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Study Protocol
(Redacted Version)

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Unique Protocol ID: 184290

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FULL/LONG TITLE OF THE STUDY

Understanding the experience of the dietetic consultation and the perceptions of its value for nutritionally vulnerable older patients, dietitians and other key stakeholders: an illuminative evaluation

SHORT STUDY TITLE / ACRONYM

Experiences and value perceptions of the dietetic consultation for the nutritionally vulnerable: an illuminative evaluation

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RESEARCH REFERENCE NUMBERS

PROTOCOL VERSION NUMBER AND DATE	Version 1.9, Date: 21/1/2020
OTHER RESEARCH REFERENCE NUMBERS	
SPONSOR / CO-SPONSORS / JOINT-SPONSORS	184290

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IRAS Number:	184290
SPONSORS Number:	Generated by the Sponsor. Enter if applicable
FUNDERS Number:	Not applicable.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigators agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigators:

Signature:

.....

Date:
31/05/2018

Name: (please print): **Dr Christine Baldwin**

Signature:

.....

Date:
31/05/2018

Name: (please print): **Professor Peter Emery**

KEY STUDY CONTACTS

Chief Investigators	Dr Christine Baldwin (Primary Research Supervisor) [redacted] Prof Peter Emery (Secondary Research Supervisor) [redacted]
Study Co-ordinator (PhD Student)	Mrs Michelle Gibbs (Research Dietitian) Research Training Fellow & PhD Student [redacted]
Sponsor	Professor Reza Razavi [redacted]

	[redacted]
Joint-sponsor(s)/co-sponsor(s)	Rachel Fay [redacted]
Funder(s)	The Dunhill Medical Trust [redacted]
Key Protocol Contributors	Mrs Michelle Gibbs Research Training Fellow & PhD Student [redacted] Dr. Christine Baldwin [redacted]

	[redacted] Professor Peter Emery Professor of Nutrition & Metabolism [redacted] Mrs. Sharon Markless Senior Lecturer in Higher Education [redacted] Dr. C. Elizabeth Weekes Senior Consultant Dietitian & NIHR Clinical Lecturer [redacted]
Committees	Dr. Christine Baldwin Lecturer in Nutrition & Dietetics [redacted]

	[redacted] Professor Peter Emery Professor of Nutrition & Metabolism [redacted] Mrs. Sharon Markless Senior Lecturer in Higher Education [redacted] Dr. C. Elizabeth Weekes Senior Consultant Dietitian & NIHR Clinical Lecturer [redacted] Dr. Louise Goff Senior Lecturer in Nutritional Sciences [redacted]

	[redacted]

STUDY SUMMARY

<table>
<tr><td>Study Title</td><td>Understanding the experience of the dietetic consultation and the perceptions of its value from the perspective of nutritionally vulnerable older patients, dietitians and other key stakeholders: an illuminative evaluation.</td></tr>
<tr><td>Internal ref. no. (or short title)</td><td>Experiences and value perceptions of the dietetic consultation for the nutritionally vulnerable: an illuminative evaluation</td></tr>
<tr><td>Study Design</td><td>Qualitative design</td></tr>
<tr><td>Study Participants</td><td>Study participants to include:
Patients:
1. Adults (aged ≥ 60 years)
2. National Health Service (NHS) number
3. Capable of giving informed consent
4. Able to communicate well in English
5. Nutritionally vulnerable according to the Nutrition Screening Tool in use at [redacted] Trust prompting referral to a dietitian
6. Receiving or likely to receive a form of oral nutrition support in the management of malnutrition
7. A variety of the characteristics below:
<table><tr><td>Age</td><td>• 60-65 years
• Over 65 years</td></tr><tr><td>Gender</td><td>• Male
• Female</td></tr><tr><td>Ethnicity</td><td>• Mixture of ethnicities to be included in the sample as represented in the local area according to the [redacted] State of the Borough ([redacted] Council, 2016) & [redacted] Demographic Fact Sheet ([redacted] Council, 2015)</td></tr><tr><td>Type of nutritional support received</td><td>• Food-based advice (food first)
• ONS
• Combination of the two strategies</td></tr><tr><td>Number of consultations</td><td>• Attended one appointment with dietitian
• Attended 2 or more appointments</td></tr><tr><td>Consultation type</td><td>• Face-to-face</td></tr></table></td></tr>
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<table>
<tr><td></td><td>
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<tr><td></td><td>• Telephone</td></tr>
<tr><td>Clinical setting</td><td>• Hospital outpatient (HOP)
• Hospital inpatient (HIP)
• Home visit (HV)
• Intermediate care (IC)</td></tr>
<tr><td>Family support</td><td>• Yes
• No</td></tr>
</table>

Dietitians:
1. Consulting registered dietitian providing the nutritional advice to patient above
2. Employee of [redacted] NHS Trust and member of the Nutrition & Dietetic Team

Key Stakeholders:
Up to 2 optional patient-nominated key stakeholders who are involved in the dietetic consultation and success of the dietetic intervention e.g. other HCP, carer or family member.
Their criteria for inclusion will include:
1. Nominated by a patient (Group 2) participating in the study
2. Involved in some aspect of the subsequent implementation of goals agreed between the patient and dietitian during the consultation i.e. the nutritional intervention
3. Available for a separate interview
4. Capable of giving informed consent
5. Able to communicate well in English

Participants with visual or hearing impairment or other physical disabilities will NOT be excluded from the study.</td></tr>
<tr><td>Planned Size of Sample (if applicable)</td><td>The minimum, theoretical sample will be constructed to reflect the variability expected to arise from the characteristics listed above, which are factors that may potentially affect the oral nutrition support consultation with the dietitian. Preliminary analysis of data will be undertaken after the first few interviews and the findings used to focus the sample and refine the topic guide for subsequent interviews. Data</td></tr>
</table>

	saturation will be sought and interviews will be continued until no further new themes emerge. Applying the principle proposed by Francis et al (2010) for defining an *a priori* point for data saturation, a minimum sample and ceasing criterion will be defined. For this study, a minimum of 3 data collection rounds providing approximately 10 data sources (i.e. 3 observations, 3 patient interviews, and interviews with associated dietitians and nominated key stakeholders, and associated documents) will form the initial analysis sample. After this point, when 3 more data collection rounds have been completed and no new themes emerge, this will define the point of data saturation. After that point, no further recruitment will occur.
Follow up duration (if applicable)	It may be necessary for the researcher to contact participants during the 24-month post-interview period. There will be no further contact with participants regarding the study thereafter.
Planned Study Period	31/01/2018 – 28/12/2020 (35 months)
Research Question/Aim(s)	Aim: To understand the experience of the dietetic consultation from the perspective of nutritionally vulnerable older patients receiving oral nutrition support and dietitians, as well as other key stakeholders involved in the process of such a consultation. Research Questions: 1. What is the experience of the dietetic consultation for nutritionally vulnerable older patients receiving oral nutrition support? 2. What is the experience of the nutrition support consultation for dietitians involved in the management of nutritionally vulnerable patients? 3. What is the experience of the dietetic consultation for the management of malnutrition for other patient-nominated key stakeholders involved? 4. How is the usefulness and value of the dietetic consultation perceived by these groups?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
The Dunhill Medical Trust [redacted]	Research Training Fellowship

ROLE OF STUDY SPONSOR AND FUNDER

The joint study sponsors will be [redacted] and [redacted] NHS Trust. The study sponsors are responsible for ensuring that specific duties are performed, properly distributed, allocated and accepted by investigators and the research institutions. The study sponsors confirm that formal arrangements are in place to ensure that specific duties are performed, properly distributed, allocated and accepted and for governance of the research from conception to completion, including design, management, financial probity, legal reputation, initiation, first recruit target and subsequent recruitment to both time and target. The sponsors are responsible for checking that the study meets all the relevant standards are put and kept in place for authorisation, management, monitoring and reporting. The study sponsors will have minimal influence on the design of the study.

The study funder, The Dunhill Medical Trust, has provided full funding for the study but will have no influence on its design and execution as described in this protocol.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Groups

As a PhD student within the Diabetes and Nutritional Sciences Division at [redacted], Michelle Gibbs (Research Dietitian/PhD Student) receives support in the conduct and coordination of her research project(s) from members of her appointed PhD Thesis Progress Committee which comprises Dr Christine Baldwin (primary PhD supervisor), Prof Peter Emery (secondary PhD supervisor), Mrs Sharon Markless (qualitative research expert), Dr C. Elizabeth Weekes (clinical dietetics expert). In addition, each PhD student also has an assigned Postgraduate Research Coordinator (Dr Louise Goff). The PhD Thesis Progress Committee will continue to provide expert advice on the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results and operates independently from the Sponsor and Funder. According to

King's College London academic regulations, for the purposes of this protocol, the research supervisors are named as chief investigators and the PhD student as the study coordinator.

Protocol contributors

This protocol was written by the Michelle Gibbs (Research Dietitian) under the close supervision of Dr. Christine Baldwin (Primary Research Supervisor) and Prof Peter Emery (Secondary Research Supervisor). This included the design and plans for the conduct of the study, data analysis and interpretation, manuscript writing, and dissemination of results as described in this protocol. Members of the PhD Thesis Progress Committee aforementioned have provided expert advice on the study design and content of the protocol. Neither the sponsor nor funder have been involved in decisions about the study design or the content of this protocol.

