care staff, through review of current prescribed medications and a review of the current caseload of oral nutrition support patients held by the HEFT Nutrition Support Service and HEFT acute dietetic service. This review can take place without the involvement of the dietitian researcher.

Exclusion Criteria for outcome measures outside of usual, standard monitoring of nutritional status:

Participant- reported measures, requiring individual consent

1. Non-native English speaking
2. Lack the capacity to consent

Non-native English speaking residents with capacity will be excluded from participating in the collection of participant-reported outcome measures, and from the qualitative phase of the trial. The decision to include this exclusion criterion is based on existing knowledge and experience of the population group and a consideration of the finances available to run the pilot trial. The dietitian researcher practices clinically within Solihull care homes and estimates that less than 5% of the resident and staff population is non-native English speaking. Given that this trial will include a small cohort only, the number recruited is likely to be very small.

This feasibility trial is being conducted as part of a student Masters project and as such, has no additional funding attached to it. This limits the option to translate information leaflets into different languages and to hire an interpreter. In the future main trial, it is anticipated that additional funding will be available to ensure that where necessary, participant information sheets are translated and trained professional interpreters are arranged to discuss trial participation where language between the researcher and the participant is not shared.

Residents that lack the capacity to consent will be excluded from taking part in the participant-reported outcome measures. This part of the trial is additional to the evaluation of usual, standard nutritional care and therefore individual informed consent is required. As this is a feasibility trial, participation in these outcome measures will not be of benefit to the wider population of adults that lack capacity and therefore, the inclusion of this resident population in this part of the study cannot be justified (Mental Capacity Act, 2005).

3.2 Care home consent, resident eligibility and cluster randomisation

Care Home Consent:

The Dietitian Researcher will provide prospective care homes with a full explanation of the study. An invitation letter and an enclosed Information sheet will be sent to the Home Manager or Head Office (if operating within a larger provider). This will be followed up one week later, by a face-to-face visit or a telephone call to allow for further discussion, following which, the care homes will be given adequate time to consider consenting to participate in the trial. They will then be asked to sign consent forms. Importantly, Managers that agree for care homes to participate in the trial, can still choose to opt out of staff participation in post dietary intervention focus groups.

Nutritional screening using 'MUST':

Residents that are eligible to receive the allocated dietary plan, within each care home that has agreed to take part, will be identified using routine malnutrition screening and a review of their care records by care home staff. This reflects the usual assessment process, prior to implementation of a dietary intervention plan for malnutrition.

Two, assigned care home staff (Nurses or Senior Carers) per care home site will conduct nutritional screening using 'MUST' to identify those with/at risk of malnutrition. 'MUST' classifies risk as low, medium or high on consideration of BMI, history of unintentional weight loss and acute illness effect (Elia, 2003; NICE, 2006). Those residents that are moderate or high risk will be considered for receipt of the dietary intervention plan that is allocated to the care home.

Monthly ‘MUST’ screening of care home residents is standard care within all of the selected care homes. The tool has been validated for use in adults, has very good to excellent inter-observer reliability in care homes (kappa values of 0.8-1.0) and has been found to be acceptable to both participants and healthcare workers (Elia, 2003). To enhance the consistency of screening practice between care home sites, dietetic-led training will be provided to all assigned staff prior to commencement of the screening process.

Review of Care Home Records in line with eligibility criteria

Following ‘MUST’ screening, the care home staff will be asked to review the care records of those residents that have been identified as moderate or high risk of malnutrition. They will check that each resident meets all of the eligibility criteria to receive the allocated dietary plan. This process will ensure that the initiation of an intervention will be safe and appropriate for the individual.

The care staff will be able to consult with the Nutrition Support dietetic service, or the care home GP, as required. Once the eligible residents have been identified, the care home staff will assign a number to each individual resident, to be detailed on all trial related materials. This will enable subsequent outcome data to be collected anonymously from each care home site.

The care home staff will also complete a screening log for the care home site, detailing the number of residents screened, the number of residents eligible to receive the dietary intervention plan and the number of residents excluded for each of the eligibility criteria. This will be provided to the dietitian for data collection. The log will be completed on a 'whole home basis' and will include no personal or identifiable resident information.

The general practitioner (GP) for each care home site that is participating in the trial will be informed in writing of the involvement of the care home in the trial (with the care home consent to do so). The GP will be advised to consult with the care home staff, if further information is required regarding the involvement of individual residents under their care.

Assessment of capacity and receipt of individual consent for additional participant-reported outcome measures

For those parts of the trial, which fall outside of the evaluation of usual nutritional care and monitoring for malnutrition, including the collection of participant-reported outcome measures, individual resident interviews and staff focus groups, consent will be sought on an individual basis. Informed consent will be sought from individual residents that are assessed by trained care home staff or the care home GP as having capacity, to take part in additional participant-centric outcome measures and individual interviews.

The care home staff will make the initial approach to residents that have capacity to consent, to discuss their possible involvement in this research. There is a risk the care home staff will suggest only the more compliant residents to be involved, but it is hoped that the care home information sheet and associated consultation with the dietitian will enable them to make an informed decision, concerning who would be able to take part. Their wealth of knowledge about the prospective participants will be invaluable to this part of the trial.

If the approached resident would like to consider being involved in this aspect of the trial, which falls outside of usual nutritional care and monitoring, the care home staff will introduce them to the dietitian. The Dietitian Researcher will provide a full

explanation of the trial to each identified individual, alongside his or her Lead Nurse/Carer and family members, if preferred. A participant information sheet will be provided and the resident will be given sufficient time to read, ask further questions and decide whether they would like to participate in the additional outcome measures and whether they would like to be considered for an individual interview following the intervention phase. The resident will then be asked to sign a consent form. Importantly, residents that agree to the collection of additional participant-reported outcome measures may still choose to opt out of being considered for individual interviews.

Loss of capacity or fluctuating capacity during research:

The capacity of residents will not be proactively monitored during the trial, but should it be brought to the attention of the Dietitian Researcher that a resident who has consented to the additional participant-reported outcome measures has lost capacity during the study; the following process will be adhered to:

Figure 2: Loss of capacity during the study

Cluster randomisation at the care home level

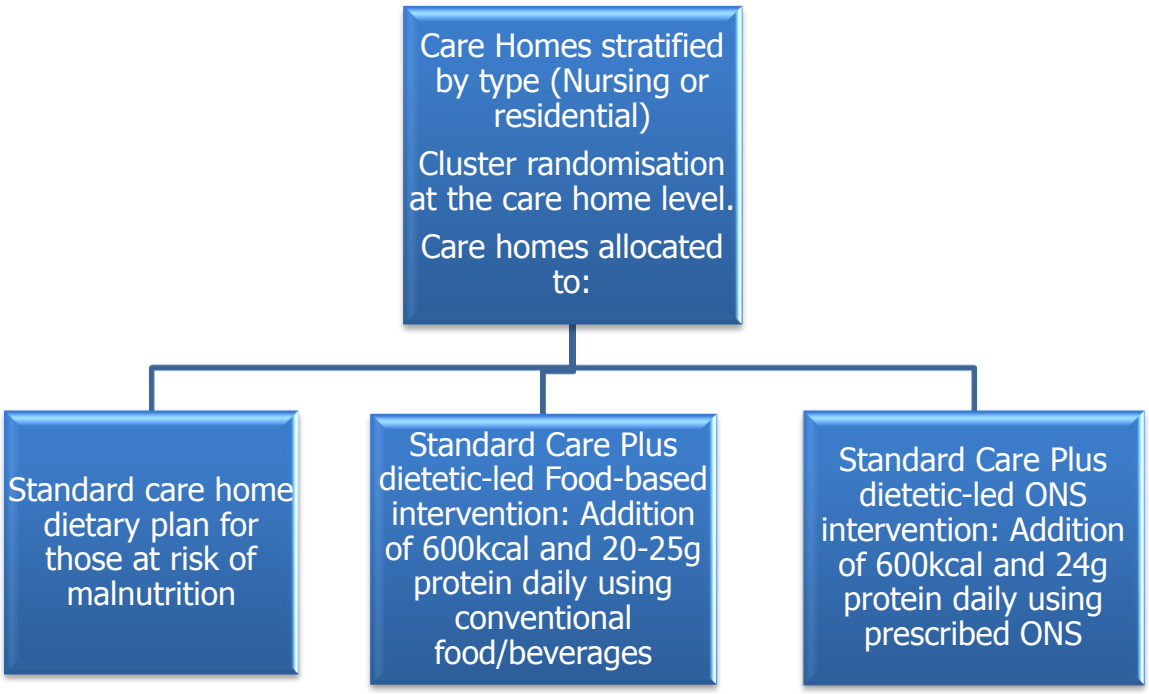


Figure 3: The randomisation process

Cluster randomisation using a computer-generated random number list will allocate each care home to either, dietetic-led food based intervention, dietetic-led ONS intervention or the standard care home dietary intervention for malnutrition. Stratification by care home type will ensure that one nursing home and one residential home is allocated to each intervention arm. The Dietitian researcher will communicate confirmation of the dietary plan allocation and the trial number to each participating care home.