KEY WORDS: patient experience; disease-related malnutrition; nutritional care; dietetic consultation; older adults; oral nutritional support

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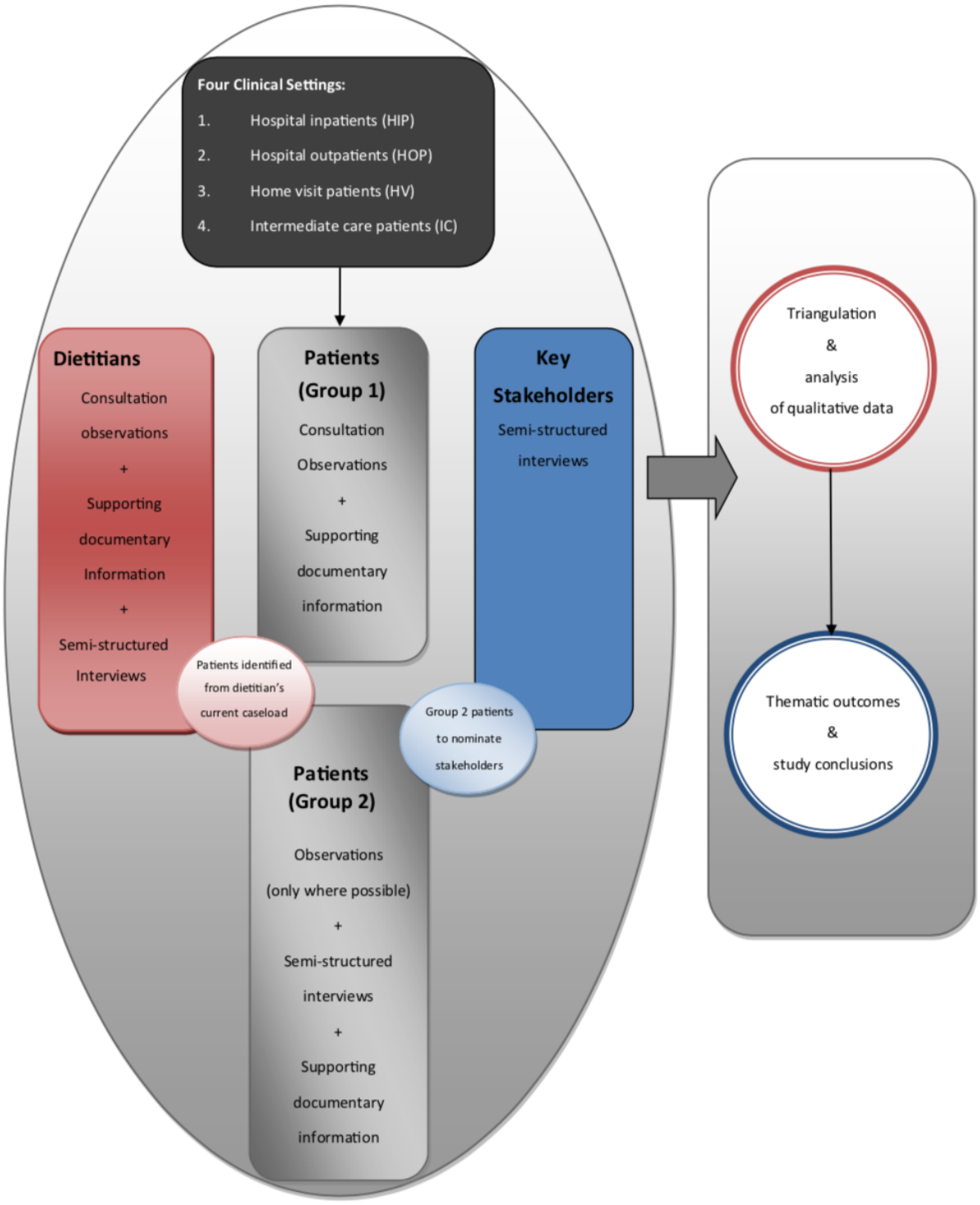
STUDY FLOW CHART



STUDY PROTOCOL

Understanding the experience of the dietetic consultation and the perceptions of its value from the perspective of nutritionally vulnerable older patients, dietitians and other key stakeholders: an illuminative evaluation.

1 BACKGROUND

Malnutrition

Malnutrition is common and associated with negative consequences to nutritional, clinical and patient-centred outcomes as well as being associated with a greater chance of developing complications of illness, prolonged length of hospital stay and more hospital admissions resulting in greater costs of healthcare. Malnutrition has been estimated to affect around 3 million people in the UK, the greatest number of whom are thought to be living in their own homes (Elia & Russell, 2009a). The prevalence of malnutrition is particularly high in older people, affecting more than 10% of people over 65 years of age and its management in this group accounts for more than half of the total cost of managing malnutrition (European Nutrition for Health Alliance, 2006). Older people not able to live in their own homes have a higher prevalence of malnutrition. In a recent survey 14 % of those living in sheltered housing and 41 % of people being cared for in nursing homes were at high or medium risk of malnutrition (Russell & Elia, 2012; Elia & Russell, 2009b).

Malnutrition is both a cause and consequence of ill health (Lean & Wiseman, 2008; NCCAC, 2006*)*. Its causes are multi-factorial, with illness making a significant contribution, although patient circumstances can also be a contributing factor. One study of 794 hospital patients in Berlin, 22% of whom were malnourished, demonstrated that risk of malnutrition was significantly increased by patient circumstantial factors such as old age, living alone, and poor educational background (Pirlich et al., 2005). However, malnutrition arising from social and environmental factors gradually diminishes once nutritional intake improves (Skipper, 2012) highlighting the importance of identifying and managing the causes of what is a complex condition.

The management of malnutrition

The management of malnutrition frequently focuses on nutritional issues with provision of food-based interventions and oral nutritional supplement drinks provided by a range of healthcare professionals representing first line strategies (Multi-professional consensus panel, 2012). Some benefits to nutritional and clinical outcomes have been reported from the use of such strategies but the effects were heterogeneous and it is not possible to characterize the groups most likely to benefit. There is low to moderate quality evidence that food-based advice given with or without oral nutritional supplements (ONS) to nutritionally vulnerable patients results in short-term improvements to nutritional intake, weight, as well as measures of body composition and muscle strength however, evidence for clinical benefits, healthcare outcomes and indeed patient-centred outcomes is frequently lacking (Baldwin & Weekes, 2011).

Several systematic reviews have sought to determine the relative efficacy of ONS but the findings were heterogeneous (Baldwin & Weekes 2012; Stratton & Elia 2007; Smith 2013; Baldwin & Weekes 2016). An early overview of systematic reviews of ONS suggested that they were associated with some clinical and nutritional benefits, supporting their use in clinical practice, but the authors didn't consider the methodological quality of the systematic reviews included and may have been overly optimistic in their interpretation of findings (Stratton and Elia, 2007). Since this time numerous other systematic reviews of ONS and the findings summarised in an overview, compared the findings of reviews and examined their methodological quality. The key findings were that there was considerable discordance for a number of nutritional, clinical and healthcare outcomes. Only 29% of reviews were of high methodological quality and therefore the findings of a substantial proportion may be at risk of bias (Baldwin & Weekes, 2016).

There are a number of factors which might contribute to the variation observed in studies of oral nutrition support including differences in clinical background of the included patients, variation in disease severity and progression and differences in healthcare setting. The frequency of consultations, intensity of dietetic input and the skills and experience of the practitioner may also contribute to the observed heterogeneity in amongst findings (Baldwin and Weekes, 2012).

Investigation of how the skills and experience of the practitioner impact on the dietetic consultation has received relatively little attention. There is a small amount of evidence that patients' perceptions and experience of the content, purpose and outcomes of a dietetic consultation differ from those of the dietitian resulting in failure of patients to adhere to dietary prescriptions, reducing the effectiveness of the consultation and leading to dissatisfaction of both patients and dietitian. A questionnaire-based study of 141 consultations between patients with diabetes and dietitians or nurses demonstrated that patients and healthcare professionals frequently disagreed on what had been discussed and indeed the decisions made (Parkin, 2003). Greater motivation in patients to achieve the desired outcomes was associated with greater autonomy within the consultation. Two further small studies of dietetic consultations for patients with diabetes demonstrated that amount of empathy demonstrated by the dietitian was associated with greater levels of patient satisfaction and greater agreement between the patient and dietitian on what was discussed in the consultation (Goodchild et al, 2005; Parkin, 2014). An ability to demonstrate empathy within a consultation is only one of several aspects of patient-centred care. Patient-centred care has been associated with improved outcomes of treatment and improved quality of life as well as significant benefits to healthcare practitioners and to healthcare organizations (Mead & Bower, 2000; Little et al, 2001; Stewart, 2001). A recent integrative review identified that patient-centred care is an important feature of dietetic practice, with benefits to both patients and dietitians, although it is an area which still presents opportunities for further research (Sladdin et al, 2017).

A qualitative study of patient's experience of the dietetic consultation for long-term conditions such as cardiovascular disease and diabetes highlighted some factors in common between patients such as the need for information, the approach used by the dietitian, the need for good communication skills and the patients' own expectations and feelings about the appointment, although there were differences in how different patients reacted to similar aspects of the consultation (Hancock et al, 2012). Two key findings were that patients that had a negative experience of the consultation were

less likely to achieve the desired outcomes and that patients frequently perceived a difference between the dietitian's agenda and what the patient expected of the consultation. A small questionnaire–based study of nutritionally vulnerable patients who had received two consultations from a dietitian reported that more than half of the patients were unaware of the role of a dietitian, the reason for the referral and greater than two thirds of patients failed to understand the link between their underlying clinical problem and nutrition (Bird et al, [n.d.]). A recent systematic review of the lived experience of patients with reduced intakes of food and drink in mainly hospital settings, highlighted the lack of support and help with eating experienced by patients in different care environments and a lack of caring dialogue about food and nutrition, although in situations where a caring attitude was exhibited by healthcare staff, patients acknowledged a greater willingness to make improvements to their nutritional intake (Larsen & Uhrenfeldt, 2013). Taken together these data suggest that 'the consultation' is a key element in determining effectiveness of dietetic care and it might be speculated that how the dietetic consultation is delivered might be a factor accounting for some of the heterogeneity in the evidence base on nutritional support interventions.

The role of the dietitian in patient management

Dietitians have a key role in providing nutritional support to patients who are nutritionally vulnerable. For the purpose of this study, the term "consultation" refers to a consensual 1:1 interaction between a dietitian and a patient for the purpose of the provision of nutritional counselling. The majority of interactions between dietitians and patients take place in individual consultations when a detailed assessment of the patient's nutritional background is taken to guide the provision of tailored dietary advice aiming to improve the patient's nutritional status. Dietitians must also take into consideration, practical issues and social factors that might be contributing to the patient's poor nutrition. For this to be effective, the dietitian needs to use an appropriate range of communication skills, or patient-centred communication.

In the context of the provision of nutritional support to nutritionally vulnerable patients, effectiveness can be considered as the ability of both parties to achieve a shared understanding of the purpose, aims and reason for the consultation, resulting in agreed management of goals. Therefore, for a consultation between a patient and a dietitian to be considered effective, a shared understanding is needed of the reasons for the consultation, the recommended goals and the proposed nutritional intervention. There are a number of elements of the consultation likely to influence effectiveness. The background, skills and experience of the dietitian is just one element. The organisational system within which consultations operate is likely to be another factor.

Organisation of dietetic services

Traditionally the dietetic management of nutritionally vulnerable patients has relied on one-to-one consultations, which are time consuming and involve patients being able to travel to appointments. Increased demands on health services and the need to meet quality targets have resulted in some dietetic services being offered in different ways, e.g. the use of telephone consultations, greater

reliance on training of carers and other health professionals to offer nutritional support and increased use of visits to patients own homes. All of these models have arisen from the need for greater efficiency of services rather than being informed by patient needs. It is not known how patients or indeed dietitians perceive this way of working or the impact on effectiveness of consultations. Taken together, features of the patient, how a consultation is delivered, communication skills used by the healthcare practitioner, and organisational elements might be considered to be part of the patient experience.

The importance of effective management of nutritionally vulnerable patients is a key priority for organisations with a stake in the care and management of nutritionally vulnerable adults. The National Institute for Health and Clinical Excellence (NICE) recently highlighted the potential for effective management of malnourished individuals as fifth of fifty-two guidelines that could generate the most cost savings to the NHS (NICE, 2017). However, the focus of guidelines and policies in this area has tended to be on the provision of services and roles of healthcare staff rather than on understanding the patient perspective. A recent report from Age UK poignantly drew attention to the patient perspective, suggesting that the first action in effective provision of nutritional care should be to 'listen to us (patients)' (Age UK, 2010).

What is patient experience?

In both clinical practice and health care research, there has been a growing interest and use of the term "patient experience" as it has become a focus for many healthcare leaders and policy makers, recognised as a top priority (Wolf et al, 2014). Over the past 10 years, there has been a drive towards both understanding how patients experience healthcare services and the best approaches to measuring expectations, satisfaction and experiences of healthcare (de Silva, 2013). Despite this, the meaning of "patient experience" remains controversial. Amidst the lack of a universally accepted definition, most would agree that "patient experience" cannot be explained without the consideration of the patient (and family) perspective (Wolf et al, 2014). Measurement approaches should ideally also consider the experience of the family and carers as extended participants in healthcare experience of the patient, but often don't, and recommendations for the best ways of understanding their views remains a notable gap in the evidence (de Silva, 2013).

The Beryl Institute, a global organisation made up of over 45,000 members who seek to improve the patient experience through collaboration and sharing of knowledge, defines patient experience as "the sum of all interactions, shaped by an organisation's culture, that influence patient perspectives, across the continuum of care" (The Beryl Institute, [n.d.]). Wolf et al (2014) recently conducted a narrative synthesis of existing literature on "patient experience", which identified a number of key themes on the meaning of the term (Wolf et al, 2014). The authors felt that despite the many efforts to define patient experience in the literature, many are limited in scope (Wolf et al, 2014). Indeed, many studies have captured the quantitative measures and outcomes relating to patient experience but there is a need for studies to capture the holistic nature of this phenomena, for which qualitative investigation is ideal. In considering whether patient experience and patient satisfaction were synonymous, authors of the narrative synthesis recommended a move beyond purely metric measures as captured in patient

satisfaction surveys, cautioning readers that patient experience is more than just satisfaction (Wolf et al 2014), a view also supported by others (de Silva, 2013, LaVela & Gallan, 2014). A study by The World Health Organisation found that although patient experience does significantly impact on patient satisfaction, other variables such as self-reported health status, expectations and personality also affect patient satisfaction levels as well as external variables such as the media (Bleich et al, 2009). In the narrative synthesis by Wolf et al (2014), the three themes which were consistently identified and may help in the creation of a framework to optimise patient experience included "active patient and family partnership and engagement, the integral need for person-centeredness, and an acknowledgement of the broad and integrated of experience overall" (Wolf et al 2014, pg. 12).

In the UK, the National Institute for Health and Clinical Excellence has published a Clinical Guideline (CG138) on the patient experience in adult NHS services, last updated in 2016 (NCGC, 2012). It offers comprehensive, up-to-date, evidence-based guidance, derived from extensive literature searches, reviews of relevant policy documents, consultation with experts and qualitative narrative synthesis culminating in a series of clinical recommendations and quality statements on patient experience of healthcare services in the NHS (NCGC, 2012). The recommendations include knowing the patient as an individual, the essential requirements of care, the importance of tailoring healthcare services for each patient, the benefits of continuity of care and relationships and enabling patients to actively participate in their care including shared decision making (NCGC, 2012). The patient remains the centrepiece of the relationship between the consultation, the experience and the outcomes. Indeed, the patient is an essential participant in the interaction we label as the consultation for which there might be quantitative, measurable outcomes or observations, often reported in studies. However, significant gaps in the literature are apparent in relation to the experience of nutritionally vulnerable patients receiving nutrition support, perhaps the more qualitative, and less quantifiable element of the dietetic consultation. Despite the comprehensiveness of the NICE thematic qualitative review, there are some limitations in its relevance to this work. It specifically identified themes and sub-themes of the experiences of patients with cancer, diabetes and cardiovascular disease and then used these to develop a generic framework extendable to all adult patients (NCGC, 2012). Therefore, included studies did not specifically address patient experiences of dietetic services for older people with malnutrition, although the themes might be extrapolated to such a patient group more generically regarding their experience of healthcare in the NHS. Furthermore, carer experiences were not addressed in this review and papers which described interventions designed to improve patient experience were excluded. Other notable limitations included the absence of grey literature searches, study selection was completed by one reviewer, the absence of a list of excluded studies, the absence of a PRISMA diagram (Liberati et al, 2009) to enable the reader to track study decisions, no descriptions of the characteristics of included studies, and no reported assessment of the quality of the included studies.

The role of the patient experience in the effectiveness of the dietetic consultation for the provision of nutritional support remains unknown and requires investigation. As seen in the Wolf et al (2014) evidence synthesis, an in-depth understanding of patient experience is often limited by the quantitative study designs adopted in many studies (Wolf et al, 2014). Furthermore, both Wolf et al (2014) and

NICE (NCGC, 2012) have reviewed the overall concept of the patient experience of healthcare services, but neither have explored this phenomenon in the literature specifically in relation to dietetic consultations. The illuminative evaluation approach proposed will allow exploration of the dietetic consultation and its function, how it is influenced by its context including the various settings in which it occurs, its advantages and disadvantages as perceived by everyone involved, the perceived value from the perspective of key stakeholders and its impact on outcomes (Partlett & Hamilton, 1972).

The patient experience of the dietetic consultation

Preliminary synthesis of studies which explore the experience of the dietetic consultation has identified 22 studies for inclusion. Of these, a small number focus on the patient experience of the consultation with the dietitian alone and centre around the following themes with regard to the patient experience:

1. Dietitian's conduct, style or approach (Hancock et al, 2012)
2. Verbal or non-verbal communication (Cant, 2009; Cant & Aroni, 2008; Hancock et al, 2012; Goodchild et al, 2005)
3. Knowledge, information and education (Roberts et al, 2014; Hancock et al, 2012; Kim et al, 2014)
4. Patient satisfaction (Isenring et al, 2008; Hung et al, 2014; Isenring et al, 2004; Izquierdo et al, 2003; Kim et al, 2014; Sutton et al, 2008)
5. Nature of appointment including structure, setting, frequency, consistency, waiting times (Hancock et al, 2012; Spikmans et al, 2013; Izquierdo et al, 2003; Sutton et al, 2008)

Of these eight studies, two were of qualitative design (Roberts et al 2014; Hancock et al, 2012), three were quantitative (Isenring et al, 2008, Hung et al 2014, Spikmans et al 2013) and three were mixed method studies (Cant, 2009; Cant & Aroni, 2008; Goodchild et al, 2005). Some of these studies also reported effects on emotional, clinical, nutritional, functional outcomes (Izqiuerdo et al, 2003; Kim et al, 2014). Additionally, an equally small number of studies examined the patient experience of a joint consultation with a dietitian and other healthcare professional including four qualitative studies, five quantitative studies and no mixed method studies, so far. While these studies have explored some of the factors which contribute to the patient's experience of the dietetic consultation and some have even attempted to measure it, they have all done so in the absence of a standard definition and none have explored the experience of the dietetic consultation exclusively for nutritionally vulnerable older adults receiving nutritional support. Many have attempted to measure "patient experience" using quantitative methods. Whilst the evidence base supports a variety of approaches to measuring patient experience, from those that employ a detailed, descriptive, qualitative exploration to those that collate quantitative data, the depth of description obtainable and the generalisability of the findings remains an important consideration when choosing amongst various approaches to investigating patient experience (de Silva, 2013). Therefore, there is a gap emerging of in depth, qualitative exploration in the area and population proposed by this study. The Health Foundation further suggest that another notable gap in the evidence is that despite successful efforts to validate surveys and other methods for measuring patient experience, subsequent improvements in patient experience has not been well

established and simply measuring patient experience should be a means to a better outcome, rather than an end in itself (de Silva, 2013).