Assigned care home staff within each care home will receive dietitian-led training to support delivery of the 6-month allocated dietetic-led intervention plan and/or a refresher on the current standard care home dietary intervention for malnutrition. This training session will also cover the completion of required documentation and will provide an opportunity for any questions.

Sampling for Phase 2: Individual Interviews

Following delivery of a 6-month dietary intervention plan within each care home, those residents that indicated on the consent form that they would like to be considered for individual interviews, will form the sampling frame for potential inclusion within the qualitative phase of the trial.

A non-random method of purposive sampling involving care home staff discussions and consideration of the findings from the participant-reported outcome measures will identify two-three potential participants per care home for individual semi structured interviews with the Dietitian researcher. The care home staff will again make the initial approach to the potential participants to discuss their possible involvement. Those that remain interested in participation will be introduced to the Dietitian, to provide further verbal and written information on this part of the study.

A focus group of between two and eight staff will be identified within each care home site that has management approval for staff participation (Gill et al., 2008). Care Home staff will be selected on the basis that they have had experience of participating in the trial and will therefore have something to say. A focus group will be held within each individual care home to ensure that the staff are comfortable in speaking to each other (Richardson and Rabiee, 2001). The groups will be held at a date and a time that is suitable for the staff and will not affect staffing levels. This may need to be before, after, or between shifts and can be scheduled accordingly, as agreed with the care home manager.

Topic guides for the resident interviews and the Staff Focus Groups have been developed using the feasibility objectives. Themes and core questions will be refined following the 6-month dietary intervention and collection of participant-reported

outcome measures. Separate information sheets for residents and staff and consent forms have been developed for this qualitative phase and will be presented to eligible residents and to staff prior to their inclusion.

3.3 Baseline Assessments

Resident Characteristics

Following confirmation of resident eligibility to receive a dietary intervention plan, the care home staff will complete a baseline assessment form for each resident. This form will include the following information:

1. Resident Number (assigned by care home staff following screening)
2. Resident gender
3. Care Home Type (Nursing, Residential, Dementia-specific)
4. Primary Diagnosis
5. Diagnosed Dysphagia (Yes or No). If Yes, to indicate recommended food and fluid modifications
6. Diagnosis of Dementia (Yes or No)
7. Risk of re-feeding syndrome (Yes or No). If yes, to indicate risk factor(s)
8. Capacity (Yes or No)
9. Informed consent received (Yes or NO)
10. sMMSE Score **(for those with capacity only)**
11. Height (to indicate whether measured, reported, or an alternative measure)

This information is required within usual, clinical practice, prior to initiation of a dietary intervention.

Baseline nutritional assessments **(Table 1)**

Nutritional assessments undertaken within usual, standard practice, include,
Dietitian Measured:

1. **Mean Nutrient Intake (energy, protein, fluid)**: Calculated from dietetic analysis of three consecutive 24-hour food record charts. Usual tableware such as bowls, plates and glasses will be measured in each care home at baseline and the size/capacity recorded. Nutrient intake will be determined using the dietary analysis software package **Diet Plan 6** (Forestfield Software Ltd, UK).
   Food record charts are completed for those at risk of malnutrition as part of usual practice within each care home. The charts provided to the dietitian will be anonymous.

2. **Anthropometry**
   As per usual, standard practice, the care home staff will make the initial approach to each resident to discuss the anthropometry measures that the dietitian will take. These measures are used to monitor nutritional status in usual, standard care and will be measured by the dietitian, because they are clinically trained to do so. The measured data will be recorded in an anonymous format by the care staff. The dietitian may be provided with the first name of the resident to enable them to establish a rapport, but they will not need to access the resident's care records or collect any personal data, in association with the following measurements:

- **Handgrip strength**: An index of general upper extremity strength (function). Measured using a **handgrip dynamometer** on the non-dominant arm (Todorovic & Micklewright, 2011). Functional changes respond more quickly to nutritional support than other anthropometric parameters (Hornby et al, 2005). Limitations of the technique include the influence of debility, age and familiarity with the technique (Thomas and Bishop, 2007).

- **Mid Arm Muscle Circumference (MAMC):** An estimate of muscle mass. Calculated using Mid Upper Arm Circumference (MUAC) (which will be measured with a tape measure by care home staff) and Tricep Skinfold Thickness (TSF) (Measured with a standardised skinfold calliper by the trained dietitian): **MAMC (cm) = MUAC (cm)- 3.14 X TSF (cm)**
  TSF can be insensitive to small changes, which could limit its use as a short-term monitoring tool within this trial (Thomas and Bishop, 2007).

Care Staff Measured:

1. **Anthropometry (anonymous data provided to the dietitian)**

- **Height (m):** Taken from clinical records, or measured using a stadiometer. Reliable measurement within the elderly population can be challenging due to vertebral compression, reduced muscle tone and changes to posture (WHO, 1995). If standing height cannot be measured, self-reported height is considered the superior secondary method or ulna length can be measured to obtain an estimate (Thomas and Bishop, 2007).

- **Weight (Kg):** Measured using clinical calibrated standing, chair or hoist scales (Todorovic & Micklewright, 2011). Body weight is affected by fluid retention, oedema and ascites (Thomas and Bishop, 2007). In the presence of such factors, a correction will be subtracted from measured weight (Todorovic & Micklewright, 2011).

- **Body Mass Index (BMI):** A measure of adiposity, calculated by: **weight (kg)/height (m²).** Validity is limited by the influence of gender, ethnicity and age on body composition (Prentice & Jebb, 2001). Reliability is questionable in the presence of confounding factors including oedema or ascites (Harris and Haboubi, 2005).

Additional outcome measures for residents that have the capacity to consent

Care Staff measured:

- Standardised Mini Mental State Examination (sMMSE) Screening:
  Assigned care staff will use the sMMSE (Molloy and Standish, 1997) to assess the cognitive abilities of the residents that have consented to participate in the collection of additional outcome measures. sMMSE score will be determined at baseline only. This assessment is completed by senior care staff or by the GP within the care homes, as part of usual cognitive assessment.
  The sMMSE has significantly better inter-rater and intra-rater reliability than the Mini Mental State Examination MMSE (Folstein et al., 1975) and takes less time to administer (10 minutes). Permission has been granted by Professor Molloy to use this tool.

The following outcome measures are not currently used within usual practice and may be considered an additional burden to residents. These outcomes will only be measured following the receipt of individual informed consent from the residents within each care home that have the capacity to do so.

Participant rated:

1. **Health state,** using The EuroQol-5D (EQ-5D**)** and
   Quality of life using the CO-OP Quality of life chart. There is no malnutrition specific measure of health state or quality of life for patients, so these well-established and validated measures will be used. The Euroqol group and the Dartmouth CO-OP project have granted permission to use the tools.

2. **Appetite and Dietary Satisfaction**, using a Visual Analogue Scale (VAS). Studies have indicated that measured food intake appears to be related to the perceptions of hunger and fullness assessed by VAS (Flint et al, 2000; Parker et al, 2004)

Table 1: Assessment Schedule

		Assessment Time		
Measure	**Completed by**	**Baseline**	**3 months**	**6 months**
Nutrient Intake	*Dietitian*	✓	✓	✓
Texture modification	*Care Home staff*	✓	✓	✓
Height	*Care Home staff*	✓		
Weight	*Care Home staff*	✓	✓	✓
BMI	*Care Home staff*	✓	✓	✓
Handgrip Strength	*Dietitian*	✓	✓	✓
MAMC	*Dietitian*	✓	✓	✓
sMMSE	*Care Home Staff*	✓		
[1]VAS	*Participant rated*	✓	✓	✓
[1]EQ-5D	*Participant rated*	✓	✓	✓
[1]CO-OP QoL	*Participant rated*	✓	✓	✓
Healthcare resource usage	*Care Home Staff*		✓	✓
Compliance	*Care Home staff*		✓	✓

[1]Participant-reported outcomes: data will only be collected from those residents that have capacity and have consented to completing the questionnaires and VAS.

3.4 Interventions

All of the residents with, or at risk of malnutrition within the participating care homes will continue to receive the standard care home dietary plan for malnutrition, with individualised dietetic-led interventions added for the residents within care homes randomised to the food-based or ONS intervention arms. A Registered Dietitian will deliver these interventions in the care homes, as per usual, standard practice.

3.4.1 Dietary Intervention Arms

Food-based Intervention

The content of the food-based intervention will be based on the guidelines developed as part of the Solihull Nutrition Support Project (2012) and national guidance for best practice, including The Malnutrition pathway (2012), which has been developed and agreed by a multi-professional consensus panel.

Assigned care staff within the care homes randomised to food-based intervention will receive instruction by the dietitian to increase resident daily nutritional intake by 600kcal and 20-25g protein, alongside the current standard dietary intervention plan for malnutrition.

Techniques to achieve the required nutrient increase will include additional fortification of conventional food with ingredients that are energy/protein dense, provision of fortified fluids (as shots or drinks) and nourishing between meal snacks. The intervention will be resident-focused, with an emphasis on adaption of familiar and well-liked food and drink items that can be provided daily within the care home. This process follows usual, standard care for implementation of dietetic-led food based intervention in the treatment of malnutrition.

The Dietitian researcher will determine compliance with the food-based treatment plan at 3 months and 6 months. The care home staff will be required to record resident intake of the recommended food-based intervention on the daily food record chart, as a proportion taken, as per usual, standard practice. The dietitian will calculate average intake from a 3-day anonymous chart at 3 months and 6 months. Compliance will be categorised into ‘compliant’, if more than 75% of the advised food/beverage is consumed daily and ‘non-compliant’ if less than 75% is consumed.

ONS Intervention

Assigned care staff within the care homes allocated to dietetic-led ONS intervention will receive instruction by the dietitian to increase resident daily intake by 600kcal and 24g protein, through the provision of 2 liquid ONS daily. The ONS will be provided alongside the current standard dietary intervention plan for malnutrition.

The ‘standard’ ready to drink ONS is comprised of a combination of macronutrients and micronutrients and is presented in liquid form (NPC, 2012). These widely used supplements provide approximately 300kcal and 12g of protein per serving (BMJ Group and the Royal Pharmaceutical Society of Great Britain 2011). Three ‘standard’ supplements will be used within this study:

Fortisip 200ml bottle, Fortisip Compact 125ml bottle and Nutriplen 125ml bottle.

Table 2: Oral nutritional supplement composition

ONS	Volume (ml)	Kcal/ml	Energy content (kcal) per serving	Protein content (g) per serving
Fortisip Bottle (Nutricia Advanced Medical Nutrition)	200	1.5	300	12
Fortisip Compact (Nutricia Advanced Medical Nutrition)	125	2.4	300	12
Nutriplen (Nualtra Ltd)	125	2.4	300	12

*Nutritional information taken from: http://www.nutricia.ie/products and http://nualtra.ie/information-for/dietitian.

Fortisip bottle and Fortisip compact will be provided by Nutricia for the first 3-months of the trial. Nutriplen will be provided by Nualtra for the second 3-months of the trial. All of the ONS will be provided to residents under the control of a registered dietitian. The Fortisip Compact and the Nutriplen supplements are more nutrient dense per ml than Fortisip, but a bottle/serving of each supplement is equivalent in nutritional content. Each resident will be provided with 2 bottles/servings daily. The Dietitian researcher will determine compliance with the intervention at 3 months and 6 months. The Care home staff will be required to record intake of ONS on the daily

drugs chart, as a proportion taken, as per usual, standard practice. The dietitian will calculate average intake from a 3-day anonymous drugs chart at 3 months and 6 months. Compliance will be categorised into ‘compliant’, if more than 75% of the advised dose is consumed daily and ‘non-compliant’ if less than 75% is consumed.

Standard Care Arm

Residents within the care homes allocated to provide the current standard care home diet for malnutrition, without added dietetic intervention, will be provided with an energy-enriched diet plan, in line with the training already provided to care home staff (including catering teams) by the Registered Dietitian. This will ensure that no resident at risk of malnutrition is denied access to first-line treatment (NEAC, 2008).

The purpose of the standard care home dietary intervention, is to provide and encourage a calorie dense diet (Department of Health, 1992), which may be achieved through provision of small, frequent meals and/or recipe enrichment with additional calories alongside prompting and assistance from care home staff where required. The care homes randomised to standard care will continue to receive monthly visits from the Dietitian in line with standard local practice. The Dietitian will meet with the nutrition leads already established at each home, but will not provide individualised plans for residents.

Although a specific dietary, intervention plan will be allocated to each participating care home, there will be no change to the usual, standard nutritional care and monitoring that is provided at the individual resident level. Should a resident not tolerate the allocated intervention plan, refuse to comply with the intervention plan, or require adjustments to meet their changing nutritional needs; the dietary intervention plan will be changed accordingly. The proportion of residents in receipt of the,

standard care home diet for malnutrition that ultimately require dietetic-led intervention within the 6-month period will be collected.

If any resident suffers a significant decline in their nutritional status and the care home staff deem it appropriate to make a formal referral to the nutrition support dietetic service, the resident will be withdrawn from the trial and no further data will be collected. This will allow the dietitian to have access to the resident's care home record and to conduct a full clinical assessment.

3.5 Outcome measures

3.5.1 Timing of Assessments

Assessments will be made at baseline, at 3 months and at 6 months. All assessments will be conducted within the care homes, in line with usual, standard practice for monitoring of nutritional status.

3.5.2 Pilot outcome measures

As this is a feasibility trial, there is no specified primary outcome measure.

Existing studies that have evaluated the effectiveness of ONS within the older malnourished community population (Hubbard et al., 2008; Parsons et al., 2011) have measured change in energy intake as the primary outcome measure. In theory, an increase in energy intake will result in weight maintenance or weight gain (Stratton et al., 2011), alongside changes in other anthropometry parameters (such as Handgrip strength and MAMC), which reflect clinical and nutritional status (Thomas and Bishop, 2007).

The 2011 Cochrane review of malnutrition intervention studies, highlighted considerable heterogeneity in the outcome measures investigated, including

mortality, morbidity and a variety of measures of nutritional status (weight, change in nutritional intake and Mid Arm Muscle Circumference (MAMC)). There is a lack of good quality evidence for all reported outcomes, particularly within the care home setting.

This trial will review the feasibility and acceptability of a range of outcome measures for use within the main trial. Outcome measures that are routinely collected within the usual monitoring of nutritional status, such as change in energy intake and anthropometric parameters (weight, BMI, handgrip strength and MAMC) will continue to be collected for all residents with, or at risk of malnutrition that are placed onto a dietary plan. This data will be provided anonymously to the dietitian.

The Cochrane study highlighted a particular need for evidence for the effects of malnutrition interventions on patient reported outcomes. Additional, participant-reported outcome measures such as quality of life (CO-OP Charts), health state (EQ-5D) and participant rated appetite and dietary satisfaction (VAS), will be explored with those residents that have capacity and have provided written informed consent to participate in the collection of this information.
The EQ-5D, CO-OP Charts and VAS appetite tools are well-established research tools. They are considered quick and easy to complete (Bowling, 2009), but require piloting within the care home population, to inform as to whether they are appropriate for completion by care home residents that have been assessed as having capacity.

This trial will also pilot a healthcare resource usage questionnaire, developed from consideration of existing instruments that have been submitted for use in residential care settings on the DIRUM database (http://www.dirum.org).This questionnaire has

been designed to only collect data that already forms part of the information that may be gathered by the Dietitian during usual, standard assessments and review consultations, but it will be piloted for completion by care home staff. Completed questionnaires will be provided to the dietitian in an anonymous format. There are no instruments specifically for malnutrition interventions, but the pilot findings may inform future development.

Sequential Qualitative assessment

Participant Semi Structured Interviews

The dietitian researcher will use a semi structured interview approach with the residents recruited into the qualitative phase of the trial. The interviews will be organised around a topic guide, designed to explore the perspectives of the residents on taking part in research, and the experiences of residents within the care homes randomised to all three dietary intervention plans.

The interviews will be conducted face-to-face, to provide a means of acquiring insight and understanding of the resident experience and values (Ritchie and Lewis, 2003) and are anticipated to last for 30 to 60 minutes for each individual.

The interview schedule will consist of the same predetermined open-ended questions for each resident, but it is anticipated that other questions will emerge during the interview process. Open-ended questions will be used to elicit the individual perspectives of each resident and to encourage them to reflect on their experiences (Warren and Karner, 2005).To gain further insight into the resident experiences; the Dietitian will use more probing questions as required. The basic research question to be explored will be the acceptability of participation in the trial. This will be explored in relation to the completion of the questionnaire, chart and

scale at baseline, 3 months and 6 months. The dietitian will also further explore quality of life and dietary satisfaction on the allocated dietary intervention plan.