Sladdin and colleagues (2017) recently published an integrative review which aimed to synthesise both qualitative and quantitative literature relating to patient-centred care in dietetic practice. Critical appraisal of this review using the SIGN methodology checklist (SIGN, 2015) suggest it is of high methodological quality with only minor limitations. Unlike the previously described narrative syntheses which considered patient experience more generically, this integrative review specifically focuses on dietetic consultations. However, it is heavily concentrated on patient-centred dietetic care which, according to Wolf et al (2014) forms one of the domains of but does not entirely equate to patient experience. Wolf et al (2014) considered such alignment with patient-centred care principles to be one aspect of the definition of patient experience, rather than the definition in itself. Furthermore, the review considers dietetic consultations non-discriminately, and is therefore not specific to nutrition support consultations in nutritionally vulnerable older adults.

Therefore, this study seeks an understanding of the experience of the dietetic consultation from the perspective of the malnourished older patient receiving nutrition support and other key stakeholders by means of illuminative evaluation and will use the information gained to inform the design of a model for the provision of nutritional care that maximises the patient experience.

2 RATIONALE

Malnutrition is highly prevalent, particularly amongst older people, and leads to an increased risk of health complications and socioeconomic burden. It remains a significant public health problem associated with poor social circumstances, economic constraints and patient–related factors such as reduced mobility, depression and social isolation playing an important part, all of which are more common in older people. Patients with malnutrition are often older patients with complex needs and therefore may require specialist knowledge and skills to provide nutritional support. Dietitians are uniquely skilled to assess and understand the multiple factors that underpin diet and to individualise nutritional support, which has the potential to improve outcomes. Although the causes of malnutrition are multifactorial, it's clinical management places emphasis on a variety of nutritional support interventions by dietitians and other healthcare professionals including oral nutritional supplements, dietary advice and food-based interventions or a combination of approaches.

The relative efficacy of oral nutritional support interventions has received variable attention, with the findings on food-based interventions suggesting lack of evidence and the extensive literature on ONS being discordant across outcomes and of variable methodological quality. Despite the heterogeneous nature of the evidence regarding the clinical management of nutritionally vulnerable patients, the factors responsible for the variability have not been identified. One possible factor is failure of the patient to adhere to the dietary recommendations, which could result from failings in the relationship achieved during the consultation between the dietitian and the patient. There are no studies that we are aware of that have examined the patient experience of the consultation with the dietitian in the context of nutritional support and indeed whether the nature of the consultation had any impact on

patient satisfaction and achievement of goals. A small group of studies have investigated elements of how dietetic and healthcare interventions are delivered, suggesting areas with potential to contribute to the success or failure of oral nutritional support interventions in the treatment of malnutrition. The patient experience of consultations is increasingly being recognised as an important part of investigating their effectiveness in healthcare. To date there are a number of limitations in this literature, including use of methodologies which have limited understanding to just one or two domains, lack of holistic patient-centred approaches to understanding patient experience and lack of a standardised, universally-accepted definition for patient experience, resulting in use of a variety of measures to describe and quantify it (Wolf et al, 2014, LaVela & Gallan, 2014). Failure to recognise the patient perspective in healthcare delivery has also been recognised at the organisational and national level as the Mid Staffordshire NHS Foundation Trust Public Inquiry repeatedly highlighted the failure to recognise the patient perspective in healthcare delivery (Francis, 2013). As patient experience of the nutritional support consultation has not been adequately explored in this population, it could be hypothesised that this is one contributing factor to the heterogeneity observed in studies of oral nutrition support interventions for the management of malnutrition. Deeper understanding of the patient-related factors impinging on the effectiveness of consultations has important implications for the design of dietetic consultations for the management of nutritional support interventions.

The research questions and aims are described in section 4 of this protocol. A review of the literature indicates a need for exploration of the patient experience and its possible impact on the success or failure of the dietetic encounter in relation to its outcomes, particularly in the population of interest. This study aims to address some of the deficiencies in the literature and these gaps are precisely why the research questions outlined urgently need investigation. The use of qualitative interviews will facilitate an in-depth understanding of the patient and practitioner experience in the management of clinically significant malnutrition and an overall illuminative evaluation approach will broaden that understanding of the dietetic consultation by triangulating multiple data sources.

3 THEORETICAL FRAMEWORK

The study will adopt the qualitative model of illuminative evaluation as proposed by Partlett & Hamilton (1972). Illuminative evaluation, a form of naturalistic enquiry, is based more on description and interpretation and less on measurement and prediction and was developed as an alternative to quantitative methods of evaluation (Partlett & Hamilton, 1972). As a qualitative model, illuminative evaluation is proposed as it best-suits the aims of the study, utilizing in-depth semi-structured interviews, observations and documentary analysis as techniques for exploring the experiences, understanding, attitudes, processes, context and the perceived impact of the dietetic consultation. Therefore, it will build on the limitations of previous studies in the area, which are mainly quantitative or capture only some of the possible domains of patient experience. Its purpose will be to evaluate the process of the dietetic consultation from all perspectives in order to gain full insight into its context and impact. It will present different angles to the experience and function of the dietetic consultation and will allow identification of features that may affect its success or failure. As an overarching approach, it will also provide in-depth illumination of how the dietetic consultation is experienced and perceived by those involved in various aspects of it, highlighting the factors which contribute to its

value and effective implementation.

Gordon (1991) explains that illuminative evaluation seeks to:

> "understand the most significant aspects of an entire milieu, including important structures and inter-relationships, negotiations between parties, reciprocal influences, alternative conceptualizations and value orientations, critical processes, resource utilization, and any other aspects of the environment deemed significant" (Gordon, 1991, p. 370).

Originally developed for evaluating innovative educational programmes, illuminative evaluation has been successfully adapted and used in studies relevant to health and social care. Sloan & Watson (2001) used illuminative evaluation to investigate the interactions within the clinical supervision process by means of in-depth interviews, critical incident journals, session documents and audio recordings of supervision. Russell et al (2004) conducted an illuminative evaluation study to explore the process of knowledge and information exchange by email to support evidence based healthcare. Gallini (2001) successfully applied the illuminative evaluation in an investigation of the response to the National Dignity in Care campaign, within an acute healthcare Trust in England.

At the core of illuminative evaluation as a model are two concepts, namely the "instructional system" and the "learning milieu" (Partlett & Hamilton, 1972). The instructional system, carries a catalogue description or idealised specification of the programme under study, where the ideal formulations, objectives, performance criteria or desired outcomes are formally recognised (Partlett & Hamilton, 1972). For this study, the instructional system will constitute professional standards of practice, evidence-based clinical guidelines, or policy documents which serve as benchmarks for the conduct of consultations and the clinical decisions made within the dietetic consultation for the provision of nutritional support. However, as the execution of the programme rarely adopts the prescriptive ideals originally formulated in the "instructional system", the second concept serves to describe the reality of its implementation, where the complicated interplay of circumstantial pressures, constraints, individual work styles or practices and environmental factors results in a unique configuration (Partlett & Hamilton, 1972). This second concept is that of the "learning milieu". Arguably, it is the diverse and complex learning milieu that arguably has the greatest impact on the experience of the dietetic encounter for all stakeholders who interact in an inevitably complex way, influenced by factors affecting the total consultation process.

For this study, the chosen qualitative design which adopts an illuminative evaluation approach is justified primarily on the basis of providing an opportunity to open-mindedly explore the unknown in relation to the patient, dietitian and other key stakeholder experiences of the nutrition support dietetic consultation. There remains a need to explore the experience of the dietetic consultation for the provision of nutrition support as a possible factor in the observed heterogeneity of response to nutritional interventions in the management of malnutrition. This need is further supported by the discordance evident in the systematic review literature as to the efficacy of various oral nutrition support strategies used by dietitians, the unknown factors which contribute to their success or failure, and the variation in dietitians' choices of nutritional support strategies for individual patients. As the

available evidence fails to answer these questions and so far, there have been no attempts in the literature to qualitatively explore the experience of the dietetic consultation in nutrition support practice from various perspectives, an interpretivist rather than a positivist paradigm was chosen. The proposed approach will paint a "portrait" of how patients, dietitians and key stakeholders experience and interpret the process and value of the dietetic consultation. It will also support the development of recommendations and inform practical suggestions for improvements to the processes involved in dietetic consultations for the management of malnutrition using oral nutrition support.

4 RESEARCH QUESTION/AIM(S)

The aim of this study is to understand the experience of the dietetic consultation from the perspective of nutritionally vulnerable older patients receiving oral nutrition support and dietitians, as well as other key stakeholders involved in the process of such a consultation.

Research Questions:

1. What is the experience of the dietetic consultation for nutritionally vulnerable older patients receiving oral nutrition support?
2. What is the experience of the nutrition support consultation for dietitians involved in the management of nutritionally vulnerable patients?
3. What is the experience of the dietetic consultation for the management of malnutrition for other patient-nominated key stakeholders involved?
4. How is the usefulness and value of the dietetic consultation perceived by these groups?

4.1 Objectives

1. To understand the experience and perceptions of usefulness and value of the dietetic consultation and its function through in-depth, semi-structured interviews, observations and supporting documentary evidence (e.g. medical/dietetic records, relevant policy documents, clinical guidelines) of nutritionally vulnerable older patients receiving oral nutrition support.
2. To understand the experience and perceptions of usefulness and value of the nutrition support dietetic consultation and its function by means of in-depth, semi-structured interviews, observations and supporting documentary evidence (e.g. medical/dietetic records, relevant policy documents, clinical guidelines) of dietitians involved in managing nutritionally vulnerable patients.
3. To understand the experience and perceptions of usefulness and value of the nutrition support dietetic consultation from the perspective other key stakeholders involved in the process of such a consultation using in-depth, semi-structured interviews, observations and supporting documentary evidence (e.g. medical/dietetic records, relevant policy documents, clinical guidelines).

4. To use in-depth, semi-structured interviews, observations and supporting documentary evidence (e.g. medical/dietetic records, relevant policy documents, clinical guidelines) to further understand the function, implementation, context and outcome of the oral nutrition support dietetic consultation.