Staff Focus Groups

The dietitian researcher will facilitate a focus group discussion with between 2 and 8 staff within each care home that participates in the trial and for which management approval has been received for focus group participation. As with the resident interviews, the focus groups will be built around a topic guide, developed to expand on the quantitative findings, by exploring further the feasibility and acceptability of the trial.

This technique has been chosen as a means of obtaining information about a range of staff experiences and to highlight any variations in perspectives between the staff within each home and between care home types (Rabiee, 2004).

The groups are anticipated to last 1 to 2 hours duration. The staff will be informed about the time commitment required within the information sheet provided prior to the qualitative phase of the trial and the focus groups will be organised at a time when it is convenient and safe for the staff to attend. It is hoped that the focus groups will generate a lot of information in a relatively short amount of time. As the staff within a care home work closely together, it is anticipated that they will be able to engage in discussion.

The qualitative research phase will be iterative in nature. Questions may be altered as the subject is explored and better understood. Digressions from the topic guide may occur, as a means of further exploring a resident or a staff group's interest or thoughts. In light of the possibility for digression, the interviews and focus groups will be audio taped, to enable transcription for analysis (Rubin and Rubin, 2005).

Audiotaping will allow the Dietitian Researcher to concentrate on interacting with the participants and will enable a more accurate transcription of the interview

Permission to audio tape the interviews and focus groups will be obtained prior to the start of the qualitative phase.

3.Safety Assessment and Reporting

The Medicines and Healthcare products Regulatory Agency (MHRA) define ONS as Non Investigational Medicinal Products (NIMPs). ONS will be provided by Nutricia and used under the control of a Registered Nutrition Support Dietitian within this trial.

Risk of re-feeding syndrome on initiation of an energy fortified diet or ONS:

Those at risk of re-feeding syndrome will be identified through routine 'MUST' screening, if they have any of the following: a BMI of less than 16kg/m^2, weight loss of greater than 15% over the last 3 to 6 months, no or negligible dietary intake for 10 consecutive days (NICE, 2006). If any resident is identified as being at risk of re-feeding syndrome at baseline, nutritional intervention will be commenced cautiously, at 10kcal/kg/day, increasing to provide the additional 600kcal and 20-25g protein by day seven. The dietitian may also request that the GP monitor electrolytes and glucose. This procedure is in line with usual, standard dietetic practice and national guidance (NICE, 2006).

Deteriorating swallow function (dysphagia) and an increased risk of aspiration:

If dysphagia is identified or suspected during the 6 month dietary intervention, by the care home staff or the dietitian researcher, this will prompt a referral to the Speech and Language Therapy (SaLT) team, as per usual standard practice.

3.1 Adverse Events (AEs) and Serious Adverse Events (SAEs)

We consider this trial to be low risk. The delivery of existing and established dietary interventions will be conducted in line with usual, standard practice as part of an evaluation of current dietetic service provision to care home residents with, or at risk of malnutrition.

The dietary interventions are well established and are currently in use to treat malnutrition in the care home population. Expected adverse events may include:

- A risk of mild side effects in response to a fortified diet or prescribed ONS, including diarrhoea, bloating, nausea and satiety. As diarrhoea is occasionally reported in practice on initiation of ONS, this has been stated clearly within the Care home information sheet. If a resident suffers with diarrhoea on commencing the ONS intervention, it will be classed as an adverse event (AE) and an indication that the supplement should be discontinued for that individual, with the option to change to the standard care home diet for malnutrition.

No other risks are anticipated and therefore it is reasonable to collect only targeted dietary intervention related AEs and only serious adverse events (SAEs) requiring hospital admissions that are due to avoidable malnutrition or dehydration.

3.2 Reporting of Adverse Events and Serious Adverse Events

The care home staff will be required to inform the Dietitian Researcher if any AEs/SAEs relating to a resident's malnutrition and/or its treatment are identified, through the completion and faxing of an anonymous adverse event form**.** The incidence and frequency of AEs will be recorded at 3 months and 6 months.

Care home staff will also report the incidence and frequency of hospital admissions, GP visits and specialist nurse visits on the resource usage form for each resident in receipt of a dietary intervention plan at 3 months and 6 months.

Death from any cause should be reported by care home staff on an anonymous AE form and faxed to the dietitian researcher.

3.3 Assessing severity and causality of AE and SAEs

All AEs and SAEs should be evaluated by a doctor (the GP) to establish the severity and the causality between the dietary intervention allocation and the AE/SAE and will be reviewed by the joint Data Monitoring/Trial Steering Committee on a three monthly basis.

4.Sample Size and Recruitment

4.1 Sample Size

As this is a feasibility trial, a formal sample size calculation is not needed (Arain et al., 2010). Six local care homes will be recruited into the trial and will be randomised into the three dietary intervention arms. Based on the capacity of the selected care homes and the risk of malnutrition within this population, we estimate that between 8 and 30 residents will be identified as moderate or high risk of malnutrition within each participating care home and will be considered for receipt of the assigned dietary intervention plan.

4.2 Recruitment

As part of the Solihull Nutrition Support Project (February 2011 to present), dietetic led training has been delivered to 17 local care homes, to standardise and improve the identification and first-line nutritional management of malnutrition. Nutrition Leads

(Nurses or Senior Carers) have been established within each care home and meet regularly with the Dietitian to ensure continued best practice. To commence recruitment as soon as possible, 6 local care homes have been identified for the study, which reflect the variability of the care home population and are anticipated will be willing to participate, based on their support for the existing project work.

5.Analysis

Anonymous resident data, provided by each participating care home, will be analysed in the treatment group to which the care home was randomised, on the intention-to-treat (ITT) principle. The Birmingham Clinical Trials Unit (BCTU) will provide support with the analysis of data.

6.1 Quantitative Analysis

As effective hypothesis testing requires a powered sample size (Arain et al., 2010), analysis will be limited to, descriptive statistics and an exploratory analysis to provide estimates of key parameters and to inform the future trial design.

The objective of the trial is to assess the feasibility and acceptability of a full-scale cluster randomised trial comparing food-based intervention, ONS intervention and standard care within a malnourished care home population. To inform the design of the full-scale trial, within this feasibility trial we will assess:

- Feasibility
- Resident and care home staff acceptability
- Recruitment and retention

Screening logs completed within each care home will provide valuable information on the numbers of residents screened using ‘MUST’, and the reasons for not

receiving the dietary treatment plan, particularly in relation to the eligibility criteria and assessment by care home staff.

Data on care home withdrawals from the trial, changes to resident dietary intervention plans, mortality, adverse events and compliance will be collected throughout the trial. This data will allow assessment of retention rates, reasons for withdrawal from the trial, or the dietary plans, and will inform aspects of feasibility and acceptability reporting, including the acceptability or appropriateness of including a standard care arm.

Data from this feasibility trial will also be used to inform suitability of participant-reported outcome measures, provide data to inform a sample size calculation and pilot the healthcare resource usage questionnaire for the full-scale trial.

Data is being collected on a number of outcome measures. The data collected will be summarised using summary statistics and an exploratory analysis will be performed. The differences between the arms at 3 months and 6 months, and in the change from baseline to 3 months and 6 months will be calculated for continuous outcome variables, such as nutrient intake and anthropometric parameters, along with 95% confidence intervals. This data will be used to review the sensitivity of the outcome measures to change. Appropriate techniques such as correlation methods will be used to assess and inform which outcome measures are most appropriate to take forwards into the substantive trial.

The data collected within this trial will also provide the data necessary for a sample size calculation and will help inform a calculation of the Intracluster correlation coefficient (ICC) for a full scale trial.

6.2 Qualitative Analysis

The qualitative data will be analysed using the Krueger (1994) and Ritchie and Spencer (1994) framework analyses, assisted by the NVivo computer program as required. The process of data analysis will begin during data collection, through the effective facilitation of the interview and focus group discussions, complemented by observational notes. Following data collection, the dietitian researcher will transcribe the audio tapes and identify major themes.

Concepts, ideas and short phrases identified within the text, will be used to develop categories and a thematic framework. Once a framework has been developed, the data will be indexed using a process of sorting, highlighting and arranging quotes to make comparisons between and within cases. Once indexed, the quotes will be re-arranged under the appropriate thematic content.

The final stage of analysis will be mapping and interpreting the data, identifying links between the quotes and exploring and explaining patterns of association.

The qualitative analysis will be interpreted alongside the quantitative feasibility and acceptability findings, to inform the design of the future main trial.

6.Research Governance

The conduct of the trial will be in accordance with the International Conference on Harmonisation guidance for Good Clinical Practice (ICH GCP) and the Department of Health's Research Governance Framework (2nd ed, 2005). This student project is being conducted with on-going advice and support of BCTU.

6.1 Ethics

The trial will be submitted for NRES approval and for local Research and Development Department (R&D) approval at each care home site.

6.2 Sponsor

The Heart of England NHS Foundation Trust has agreed to sponsor the trial

7.3 Joint Trial Steering Committee (TSC)/Data Monitoring Committee (DMC)

The joint TSC/DMC will include the Dietitian Researcher, Chief Investigator of the pilot trial and three or more independent members. The independent members will include an independent statistician, a dietitian not involved in the trial and care home staff, independent from the trial. The TSC/DMC will meet every 3 months to undertake safety monitoring.

7.4 Confidentiality of Personal data

This trial will collect anonymous resident data only. No personal information will be collected, with the exception of resident name and signature, for those residents that consent to take part in the participant-reported outcome measures and individual interviews. This information will be collected on paper consent forms and will be securely stored at the HEFT Nutrition Support Service office base, within locked cabinets. Residents will be asked to consent to this.

Consent to provide the dietitian with anonymous outcome data will be received by each participating care home. The participating care homes will be informed that their trial data and information will be securely stored at HEFT Nutrition Support Service office base and will be asked to consent to this. The data will be entered

onto a secure computer database. All information collected for the trial will be treated as strictly confidential. Members of the existing care team only, will conduct a review of resident care records, prior to initiation of the allocated dietary intervention plan.

7.5 Long-term storage of data

In line with Good Clinical Practice guidelines, all essential documentation and data will be retained for at least 5 years.

8 Trial Organisation

8.1 Care Homes

The Care home Manager and care staff will be involved throughout the trial process, as 'research partners' and will support the following aspects of the trial:

- **Recruitment and consent**: the staff and residents have contributed to the development of the trial and participant information sheets. The senior care home staff will make decisions on capacity to consent, will undertake the malnutrition screening process using MUST and will review resident care records against the inclusion and exclusion criteria.
- **Delivering Interventions**: The care home staff will be responsible for the delivery of the allocated dietetic-led intervention and/or standard care to the eligible residents.
- **Data gathering**- Assigned care home staff will take responsibility for gathering data for the trial, including outcome measures: weight, height, BMI and resource utilisation. They will also record daily food intake, compliance with the interventions and will deliver the EQ-5D and VAS questionnaires to those residents that have capacity and have consented to participate in these additional outcome measures.
- **Interpretation of findings**- Through focus groups and feedback.
- **Future trial design:** The collective opinions and feedback from care home staff and residents will be used to inform the future trial design.

8.2 Finance

This trial is being undertaken as a student project, as part of the National Institute for Health Research (NIHR) Clinical Academic Training Programme for AHP's (Masters in Research). The trial will be self-funded and will involve no research costs for the NHS trust as no additional follow up visits or investigations are needed, other than those that would normally be required for standard care of residents.

8.3 Training

A training session will be held within each care home for assigned care staff prior to commencement of the trial.

9 Project Timetable

Time:	**Action:**
September 2013	National Research Ethics Service application submitted and approval obtained
October 2013	Local R&D approval applications submitted
October/November 2013	Local R&D approvals obtained Care Home recruitment and training and resident consent and recruitment for participant-reported outcome measures commences
December 2013	Baseline Assessments completed and 6-month intervention commenced in all 6 care homes. (Commencement may be staggered)
July 2014	6 month follow up completed in all 6 care homes Quantitative data analysis and qualitative data collection commences
December 2014	Data analysis and write up of trial report completed

APPENDIX 9:
PARTICIPANT INFORMATION SHEET FOR QUESTIONNAIRES

Resident perception of quality of life, health state, appetite and dietary satisfaction on a dietary plan for malnutrition

Information Sheet

Researcher/Dietitian Contact Details:

Patient Services Department (formerly PALS):

Participant Information Sheet

You are being invited to provide information in a **research study**. Before you decide whether you would like to provide this information, it is important you understand why the study is being done and what your participation will involve.
Please read the following information carefully and discuss it with others if you wish. Ask us if anything is not clear or if you would like more information.
Take time to decide whether you wish to take part.

Thank you for reading this.

What is the purpose of the study?

- **We want to gather information on care home resident experiences of following a dietary plan for malnutrition (undernutrition).**
- **We want to use this information to compare different dietary plans that are currently being used in care homes**
- **This study will be a pilot (a small experiment) to help us to find out if our study plan works and if we need to change anything**
- **We plan for a larger study in the future to give us information on which dietary plan works best**

Why have I been asked to provide information?

- **Your care home is one of six that has agreed to allow us to evaluate a current dietary plan for malnutrition.**
- **We are asking you to tell us about your experiences of receiving this dietary plan, because you are at risk of malnutrition (undernutrition) and your opinion of the diet will help us to decide how well it is working.**

Do I have to provide this information?

- **The decision is yours**
- **If you decide to take part, you will be given this information sheet and we will ask you to sign a consent form**
- **You can change your mind at any time, you do not have to give a reason**
- **If you do not wish to take part or if you withdraw, this will not affect the care you receive**

How will I share my experiences of the diet that I am following?

- **Your care staff will ask you to complete 2 short questionnaires and 2 scales**

- **These questionnaires and scales will ask about your quality of life, your appetite and your satisfaction with your diet.**

- **You will not have to write anything. The questions will ask you to tick a box or to place a mark on a scale.**

- **You will not need to give your name. All the information you provide will be anonymous (your identity will be unknown)**

- **You will be asked to complete these questionnaires, 3 times in 6 months**

After the six months

- **After 6 months, the Dietitian may wish to speak with you individually (interview) to find out more about your experiences of completing these questionnaires and your opinion of the diet you have been receiving**
- **This is optional. You can tell us on the consent form if you do not wish to be interviewed**
- **Even if you say 'yes' now, you can change your mind later**

What are the possible disadvantages and risks of providing this information?

- **We do not think there are any disadvantages or risks to completing the questionnaires and scales to provide us with information.**

What are the possible benefits of taking part?

- **You may not get a direct benefit from taking part, but the information we get from you may help us to treat people better in the future**

- **We will use our findings for a future bigger study**

What if I wish to make a complaint about my involvement?

- **If you wish to complain or have concerns about the way you have been treated, ask the care home staff if you can speak with the Heart of England NHS Foundation Trust complaints Manager.**

You can also ask your carers or family to do this on your behalf

- **If you have any concerns or questions, please contact the Dietitian, who will do her best to answer your concerns:**

- **If you remain unhappy and wish to complain formally, you can contact your Patient Services Department (formerly PALS) on**

Will anyone know that I have taken part in this study?

- **All information you give us will remain anonymous, it will not be possible for anyone to work out that you have provided the information**
- **No personal details will be collected, with the exception of your name and signature on the consent form. This form will be stored in a locked cabinet at the Heart of England NHS Foundation Trust Nutrition Support Service office base.**
- **No names will be given when the results are written up**

What will happen to the results of the research study?

- **The results may be put into a nutrition journal after the study but no care homes or residents will be named**

Who is organising and funding the research?

- **The study is part of a student project that the Dietitian is completing**
- **It is self-funded**
- **No payments will be made to anyone involved in the study**

Who has looked at the research?

- **A group of people not involved in the study has looked at the research. This group is a Research Ethics Committee.**
- **They look at the research idea to protect your safety, rights, well-being and dignity**
- **This study has been reviewed and approved by *insert committee and date***

Contact for Further Information

Should you want further information about the study please contact:

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this information sheet

CARE HOME TRIAL NUMBER:

APPENDIX 10:
PARTICIPANT CONSENT FORM

Resident perception of quality of life, health state, appetite and dietary satisfaction on a dietary plan for malnutrition

	Please Initial Box
7. I confirm that I have read and understand the information sheet dated ***insert date*** for the above study and have been able to ask questions.	
8. I understand that providing information to the dietitian is voluntary and I am free to withdraw or decline at any time without giving a reason, - without the quality of my nutritional care - or legal rights being affected.	
9. I agree to provide information to the dietitian, through the completion of anonymous questionnaires and visual scales	
10. I agree to being considered for an interview with the dietitian after the study to discuss my experiences (optional)	
11. I agree to this consent form being securely stored at an NHS office base	

Name of participant: **Date:**

Signature:

Name of person informing participant:

Date: **Signature:**

For further information about the study please contact:

APPENDIX 11
FOOD-BASED INTERVENTION RECIPES

Intervention:	Recipe:
Fruit fool	300ml fruit puree, 150g custard, 2tbsp milk powder, 150ml evaporated milk, 1tbsp Honey (makes 3)
Chocolate mousse	1 sachet instant chocolate dessert, 4tbsp milk powder, 150ml double cream, 150ml full cream milk (makes 2)
Milkshake	200ml full cream milk, 1tbsp milk powder, 1tbsp double cream, milkshake powder to taste
Hot chocolate	200ml full cream milk, 1tbsp milk powder, 1tbsp double cream, drinking chocolate powder to taste
Malted drink	200ml full cream milk, 1tbsp milk powder, 1tbsp double cream, malted powder (Horlicks/ovaltine or equivalent) to taste
Coffee	200ml full cream milk, 1tbsp milk powder, 1 heaped tsp of coffee granules, 2tbsp double cream
Fruit smoothie	200ml full cream milk, 2 tbsp milk powder, 3tbsp double cream, 1 ripe banana/other fruit, 30g ice cream

Tbsp = Tablespoon

The nutritional content of the above recipes was analysed by the Primary researcher using the nutritional software package, Diet Plan 6.