4.2 Outcomes

Outcomes of this study will include themes and sub-themes related to the patient experience, dietitian experience and key stakeholder experience of the consultation with quotes to provide context to the themes and to represent the voice of the participant regarding important factors affecting the patient experience.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study Design

As aforementioned, the study will adopt the qualitative, illuminative evaluation model (Partlett & Hamilton, 1972) to gather data on the nutrition support consultation experiences for patients, associated dietitians and key stakeholders.

As the overall aim of illuminative evaluation is to describe and interpret the programme and process under study to facilitate understanding and improvement, the paradigm stipulates a variety of data collection sources so that the milieu under study can be understood from diverse perspectives (Gordon, 1991). Partlett and Hamilton (1972) suggest that there are typically four elements involved in illuminative evaluation: observations, interviews, questionnaire/test data & documentary information.

However, Partlett & Hamilton propose that illuminative evaluation is not a prescriptive methodological package but a general and adaptable research strategy (Partlett & Hamilton, 1972). The choice of data collection methods is dictated by the process under investigation, although there is a definite emphasis on observation and participant interviews particularly because of the concentration on the process under study as central to the “learning milieu” (Partlett & Hamilton, 1972).

The Health Foundation recommend when attempting to measure patient experience and deciding on an appropriate data collection method, that available time, expertise and resources be taken into consideration (de Silva, 2013). Taking this into account for this study as well as the nature of the consultation process under investigation, data will be collected using:

- Observations
- Interviews
- Documentary information.

This will provide the widest range of data sources feasible.

The variety of general characteristics to be considered in the patient sample are summarised below:

Age	• 60-65 years • Over 65 years
Gender	• Male • Female
Ethnicity	• Mixture of ethnicities to be included in the sample as represented in the local area according to the [redacted] State of the Borough ([redacted] Council, 2016) & [redacted] Demographic Fact Sheet ([redacted] Council, 2015)
Type of nutritional support received	• Food-based advice (food first) • ONS • Combination of the two strategies
Number of consultations	• Attended one appointment with dietitian • Attended 2 or more appointments
Consultation type	• Face-to-face • Telephone
Clinical setting	• Hospital outpatient (HOP) • Hospital inpatient (HIP) • Home visit (HV) • Intermediate care (IC)
Family support	• Yes • No

Observations

Observations will be used to record the sequence of events of the consultation, verbal and non-verbal communication and the patient and dietitian interaction throughout. Dietetic consultations will be observed in each setting to include the hospital ward, the outpatient clinic, the intermediate care setting and within the patient's own home as relevant. Observations will not be audio-recorded due to the risk of recording potentially sensitive conservations from nearby, non-participants. Instead, observations will be made and detailed field notes recorded as described here. In order to avoid patients associating the Research Dietitian with their clinical and nutritional care, the patients who are observed (Group 1) will not be interviewed. Rather, the focus of the observations will be on elements of the patient and dietitian communication and interaction during the consultation. However, where

possible some Group 2 patients may be observed by another member of the research team. The series of steps outlined by Creswell (2013) and recommended for the conduct of observations in qualitative enquiry will be followed:

1. Required permissions will be sought from various observation sites in the form of verbal agreement from ward managers, clinical dietetic leads, intermediate care managers and the patients themselves. Written agreement for observation will also be sought from participants as part of the informed consent procedures.
2. Within each setting, the details of what and who will be observed will be specified. For consultations that take place in any of the four settings proposed, the entire dietetic encounter between the patient (and carer/relative, if present) and the dietitian will be observed. Joint consultations involving other healthcare professionals will be included only if the additional healthcare professional consents to being observed. The exact nature of what is observed will be predefined and informed by literature review. Some aspects of the interaction to be observed within the various settings might include but not limited to:
    a. The patient – age, nutritional status, clinical condition, general state of well-being, willingness to see dietitian, knowledge & understanding, apparent satisfaction, mobility.
    b. The dietitian – general conduct, style or approach, communication (verbal/non-verbal and use of patient-centred communication), knowledge & information delivery, education style
    c. The setting/environment – the time of day, atmosphere on the ward/home/clinic, privacy, waiting time (if applicable),
    d. The consultation – whether initial appointment or review, duration, structure, frequency (if applicable), focus, agreed goals.
3. The role as an observer will be defined. This will be as a non-participant observer, so that the researcher will remain an outsider to the process under study, watching and taking notes without an active role in the consultation. This will involve data collection without direct involvement in the activity of the dietetic consultation.
4. An observational protocol will be used as a method for collection observation data in the field. The final content of the proforma will be informed by the literature review but will allow both descriptive and reflective notes (own thoughts, experiences, hunches). The date, setting and time of observation will be recorded alongside the field notes.
5. Details of the participants, physical setting, notable events or activities will be recorded along with a description of what happened and own reflections (insights, ideas, initial interpretations) will also be noted.
6. The dietitian involved in the consultation will introduce the Research Dietitian (outsider) and explain her role before the observation begins to ensure the patient is still happy for the consultation to be observed.
7. Once the consultation is completed, the researcher will thank the participants and remind them of the use of the data and its role in the study.
8. Complete field notes will be prepared as soon as possible following the observation to give a rich, dense description of the participants and the consultation observed.

Interviews

Interviews will be used to uncover the participant's experience of the consultation and perceptions of its value. The use of qualitative interviews has the greatest potential to uncover the range and complexity of experiences of dietetic consultations as well as to facilitate identification of factors influencing the practices of dietitians providing nutritional support. Interviews will be undertaken with patients booked to see a dietitian for advice on nutritional support and their consulting dietitian. In addition, included patients will be asked to nominate up to two additional individuals considered to be key stakeholders in their care, i.e. have some notable involvement in the dietetic consultation or its outcome. They might include carers, spouses or partners, or other healthcare professionals but must be nominated by the patient.

As several different types of participants will be interviewed, separate interview topic guides will be developed for each participant type. The key themes identified by Wolf and colleagues (2014), the quality standards outlined in the recent NICE guidelines on patient experience (NCGC, 2012) as well as topics explored quantitatively in a questionnaire study examining current oral nutrition support practice amongst UK dietitians (Gibbs, 2014) will contribute to the construct of the interview topic guides. Review of the literature will also inform the topic guide for interview.

The first few in-depth interviews undertaken will also help to guide the focus of the remaining interviews including participant recruitment, in line with the recommendation to start with a wide focus without pre-judgement, and then to narrow the field of focus as the study progresses (Cohen, 2011). This is also referred to in illuminative evaluation as "progressive focusing" (Partlett & Hamilton, 1972).

All interviews will be conducted by one researcher (MG). They will be audio-recorded and transcribed using the professional transcription services of [redacted] Research Support.

a. Patient interviews:

Qualitative semi-structured interviews will be used to collect data on the experiences of patients who have been identified as malnourished or at risk of malnutrition and referred to a dietitian for management. In order to avoid patients associating the Research Dietitian with their clinical and nutritional care, a separate group of patients (Group 2) will be selected for qualitative interviews, so that those patients who participate in the consultation observations (Group 1) will not be interviewed. A suitable time for the interview will be agreed and arranged with the patient. For hospital inpatients, an interview in a private room on the ward will be arranged. This will also apply to those in intermediate care. For all other patients, an interview in their own home or at [redacted] will be arranged. If interview at the patient's home isn't possible, patients will be invited to [redacted] for interview in a private room. For the community dwelling-patients face-to face interviews will be conducted at the patient's home unless the patient explicitly objects to this. As with the hospital/intermediate care patients, should interview at the patient's home not be possible, patients will be invited to [redacted],

[redacted] for interview in a private room. In such cases, travel expenses for a return journey to and from [redacted] will be subsequently reimbursed.

The critical incident technique was developed by Flanagan for the collection and analysis of objective, reliable information about specific human activities (Flanagan, 1954). Although this methodology will not be adopted in its entirety, it will be used to help formulate the semi-structured interview guide for the older patients by use of specific questions throughout. The majority of nutritionally vulnerable patients are elderly and less structured forms of interviewing which aim to explore the abstract and general may be more difficult for older patients. Critical incident technique typically uses specific questions that seek to identify contextualised examples of the real-life human activity of interest and its significance for the participant. The greater structure and specificity of questions make this technique particularly valuable for interviewing this group of patients. The steps of the critical incident technique will not be followed explicitly but the style of interview questioning will be adopted as appropriate in constructing the interview guide. Participants will be asked to focus on the recently observed consultation with the dietitian. Questions and prompts will be used (as appropriate) to encourage patients to describe positive or negative experiences of the consultation. It has been demonstrated to be important that the definition of "successful" or "unsuccessful" in the context of describing the consultation is determined by the participants themselves, to avoid imposing definitions that reflect the researchers' perspective.

b. Dietitian interviews:

Semi-structured interviews will be used to understand the experience and perceptions of value of the consultation for the dietitians involved in providing nutritional support to participating patients. A suitable time will be agreed with the dietitian for the qualitative interview. Interviews will take place in a private room either within the healthcare environment or at [redacted].

It has been demonstrated in consultations between some patients and dietitians that the recollection of goals agreed in the consultation frequently differ. To facilitate exploration of views from both parties involved in the oral nutritional support consultation, patient and dietitian "pairs" will be included in the study, where possible. Dietitians taking part in the study may be observed only, interviewed only or both observed and interviewed in order to capture as many elements as possible of their experience of the dietetic consultation. The semi-structured interviews will be based on a pre-developed topic guide specific for the dietitians guided by the literature review. Open-ended questions will be used to draw out experiences of providing nutritional support in different healthcare settings, and of factors guiding the provision of different types of nutritional support.

c. Key stakeholder interviews:

Semi-structured interviews will be used to explore the experience of the consultation for carers/relatives/other healthcare professionals who have been nominated by the patient. The experience of carers and others indirectly involved in the healthcare process for any given patient is an area which has received little attention in the literature and it is not clear whether the experience of such individuals should be measured using the same tools for exploring the patient experience (de Silva, 2013). However, for the purpose of this study, and because the key stakeholders will be nominated by the patient and therefore could include a range of possible individuals with a wide range of knowledge, expertise, input and involvement, separate interview guides will be produced for this participant group. The extent to which they are involved in the consultation, their communication with the dietitian, or the degree to which they might be involved in the implementation of the nutritional intervention for the patient will also be explored.