APPENDIX 12
FOOD-BASED INTERVENTION CHOICES

Table A12.1: Agreed FB intervention choices at Baseline and at the 3-month review (T1)

Resident number	Agreed intervention	
	B	T1
SG01	Fruit fool	Fruit fool
SG02	Fruit fool	Fruit fool
SG03	Chocolate mousse	*Fruit fool
SG04	Chocolate mousse	Chocolate mousse
SG05	Hot chocolate x 2	*Fruit fool
SG06	Fruit fool	Fruit fool
SG07	Fruit fool	Fruit fool
SG08	Fruit fool	Fruit fool
SG09	Fruit fool	Fruit fool
SS01	Milkshake, malted drink	Milkshake, malted drink
SS03	Hot chocolate, malted drink	Hot chocolate, malted drink
SS04	Fruit fool	*Hot chocolate, malted drink
SS05	Milkshake, malted drink	Milkshake, malted drink
SS06	Milkshake, malted drink	Milkshake, malted drink
SS07	Milkshake, malted drink	Milkshake, malted drink
SS08	Fruit fool	**Left trial
SS09	Fruit fool	Fruit fool
SS10	Fruit fool	Fruit fool
SS11	Fruit fool	Fruit fool
SS12	Milkshake, malted drink	Milkshake, malted drink
SS13	Milkshake, malted drink	**Left trial
SS14	Milky coffee x 2	Milky coffee x 2
SS15	Fruit fool	Fruit fool
SS16	Milkshake, malted drink	**Left trial
SS17	Fruit smoothie, malted drink	*Malted drink, hot chocolate
SS18	Fruit smoothie, malted drink	*Malted drink, hot chocolate
SS19	Milky coffee, malted drink	Milky coffee, malted drink
SS20	Milkshake, malted drink	Milkshake, malted drink
SS21	Malted drink x 2	Malted drink x 2
SS22	Milkshake, malted drink	**Left trial
SS23	Fruit fool	*Hot chocolate x 2

*FB intervention alterations at T1 to accommodate for changing resident preferences; **resident had left the trial by the T1 data collection interval

APPENDIX 13:
ADVERSE EVENT FORM

The only adverse events being recorded in this trial are gastrointestinal symptoms (such as diarrhoea, bloating, nausea and early satiety) and serious adverse events requiring a hospital or GP visit that are due to avoidable malnutrition or dehydration. If such an adverse event is noted, please complete page 1 of this form and fax to

Resident Number:	Care Home Trial Number:

Adverse Event:

Date Event started:	Date event ceased:
Outcome: Fatal: ☐ Recovered: ☐ Continuing: ☐	
Details of Adverse Event: Causality (in the opinion of the GP or other professional):	
How was the event treated? (e.g. call out to GP)	

Did the event require hospitalisation? Yes ☐ No ☐

If Yes, please indicate the number of days: ☐

Did the event require the resident to change dietary intervention plans?

Yes ☐ No ☐

Reason why you consider the event to be related to nutritional status or treatment allocation :

Would the event be considered:

Expected ☐ Unexpected ☐

(in accordance with the expected side effects/trial protocol)

If expected, please tick one:

GI symptoms ☐ Re-feeding syndrome ☐ Dysphagia/risk of aspiration ☐

Name of person reporting

Signed Dated: / /

APPENDIX 14:
BASELINE RESIDENT ASSESSMENT FORM

(To be completed by care home staff)

Assigned Resident Number:

Care Home Name: **Care Home Type:**	**Care Home Trial Number:**

Medical Details:

Primary Diagnosis:	

Diagnosis of Dysphagia?	Yes ☐ No ☐
If YES, **FOOD** **FLUID:**	Normal ☐ Fork-mashable ☐ Thick puree ☐ Thin Puree ☐ Stage 1 ☐ 2 ☐ 3 ☐
Diagnosis of Dementia?	Yes ☐ No ☐
Assessed as having capacity?	Yes ☐ No ☐
If Yes, has informed consent been received for participant-reported outcomes?	Yes ☐ No ☐
Height (m):	☐ Measured ☐ Reported ☐ Alternative measure ☐

Form Completed by (print name):

Signed:_____ Date:_____

APPENDIX 15:
HEALTHCARE RESOURCE USAGE QUESTIONNAIRE

To be completed by care home staff

We would like to know how much use this resident has made of health services over the last 3 months. Please complete using care records after 3 months on the dietary intervention plan and after 6 months of the plan

Resident number: ☐

Care Home Trial Number: ☐

Please indicate with a tick, which Questionnaire is being completed:

3 Months ☐ 6 Months ☐

1. **Over the past 3 months, please indicate if and how often the following services have been used:**

Service	**No** (service not used)	**Yes** (service used)	**If yes, please indicate the number of visits**
GP			
District Nurse			
Dietitian			
Tissue Viability Nurse			
Another specialist nurse (e.g. respiratory, Heart Failure, Mental Health). If yes please specify the speciality			
Speech and Language Therapist			

If information not available, please tick ☐

2. **Over the last 3 months, has the resident been admitted to hospital for any reason? YES ☐ NO ☐**

For outpatient appointments go to 2a, A&E, go to 2b and inpatients, go to 2c
If information not available on appt type, please tick box ☐

2a Outpatient appointments

Episode	Name of Hospital	Reason for the appointment	Department/speciality	Number of appointments
1st				
2nd				
3rd				

2b Accident and Emergency

Episode	Name of Hospital	Reason for the visit	Was this related to malnutrition/dehydration?
1st			
2nd			
3rd			

2c Hospital Inpatients (If a day case, indicate '0' under length of admission)

Episode	Name of Hospital	Ward Type:	Reason for Admission:	Length of Admission:
1st				
2nd				
3rd				

APPENDIX 16:
VISUAL ANALOGUE SCALE (VAS) FOR APPETITE AND DIETARY SATISFACTION

CARE HOME TRIAL NUMBER:	RESIDENT NUMBER:

We would like to know more about your appetite and satisfaction with your current diet. To help us to do this, please use a pen or a pencil to draw an **'X'** on each of the lines below, to indicate how you are feeling in response to each of the questions:

- **How hungry do you feel today?**

Please indicate your feelings by marking the line below with an 'X':

Not hungry at all		Extremely hungry

- **Would you like to eat something now?**

Please indicate your feelings by marking the line below with an 'X':

No, not at all		Yes, very much

- **How satisfied do you feel with your current diet?**

Please indicate your feelings by marking the line below with an 'X':

Not satisfied at all		Very Satisfied

- **How pleasant are the meals provided?**

Please indicate your feelings by marking the line below with an 'X':

Not pleasant at all		Very pleasant

- **How pleasant are the 'between-meal' snacks provided?**

Please indicate your feelings by marking the line below with an 'X':

Not pleasant at all		Very pleasant

- **How pleasant are the drinks provided?**

Please indicate your feelings by marking the line below with an 'X':

Not pleasant at all		Very pleasant

APPENDIX 17:
TERMINATION OF RESIDENT INVOLVEMENT FORM

To be completed by care home staff

Resident Number:	**Care Home Trial Number:**

Plan terminated on (Date):

Has the resident died? (please tick)	**Yes** ☐ **No** ☐
If yes, what was the cause of death?	
If No, what was the reason for terminating the plan? (Hospital admission, moved out of the care home, commencement of artificial feeding)	

Weight on terminating the plan (kg):	
BMI on terminating the plan (kg/m²)	
Malnutrition risk on terminating the plan (Low, Medium, High)	

Your Care Home was randomised to the:
[food-based intervention] / [ONS intervention] / [usual nutritional care]

Form Completed by (print name):

Signed:_____ Date:_____

APPENDIX 18
QUALITATIVE METHODOLOGY

A18.1 Objectives

To explore with care home residents

1. The reasons for compliance and non-compliance with the interventions and outcomes measurement
2. Aspects of health, well-being and nutritional status with different nutritional interventions
3. Understanding and perceptions of the study questionnaires

To explore with care home staff,

4. The reasons for residents not meeting the eligibility criteria for the trial, switching intervention arms or dropping out of the trial
5. The reasons for compliance and non-compliance with the trial protocol in relation to provision of interventions, participant questionnaires and completion of nutritional screening
6. Understanding and perceptions of the healthcare resource usage questionnaire and the 'MUST' tool
7. Issues around retaining older adult care home residents in the RCT

A 18.2 Qualitative design

In phase 2 of the trial, the Primary researcher employed phenomenological methodology, to gather descriptions of resident and staff experiences of phase 1 of the trial. A semi structured interview approach was used with those residents recruited into the qualitative phase of the trial, whilst trial acceptability and feasibility was discussed with care home staff using focus group techniques. It was decided that individual semi-structured interviews would be the most appropriate data collection tool for use with care home residents, because they enable the interviewer to explore more deeply into social and personal matters, than would be possible with the use of focus groups (Chilban, 1996; Johnson, 2002; Rubin and Rubin, 2005). Interviews can also offer greater validity, because respondents are able to ask for questions to be further explained, which allows the interviewer to identify any

problems with comprehension and to rephrase questions. This may be less feasible within the group setting (Bryman, 2004).

An acknowledged weakness of the semi-structured interview approach is the risk of bias. Characteristics of the interviewer, such as gender, profession, socio-economic status and ethnicity can all affect a respondent's replies (Bryman, 2004). Bias can also arise from the interviewer's questioning style, if this leads and encourages respondents to answer in a particular way.

The focus group technique was chosen for use with care home staff, as a means of obtaining information about a range of staff experiences and to highlight any variations in perspectives between the staff within each home and between care home types (Rabiee, 2004). Within the limited period of this MRes (2 years, part-time), focus groups were considered a practical alternative to individual staff interviews, enabling the views of more people to be included (Ritchie and Lewis, 2003) and for a relatively large amount of information to be collected in a short time. As the staff within a care home work closely together, it was also considered that the group environment would stimulate engagement and discussion.

A 18.3 Sampling for the Qualitative phase

Once data collection was complete for the feasibility trial, those residents that indicated on the consent form that they would like to be considered for individual interviews formed the sampling frame for potential inclusion within the qualitative phase of the trial. A non-random method of purposive sampling involving care home staff discussions and consideration of the PROMs was used to identify potential participants per care home for individual semi structured interviews with the Primary researcher. The care home staff again made the initial approach to the potential participants to discuss their involvement. Those that remained interested in participation were introduced to the researcher, to provide further verbal and written information on this part of the trial.

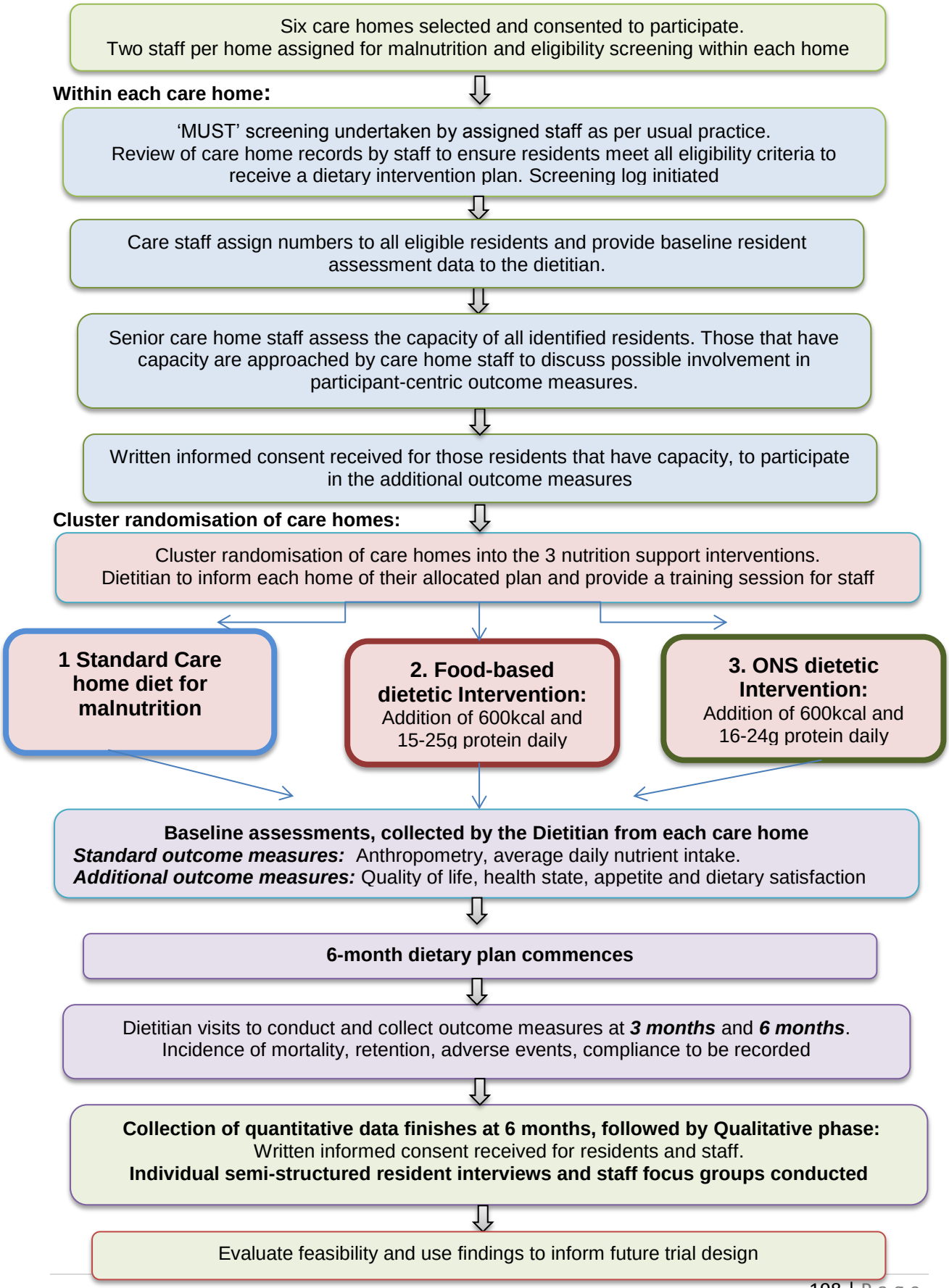
A focus group of staff (maximum of 8) was identified within each care home site that had management approval for staff participation (Gill et al., 2008). Care Home staff were selected on the basis that they had participated in the trial and would therefore have something to say. Separate information sheets for residents

and staff and consent forms were developed for the qualitative phase and were presented to eligible residents and staff prior to their inclusion.

A 18.4 Qualitative Analysis

The qualitative data will be analysed using the Krueger (Krueger, 1994) and Ritchie and Spencer (Ritchie and Spencer, 1994) framework analyses, assisted by the NVivo computer program as required. The process of data analysis will begin during data collection, through the effective facilitation of the interview and focus group discussions, complemented by observational notes. Following data collection, the dietitian researcher will transcribe the audio tapes and identify major themes. Concepts, ideas and short phrases identified within the text, will be used to develop categories and a thematic framework. Once a framework has been developed, the data will be indexed using a process of sorting, highlighting and arranging quotes to make comparisons between and within cases. Once indexed, the quotes will be re-arranged under the appropriate thematic content. The final stage of analysis will be mapping and interpreting the data, identifying links between the quotes and exploring and explaining patterns of association. The qualitative analysis will be interpreted alongside the quantitative feasibility and acceptability findings, to inform the design of the future definitive trial.