Patient–nominated key stakeholders will be nominated by the patients (Group 2) who will be interviewed and they will be invited to [redacted] for a separate interview. It is preferred that they are interviewed privately to avoid their responses being influenced by the presence of the patient in the interview.

Documentary Information

Documentary information will be used to further understand the full range of factors affecting the consultation experience through data triangulation. As required for good clinical practice, dietitians are required to document the details of each consultation in the patient's medical records and sometimes additionally in dietetic departmental records although the two often merge to avoid having duplicate records. The data required from medical/dietetic records will include the patient's date of birth, gender, nutritional status, ethnicity, number of dietitian appointments, clinical setting, details of the agreed nutritional intervention, social circumstances/family support, and the clinical dietitian's documentation of the details of the consultation. Any copies of patient records will be anonymised but labelled with a unique participant identifier to enable interpretation alongside the interview and observational data. Data for documentary analysis will be obtained as soon as possible after the consultation observation (Group 1), which may depend on how quickly consultation notes are documented by the clinical dietitian but it is anticipated that this will be within a couple of days of the consultation. Documentary data may be obtained prior to the qualitative interview (Group 2) and might also be used to modify the interview topic guides as appropriate. All cases will include the dietitian's medical/dietetic notes of the consultation as a triangulated data source.

As part of the illuminative evaluation approach to be used, these records as well as relevant clinical guidelines or trust policies will be included for document analysis as relevant. These may include local departmental protocols or pathways for management of malnutrition or national clinical guidelines, or other relevant published documents.

Supporting documentary information will be required for all patients in the study (Groups 1 & 2) to help in the triangulation of data. As the limitations of this data source have been considered, every effort to improve the credibility of this information e.g. through triangulation with other data sources will

be undertaken. The document analysis procedures for application to qualitative research as outlined by Bowen (2009) will be used.

Data Analysis

Data analysis will commence as soon as possible after the first few observation notes have been written up and interviews transcribed and will take the form of thematic analysis. Documents will be first categorised into:

1. 'Umbrella Documents' comprising mainly local and national clinical guidelines, standards and policy documents
2. 'Patient-level documents' comprising the medical/ dietetic notes and any other individualised documents pertaining to that particular consultation as relevant to the study.

The Umbrella Documents will be used to create a guiding framework for analysing the Patient-level documents but will be eventually used in the triangulation of all data sources. A core principle of illuminative evaluation as recommended by Partlett & Hamilton (1972) is that there are three stages in that researchers "observe [or interview], inquire further and then seek to explain" (p18). So, it is important that further inquiry is informed by preliminary analysis of the observations and interviews that have gone before to allow progressive focussing and refinement of the data collection that follows. Transcripts of each interview will be read and re-read alongside listening to recordings of interviews several times. Once this is achieved for the first few observations and interview transcripts, possible codes will be noted to begin to develop a coding structure. It is acknowledged that meaning and explanations begin to emerge from the start of data collection and that these may be used to guide subsequent data collection as well as analysis, although final conclusions will not be drawn until all data are collected. Memos will be used to record thorough processes for code classification. Codes will then be grouped into categories and categories into themes. As themes emerge from the data, this will allow us to begin to draw conclusions and analysis will continue until no new themes emerge. As analysis progresses, interpretation will continue with the development of patterns and explanations with reference to the literature. Data management software will be used to collate and manage the large volume of data, following appropriate training.

Data Storage, Transfer, Access & Archiving

During the course of the research study, all data will be the responsibility of the Research Dietitian under the supervision of the Chief Investigators, who will ensure that any personal study data are kept in secure conditions i.e. on password-protected Trust/ University computers or in a locked filing cabinet in the [redacted]. These will only be accessible only by the Research Dietitian or Chief Investigators. All data collected will be stored using password-protected software and will be accessed only by the Research Dietitian or Chief Investigators for the purposes of analysis.

Interviews will be recorded using a digital recording device. A second digital recording device will be used to protect against potential equipment failure.

The professional transcription services of [redacted] Research Support will be used to transcribe the qualitative interviews. Data transfer between the Research Dietitian and [redacted] Research Support will employ the following secure method: a secure disk or memory stick will be sent by post using Royal Mail Special Delivery to send the audio recordings to [redacted] Research Support. [redacted] Research Support will then email the transcript back and password protect it. Details of the password would be sent by [redacted] Research Support in a separate email. The memory stick will be returned to the Research Dietitian by [redacted] Research Support by Royal Mail Special Delivery for safe discard.

Copies of the confidentiality agreement, data protection agreement and general security policies and procedures from [redacted] Research Support are available on request.

When the study is complete, the research records will be kept for a further five years in accordance with the requirements of the Research Governance Framework and Health Board Policy.

6 STUDY SETTING

Data will be collected from the following four clinical settings including:

1. Hospital ward
2. Outpatient clinic
3. Intermediate care
4. Community (home visits)

A variety of clinical settings was chosen for the purpose of maximum variation sampling in order to cover a broad range of clinical experiences. The four clinical settings represent both institutionalised and non-institutionalised patients which might highlight differences in the nutritional management of malnutrition by dietitians working in these settings. Amongst these clinical settings, there are conceivable variations in the amount of time available for individual dietetic consultations, frequency of dietetic consultations, impact of the artificial (e.g. hospital ward) versus real life (e.g. home) setting, degree of illness or wellness of the patient, and differences in organisational constraints, amongst other factors which may influence the process of the dietetic consultation. Thus, the impact of these on the patient's perception of the dietetic consultation merits further exploration and will be achieved by recruitment of patients from a variety of settings.

Patient recruitment procedures will vary according to clinical setting and are detailed under 'Recruitment' below. Dietitians will be accessed from the Nutrition & Dietetic Service within the [redacted] NHS Trust. Patients will be accessed from the current caseload (including new referrals) of the clinical dietitians included in the sample. Key stakeholders will be accessed by means of patient nomination by patients in Group 2 (those being interviewed).

Hospital ward:

It is anticipated that recruitment of hospital inpatients (HIP) will come from the three wards on the older person's unit at [redacted]. However, any patients potentially eligible for the study will be approached for recruitment irrespective of their acute ward admission across the Trust.

Outpatient clinic:

It is anticipated that recruitment of hospital outpatients (HOP) will come from the [redacted] Hospital where the dietitians are likely to see older patients and provide nutritional support. Any additional clinics covered by dietitians employed by the Trust and participating in the study will also be considered, irrespective of their speciality area, as long as the patient meets the study inclusion criteria.

Intermediate care:

It is anticipated that recruitment of Intermediate Care (IC) patients will come from the [redacted] where patients are seen by dietitians from the [redacted] team.

Community (home visits):

It is anticipated that recruitment of home visit (HV) patients living in the community will come from the caseload of the [redacted] team of dietitians who regularly see patients in their own homes who may require nutritional support.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Details of the study inclusion and exclusion criteria are given below.

7.1.1 Inclusion criteria

Study participants to include:

Patients:

- Adults (aged ≥ 60 years)
- National Health Service (NHS) number
- Capable of giving informed consent
- Able to communicate well in English
- Nutritionally vulnerable according to the Nutrition Screening Tool in use at [redacted] Trust prompting referral to a dietitian
- Likely to receive a form of oral nutrition support in the management of malnutrition

- Not receiving end-of-life care i.e. with a life expectancy of more than three months (as determined by a Consultant or GP in accordance with local policies). However, a decision will be made in consultation with the multidisciplinary team and the patient in such cases regarding inclusion/exclusion as this is a one-off patient interview with the patient with no subsequent, active follow-up. Therefore, restrictions on participation will not be placed upon the patient if considered appropriate for inclusion by the parties aforementioned.
- Consents to having their qualitative interview audio-recorded (Group 2)
- A variety of the characteristics below:

Age	• 60-65 years • Over 65 years
Gender	• Male • Female
Ethnicity	• Mixture of ethnicities to be included in the sample as represented in the local area according to the [redacted] State of the Borough ([redacted] Council, 2016) & [redacted] Demographic Fact Sheet ([redacted] Council, 2015)
Type of nutritional support received	• Food-based advice (food first) • ONS • Combination of the two strategies
Number of consultations	• Attended one appointment with dietitian • Attended 2 or more appointments
Consultation type	• Face-to-face • Telephone
Clinical setting	• Hospital outpatient (HOP) • Hospital inpatient (HIP) • Home visit (HV) • Intermediate care (IC)
Family support	• Yes • No

Dietitians:

- Consulting dietitian providing the nutritional advice to participating patient
- Employee of [redacted] NHS Trust and member of the Nutrition & Dietetic team
- Minimum of three different dietitians across the healthcare settings to be included

Key Stakeholders:

Up to 2 optional patient-nominated key stakeholders who are involved in the dietetic consultation and success of the dietetic intervention e.g. other HCP, family member, carer or friend. Their criteria for inclusion will include:

- Nominated by the patient (from Group 2) participating in the study
- Involved in some aspect of the implementation of goals agreed between the patient and dietitian during the consultation i.e. the nutritional intervention
- Available for separate interview at a mutually agreed location
- Capable of giving informed consent
- Able to communicate well in English

Participants with visual or hearing impairment or other physical disabilities will NOT be excluded from the study.

7.1.2 Exclusion criteria

Exclusion criteria (patients):

- Participated or due to participate in another aspect of the study i.e. a patient will not be recruited to participate in consultation observations (Group 1) if they have already been or due to be recruited to take part in the qualitative interviews and vice versa (Group 2).
- Outside of stated age range for inclusion
- Incapable of giving informed consent
- Cognitive impairment
- No National Health Service (NHS) number
- Unable to communicate well in English
- Not considered nutritionally vulnerable according to Nutrition Screening Tool
- Not referred to a dietitian for nutrition support
- Patients receiving artificial nutrition support
- Judged to be receiving end-of life care (i.e. unlikely to live for more than three months as assessed by a consultant or GP in accordance with local policies). However, a decision will be made in consultation with the multidisciplinary team and the patient in such cases regarding inclusion/exclusion as this is a one-off patient interview with the patient with no subsequent, active follow-up. Therefore, restrictions on participation will not be placed upon the patient if considered appropriate for inclusion by the parties aforementioned.
- Does not wish to have their qualitative interview audio-recorded (Group 2)

7.2 Sampling

As described by Brinkmann (2013), information-oriented selection will be used to ensure that participants are chosen on the basis of expectations of the information they will provide in relation to the study. More specifically, maximum variation sampling will be employed to ensure data from the widest variety of patient circumstances can be captured (Brinkmann, 2013). Therefore, patients of differing age brackets, both males and females, those receiving different types of oral nutritional support, those who have had just one or more than one consultation, different consultation modes, different clinical settings and the presence or absence of family support will all be recruited. Maximum variation sampling technique has been theoretically justified on the basis of prior knowledge of some of the factors which could potentially influence the outcome of a nutrition support consultation. It has already been stated that each patient from Group 2 will be invited to nominate a maximum of two key stakeholders for separate interview and the consulting dietitian will be invited for interview in all cases. Therefore, for each patient interviewed, there could be up to three additional persons interviewed.

7.2.1 Size of sample

It is not possible at this stage to specify a sample size as it is planned to continue sampling and recruitment until data saturation is reached and until no new themes emerge. However, Brinkmann (2013) has expressed caution against recruiting large samples (over 50 interviews) for qualitative interview studies and argues that in such cases a survey might be more appropriate. Data saturation will be sought and interviews will be continued until no further new themes emerge. Applying the principle proposed by Francis et al (2010) for defining an a priori point for data saturation, a minimum sample and ceasing criterion will be defined. For this study, a minimum of 3 data collection rounds providing approximately 10 data sources (i.e. 3 observations, 3 patient interviews, and interviews with associated dietitians and nominated key stakeholders, and associated documents) will form the initial analysis sample. After this point, when 3 more data collection rounds have been completed and no new themes emerge, this will define the point of data saturation. After that point, no further recruitment will occur.

7.2.2 Sampling technique

The population to be sampled are nutritionally vulnerable older adults seeing a dietitian for oral nutritional support. Purposive sampling will be used to derive a small, defined sample for illuminative evaluation of the dietetic consultation. The rationale for this sampling strategy is to intentionally recruit a small, defined sample of participants with specific characteristics to illuminate their experiences of the oral nutrition support consultation by means of in-depth interviews, triangulated with observational and documentary data. Purposive sampling will allow selection of participants to represent the widest possible range of experiences to shed light on the phenomenon of interest. There will be a snowball effect with regard to sampling of the key stakeholders as these will be recruited on the basis of patient (Group 2) nomination, however, the core patient sample (Groups 1 & 2) will be recruited purposively.

7.3 Recruitment

Recruitment procedures will vary according to clinical setting and are detailed here in turn:

Hospital ward:

1. Clinical dietitians working in the department of [redacted] Hospital, who regularly see patients on the elderly care wards for nutrition support will be briefed on the study eligibility criteria.
2. Clinical dietitians will be invited to participate in the study and will be provided with a Participant Information Sheet (specific to the clinical dietitians).
3. Clinical dietitians will be asked to provide written, informed consent. This will be by means of a consent form which will be signed and dated by both the participating clinical dietitian and the Research Dietitian. The clinical dietitians may be asked to participate in the consultation observations only, qualitative interviews only or both the observations and interviews. They may also be asked to assist the Research Dietitian in acquiring relevant supporting documentation.
4. Clinical dietitians will be asked to pre-screen potential patients on their current caseload, in collaboration with the Research Dietitian, to identify all those who meet the study inclusion criteria. This is in order to reduce selection bias by the clinical dietitians who may apply their own biases in selection of potential participants due to their familiarity with the patients in a care capacity. As the Research Dietitian will not know the patients, selection of patients for invitation will be purely based upon the inclusion criteria and the requirement for maximum variation in the sampling strategy. The Research Dietitian will not be reviewing the patient's entire medical/dietetic record at this stage, and will only access patient information directly related to the inclusion and exclusion criteria, required to determine their study eligibility. This pre-screening procedure will be completed in close collaboration the clinical dietitians as the Research Dietitian will not access patient records independently at this stage. The clinical dietitians will be reminded to remain objective at all times during the pre-screening process to ensure any unfounded selectivity is avoided.
5. The clinical dietitians will be asked to approach potential participant patients, currently under their care who are pending a dietetic consultation or review, for potential inclusion based on the pre-screening procedures.
6. A brief introduction to the study will be provided by the clinical dietitian and if the patient is interested, the clinical dietitian will inform the Research Dietitian who will provide the patient with the participant information sheet on the ward and an opportunity to ask any questions.
7. The Research Dietitian will leave the patient to consider the invitation for a minimum of 24 hours (this may be less under some circumstances). The patient will then be asked to complete written, informed consent procedures with the Research Dietitian before any data collection commences.
8. For patients whose consultations will be observed (Group 1), the next scheduled dietetic consultation will be arranged for observation on the ward.
9. For patients who will be interviewed (Group 2), the Research Dietitian will agree a date and time for the private, qualitative interview with the patient. Written, informed consent procedures

will be followed at this stage. Any relevant supporting documentary information may be reviewed before or after the qualitative interview, as required and as available. Patients will also be asked to nominate a maximum of two key stakeholders to be contacted for invitation to a separate interview. Contact details of the nominated key stakeholders will be obtained from the patient. If the nominated key stakeholder is present at the time of nomination, the Research Dietitian will provide an overview of the study and explain why they are being invited to participate. Otherwise, the Research Dietitian will contact the nominated key stakeholders by telephone or letter to invite them to participate in the study. They will be sent a Participant Information Sheet specific for the key stakeholders by post (or hand delivered if present on the ward) and allowed enough time to consider their participation. The Research Dietitian will then contact the key stakeholders by telephone to find out whether they would like to participate in the study and if yes, will arrange a mutually agreed date/ time/ venue for a separate qualitative interview. Written, informed consent procedures will be followed for the key stakeholders.

Outpatient clinic:

1. Clinical dietitians working in the department of Nutrition & Dietetics at [redacted] NHS Trust, who regularly see patients for nutrition support in the outpatient clinics will be briefed on the study eligibility criteria.
2. Clinical dietitians will be invited to participate in the study and will be provided with a Participant Information Sheet (specific to the clinical dietitians).
3. Clinical dietitians will be asked to provide written, informed consent. This will be by means of a consent form which will be signed and dated by both the participating clinical dietitian and the Research Dietitian. The clinical dietitians may be asked to participate in the consultation observations only, qualitative interviews only or both the observations and interviews. They may also be asked to assist the Research Dietitian in acquiring relevant supporting documentation.
4. Clinical dietitians will be asked to pre-screen clinic lists for potential patients, in collaboration with the Research Dietitian, to identify all those who meet the study inclusion criteria. This is in order to reduce selection bias by the clinical dietitians who may apply their own biases in selection of potential participants due to their familiarity with the patients in a care capacity. As the Research Dietitian will not know the patients, selection of patients for invitation will be purely based upon the inclusion criteria and the requirement for maximum variation in the sampling strategy. The Research Dietitian will not be reviewing the patient's entire medical/dietetic record at this stage, and will only access patient information directly related to the inclusion and exclusion criteria, required to determine their study eligibility. This pre-screening procedure will be completed in close collaboration the clinical dietitians as the Research Dietitian will not access patient records independently at this stage. The clinical dietitians will be reminded to remain objective at all times during the pre-screening process to ensure any unfounded selectivity is avoided.
5. The clinical dietitians who see patients in these outpatient settings will be asked to review their clinic lists for eligible patients who are pending a dietetic consultation or review in clinic, for potential inclusion based on the pre-screening procedures. A brief introduction and invitation

to the study will be provided by means of a departmental headed letter sent to the patient by post along with a PIS in advance of the clinic date.

6. This will allow the patient sufficient time to consider the invitation to participate in the study.
7. The patient will be informed in that letter that they may be approached by a member of the research team in the clinic waiting area when they arrive for their clinic appointment to find out whether they would be interested in taking part in the study and be given the opportunity to have any questions answered regarding the study.
8. For patients whose consultations will be observed (Group 1), on arrival to their outpatient appointment with the clinical dietitian, they will be asked to complete the written, informed consent procedures before observation of the dietetic consultation commences. Any relevant supporting documentary information may be reviewed after the consultation observation, as required and as available.
9. For patients who will be interviewed (Group 2), a date and time for the private, qualitative interview with the patient will be arranged. Again, written, informed consent procedures will be followed at this stage. Any relevant supporting documentary information may be reviewed before or after the qualitative interview, as required and as available. The patient will also be given the option to nominate a maximum of two key stakeholders to be contacted for invitation to a separate interview. Contact details of any nominated key stakeholders will be obtained from the patient. If the nominated key stakeholder is present at the time of nomination, an overview of the study will be provided and why they are being invited to participate will be explained. Otherwise, the research team will contact any nominated key stakeholders by telephone or letter to invite them to participate in the study and will provide them with a Participant Information Sheet specific for the key stakeholders by post (or by hand if present). They will be given time to consider their participation. The research team will again contact the key stakeholders to find out whether they would like to participate in the study and if yes, will arrange a mutually agreed date/time/venue for a separate qualitative interview. Written informed consent will also be followed for the key stakeholders.