APPENDIX 19:
TRIAL SCHEMA



APPENDIX 20
SUMMARY OF PARTICIPANT-REPORTED OUTCOME MEASURES DATA

Table A20.1: Visual Analogue Scale (VAS) responses at 3-months (T1) and at 6-months (T2)

VAS dimension	SC		FB		ONS	
	T1 n =1	T2 n =1	T1 n =2	T2 n =1	T1 n =5	T2 n =5
	Rating	Rating	Mean (SD)	Rating	Mean (SD)	Mean (SD)
Hunger	1	1	2.5 (4)	7	3.6 (5)	3.8 (3)
Appetite	5	5	7 (3)	1	5 (5)	3.4 (3)
Dietary satisfaction	8	8	7 (3)	7	4 (30	6.8 (3)
Pleasantness of meals	8	8	7 (3)	8	6 (4)	6.8 (3)
Pleasantness of snacks	7	6	7 (3)	8	3.2 (3)	7 (3)
Pleasantness of drinks	10	8	7 (3)	8	8.6 (0.5)	7.8 (2)

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; VAS= Visual Analogue Scale, T1= Month-3; T2= Month-6

Data are Means (SD) where n>1 and dimension rating where n=1

Table A20.2: Other PROM responses at 3-months (T1) and at 6-months (T2)

PROM	SC		FB		ONS	
	T1 n =1	T2 n =1	T1 n =2	T2 n =1	T1 n =5	T2 n =5
COOP QoL Score*	6	6	4 (2 - 6)	6	2 (2 - 4)	4 (3- 6)
EQ5D Overall VAS score	45	45	70 (28)	50	60 (23)	56 (19)
EQ5D Index Value**	-0.112	0.011	0.16 (0.3)	-0.028	0.37 (0.3)	0.45 (0.3)

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; PROM= Participant Reported Outcome Measure; VAS= Visual Analogue Scale

Data are Means (SD) for continuous data, or Median (IQR) for ordinal data (COOP)* where n >1. Data are PROM score where n=1

**The EQ5D Index vale for health state was generated from the EQ5D-5L descriptive system, using an algorithm based on a sample from the adult UK population (Herdman et al, 2011).

APPENDIX 21
HOSPITAL ADMISSIONS

Table A21.1: Hospital admissions as recorded by care home staff from baseline- 3-months (T1) and 3-months to 6-months (T2)

Reason for admission	T1	T2
	Number of visits recorded (n)	Number of visits recorded (n)
A&E		
Falls	5	4
Suspected stroke	1	
Chest infection	1	
Outpatient appointments		
Biopsy	1	
Removal of growth on gum	1	
Parkinson's Disease Clinic	1	1
Dermatology appointment	1	1
Fracture to lower arm	1	
In growing eyelashes	1	
Diabetes check-up		1
Inpatient admissions		
Unwell- GP requested admission	1*	
Shingles		1*
Worsening symptoms of Parkinson's Disease		1*
Aspiration Pneumonia		1**
TOTAL:	**14**	**10**

A&E= Accident and Emergency
*Admitted for one-day only; **Led to an extended hospital stay and resident did not return to the care home (recorded on Figure 6)

APPENDIX 22
HEALTHCARE PROFESSIONAL VISITS

Table A22.1: GP call-outs as recorded by care home staff from baseline- 3-months (T1) and 3-months to 6-months (T2)

Reason for call-out	T1	T2
	Number of visits recorded (n)	Number of visits recorded (n)
Medication review	7	15
Cellulitis	7	3
Wrist pain	1	
Sore mouth	1	
Infected hand	1	
Foot pain	1	2
Chest examination	18	12
Urinary tract infection	10	8
Left-sided weakness	1	
Small growth abdomen	1	
Eye drops needed	1	2
Diarrhoea and vomiting	5	1
Constipation	1	
Bunion	2	
Blood test	1	3
Following CPN		3
Follow up after admission		2
Shingles		1
Bereavement		1
Face rash		1
Clinical deterioration		4
Stool sample		1
TOTAL:	**58**	**59**

CPN= Community Psychiatric Nurse

Table A22.2 District Nurse visits as recorded by care home staff from baseline- 3-months (T1) and 3-months to 6-months (T2)

Reason for visit	T1	T2
	Number of visits recorded (n)	Number of visits recorded (n)
Catheter change	1	
Swollen legs	1	
Wound care	13	10
Pressure area check	9	17
Follow up after a fall	2	
Blood test	1	
Dementia review	1	
Leg ulcers	5	
Diabetes review		3
TOTAL	**33**	**30**

APPENDIX 23
PHYSICAL OUTCOME MEASURES AND NUTRIENT INTAKE

Table A23.1: Physical outcome measures and nutrient intake: at 3-months (T1) and at 6-months (T2)

Outcome measure	SC		FB		ONS	
	T1 n =19	T2 n =19	T1 n =27	T2 n =23	T1 n =21	T2 n =21
Weight (kg)	n= 19 48 (8)	n= 19 49 (7.2)	n= 27 56 (12)	n= 23 56 (13.3)	n= 21 50 (11)	n= 21 50 (11.5)
BMI (kg/m^2)	n= 19 18.6 (2.1)	n= 19 18.98 (1.9)	n= 27 21.7 (4.4)	n= 23 22.03 (4.8)	n= 21 19.7 (3.2)	n= 21 19.68 (3.4)
MAC (cm)	n= 13 21 (2.1)	n= 13 21.2 (1.8)	n= 24 22 (3)	n= 19 22.2 (3.1)	n= 18 21 (2.9)	n= 18 21.7 (3.2)
TSF (mm)	n= 11 10. 3 (4.4)	n= 11 9.2 (2.8)	n= 19 11.7 (5.4)	n= 16 12.95 (6.4)	n= 15 10.4 (3.4)	n= 13 10 (4.1)
MAMC (cm)	n= 10 18.4 (2.1)	n= 11 18.28 (2.3)	n= 19 18.4 (2.4)	n= 15 18.14 (1.95)	n= 16 18.3 (2.4)	n= 14 18.44 (2.5)
HGD (kg)	n= 7 9.1 (9.1)	n= 6 10.4 (9.4)	n= 17 8.3 (4.5)	n= 11 7.9 (5.6)	n= 6 8.1 (4.4)	n= 6 10 (3.4)
Energy Intake (kcal)	n= 18 1578 (356)	n= 17 1652 (330)	n= 27 2169 (474)	n= 23 2059 (436)	n= 21 2014 (467)	n= 21 1987 (472)
Protein Intake (g)	n= 18 48 (10)	n= 17 45 (39- 55.5)	n= 27 79 (15)	n= 23 78 (65- 92)	n= 21 72 (20)	n= 21 68 (52- 79)
Fluid Intake (ml)	n= 18 1600 (1400- 1800)	n= 17 1318 (233)	n= 27 1600 (1400- 1600)	n= 23 1506 (204)	n= 21 1250 (1013- 1450)	n= 21 1312 (227)

SC= Standard Care; FB= Food-Based; ONS= Oral Nutritional Supplements; BMI= Body Mass Index; MAC= Mid Upper Arm Circumference; TSF= Tricep Skinfold Thickness; MAMC= Mid Arm Muscle Circumference; HgD= Handgrip Dynamometer

Normal data is presented as Mean change (SD), otherwise is Median change (IQR).

APPENDIX 24
CALCULATION OF THE ICC AND SAMPLE SIZE

A 24.1 The Intra cluster correlation coefficient (ICC)

The ICC is a measure of the similarity of clustered data and is calculated using:

ICC = Between cluster variability

(Within cluster variability + between cluster variability)

For each desired outcome measure. When post-intervention data from all trial arms are used in the estimation of the ICC, a regression-based method is required (Eldridge et al., 2009). The value of the ICC ranges from zero to one. An ICC of zero suggests that the subjects within clusters are no more similar to each other than subjects from different clusters, whereas an ICC of one suggests that subjects within a cluster have identical outcomes (Hayes and Moulton, 2009).

A 24.2 Design effect and effective sample size

The ICC can be used to determine the increase in variance due to clustering, referred to as the Design Effect (DE), which varies for each outcome measure:

DE = 1 + (m-1) x ICC

Where, **m** is the average number of subjects in each cluster (Hayes and Bennett, 1999).

Further searching of the existing literature and further piloting within the older adult care home population is required to identify the most appropriate primary outcome measure for a definitive trial and to estimate the population variance of the outcome. The desired power and significance level can be used alongside the anticipated difference between means (effect size), estimated from the literature and pilot work, to calculate the size of the sample that would be required if no clustering was present.

The calculated DE can then be used to estimate the necessary inflation of the sample size (compared to that calculated for an individually randomised trial), to take account of the similarities in the clustered data:

$$\textbf{Effective Sample Size (ESS)} = \frac{\textbf{(m x k)}}{\textbf{DE}}$$

Where, **(m x k)** is the total number of subjects in a clustered trial
m is the number of subjects in a cluster and
k is the total number of clusters

Generally, a greater ICC requires the enrolment of a greater number of trial participants (Donner, 1992).

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