Intermediate care:

1. The [redacted] dietitians working in the department of Nutrition & Dietetics at [redacted] NHS Trust, who regularly see patients for Nutrition Support in the intermediate care setting will be briefed on the study eligibility criteria.
2. [redacted] dietitians will be invited to participate in the study and will be provided with a Participant Information Sheet (specific to the clinical dietitians).
3. [redacted] dietitians will be asked to provide written, informed consent. This will be by means of a consent form which will be signed and dated by both the participating clinical dietitian and the Research Dietitian. The [redacted] dietitians may be asked to participate in the consultation observations only, qualitative interviews only or both the observations and interviews. They may also be asked to assist the Research Dietitian in acquiring relevant supporting documentation.

4. The [redacted] dietitians will be asked to pre-screen potential patients on their current caseload, in collaboration with the Research Dietitian, to identify all those who meet the study inclusion criteria. This is in order to reduce selection bias by the [redacted] dietitians who may apply their own biases in selection of potential participants due to their familiarity with the patients in a care capacity. As the Research Dietitian will not know the patients, selection of patients for invitation will be purely based upon the inclusion criteria and the requirement for maximum variation in the sampling strategy. The Research Dietitian will not be reviewing the patient's entire medical/dietetic record at this stage, and will only access patient information directly related to the inclusion and exclusion criteria, required to determine their study eligibility. This pre-screening procedure will be completed in close collaboration the [redacted] dietitians as the Research Dietitian will not access patient records independently at this stage. The LAMP dietitians will be reminded to remain objective at all times during the pre-screening process to ensure any unfounded selectivity is avoided.
5. The [redacted] dietitians will be asked to approach potential participant patients, currently under their care who are pending a dietetic consultation or review, for potential inclusion based on the pre-screening procedures.
6. A brief introduction to the study will be provided by the [redacted] dietitians and if the patient is interested, the [redacted] dietitian will inform the Research Dietitian, who will provide the patient with the PIS and an opportunity to ask any questions.
7. The Research Dietitian will leave the patient to consider the invitation for a minimum of 24 hours (may be less under some circumstances) for the patient to consider the invitation to participate in the study.
8. For patients whose consultations will be observed (Group 1), the next scheduled dietetic consultation will be arranged for observation at the intermediate care unit. Any relevant supporting documentary information may be reviewed before or after the consultation observation, as required and as available.
9. For patients who will be interviewed (Group 2), the Research Dietitian will agree a date and time for the private, qualitative interview with the patient. Written, informed consent procedures will be followed at this stage. Any relevant supporting documentary information may be reviewed before or after the qualitative interview, as required and as available. Patients will also be asked, to nominate a maximum of two key stakeholders to be contacted for invitation to a separate interview. Contact details of the nominated key stakeholders will be obtained from the patient. If the nominated key stakeholder is present at the time of nomination, the Research Dietitian will provide an overview of the study and explain why they are being invited to participate. Otherwise, the Research Dietitian will contact the nominated key stakeholders by telephone or letter to invite them to participate in the study. They will be sent a Participant Information Sheet specific for the key stakeholders by post (or hand delivered if present) and allow them enough time to consider their participation. The Research Dietitian will then contact the key stakeholders by telephone to find out whether they would like to participate in the study and if yes, will arrange a mutually agreed date/ time/ venue for a separate qualitative interview. Written, informed consent procedures will be followed for the key stakeholders.

Community (home visits):

1. The [redacted] dietitians working in the department of Nutrition & Dietetics at [redacted] NHS Trust, who regularly see patients for Nutrition Support in the community setting will be briefed on the study eligibility criteria.
2. [redacted] dietitians will be invited to participate in the study and will be provided with a Participant Information Sheet (specific to the clinical dietitians).
3. [redacted] dietitians will be asked to provide written, informed consent. This will be by means of a consent form which will be signed and dated by both the participating clinical dietitian and the Research Dietitian. The [redacted] dietitians may be asked to participate in the consultation observations only, qualitative interviews only or both the observations and interviews. They may also be asked to assist the Research Dietitian in acquiring relevant supporting documentation.
4. The [redacted] dietitians who see patients in the community setting will be asked to identify patients, currently under their care (or newly referred), for potential inclusion based on the inclusion criteria.
5. The [redacted] dietitians will be asked to pre-screen potential patients on their current caseload, in collaboration with the Research Dietitian, to identify all those who meet the study inclusion criteria. This is in order to reduce selection bias by the [redacted] dietitians who may apply their own biases in selection of potential participants due to their familiarity with the patients in a care capacity. As the Research Dietitian will not know the patients, selection of patients for invitation will be purely based upon the inclusion criteria and the requirement for maximum variation in the sampling strategy. The Research Dietitian will not be reviewing the patient's entire medical/dietetic record at this stage, and will only access patient information directly related to the inclusion and exclusion criteria, required to determine their study eligibility. This pre-screening procedure will be completed in close collaboration the [redacted] dietitians as the Research Dietitian will not access patient records independently at this stage. The [redacted] dietitians will be reminded to remain objective at all times during the pre-screening process to ensure any unfounded selectivity is avoided.
6. A brief introduction and invitation to the study will be provided by means of a departmental headed letter and PIS sent either along with the home visit appointment booking letter or separately.
7. The patient will be informed in that letter that they will be contacted by telephone following their receipt of the letter but before the home visit appointment to find out whether they would be interested in taking part in the study.
10. The Research Dietitian will leave at least 24 hours after anticipated receipt (3-5 days after posting) for the patient to consider the invitation to participate (maybe less under some circumstances).
8. If the patient expresses a willingness to participate when contacted by telephone (either by the [redacted] dietetic assistants or by the Research Dietitian), they will be given the opportunity to ask the Research Dietitian questions about the study.

9. The Research Dietitian will answer any questions they may have about the study. If the patient is contacted by the [redacted] dietetic assistants and there are any queries about the study or their participation, the Research Dietitian will contact the patient to answer these questions.
10. The patient will be asked to provide written, informed consent.
11. For patients whose consultations will be observed (Group 1), the Research Dietitian will arrange to attend an upcoming home visit booked for that patient. Prior to that home visit, the [redacted] dietitian will check with the patient that they would still like to participate and whether it's still okay for the Research Dietitian to attend the home visit. On arrival for the home visit appointment, the patient will be asked by the Research Dietitian to complete the written, informed consent procedures before observation of the dietetic consultation commences.
11. For patients who will be interviewed (Group 2), the Research Dietitian will agree a date and time for the private, qualitative interview with the patient. Written, informed consent procedures will be followed at this stage. Any relevant supporting documentary information may be reviewed before or after the qualitative interview, as required and as available. Patients will also be asked, to nominate a maximum of two key stakeholders to be contacted for invitation to a separate interview. Contact details of the nominated key stakeholders will be obtained from the patient. If the nominated key stakeholder is present at the time of nomination, the Research Dietitian will provide an overview of the study and explain why they are being invited to participate. Otherwise, the Research Dietitian will contact the nominated key stakeholders by telephone or letter to invite them to participate in the study. They will be sent a Participant Information Sheet specific for the key stakeholders by post (or hand delivered if present) and allow them enough time to consider their participation. The Research Dietitian will then contact the key stakeholders by telephone to find out whether they would like to participate in the study and if yes, will arrange a mutually agreed date/ time/ venue for a separate qualitative interview. Written, informed consent procedures will be followed for the key stakeholders.

7.3.1 Sample identification

Dietitians to be approached for inclusion will be identified by the Research Dietitian in discussion with the clinical dietetic leads at both [redacted] Hospitals and will be invited to the study either face-to-face or by email, as appropriate. The dietitians who have agreed to participate in the study will then be asked to review their clinical caseloads (including both new referrals and follow-ups) alongside the Research Dietitian in a pre-screening exercise to identify patients who might be eligible for inclusion in the study. This will constitute review of electronic patient records and departmental/dietetic records by the clinical dietitian caring for that patient, who would be a member of their care team, in collaboration with the Research Dietitian. Potentially eligible patients as identified during the pre-screening process and in discussion with the Research Dietitian to ensure they meet all eligibility criteria and characteristics required for maximum variation sampling will be approached for invitation to participate in the study. Key stakeholders will be nominated by the patients included and their name and contact details will be obtained from the patient.

Payments to participants to reimburse reasonable travel expenses for any visits additional to normal care are intended. This will apply to the patients and key stakeholders who opt to have their qualitative

interviews at [redacted]. Therefore, the cost of a return journey between their home address and [redacted] will be reimbursed once the interview has been completed.

7.3.2 Consent

The Research Dietitian will obtain written informed consent from each dietitian, patient and key stakeholder prior to participation. This will follow full explanation of the aims, methods, anticipated benefits and potential hazards of the study. A Participant Information Sheet (PIS) will be offered, the potential participant will be encouraged to ask any questions, and time will be allowed (minimum 24 hours but maybe less under some circumstances) for them to consider the potential impact of consenting to study inclusion. If for any reason, a potential participant makes a decision in less than 24 hours this will be documented together with a justification for this decision. The date that the PIS is given to the patient will be documented within the patient's notes. Signed participant consent will be obtained. The original signed form will be placed in the study records, a copy will be given to the participant and for patients included, a copy will be placed in the patient's notes. The right of the participant to refuse to participate without giving reasons will be respected.

The Mental Capacity Act 2005 states that no person can give consent on behalf of another adult. Accordingly, where a prospective participant is unable to provide informed consent they will be excluded from the study. Where uncertainty exists as to an individual's capacity, an assessment consistent with the Mental Capacity Act 2005 will be made by the clinical dietitian caring for the patient. Due to its nature, the proposed study will be minimally invasive providing no additional risk to the participant.

In order to fully explore the processes and function of the dietetic consultation, and determine its impact on the overall experience for dietitians, patients and key stakeholders, it will be necessary for the Research Dietitian to access relevant medical/dietetic records. These data will be accessed, analysed and stored securely at all times. Any patient-identifiable data will be anonymised but will be linked to the interview and observational data for data analysis purposes. Each potential participant will be informed of this, should they agree to inclusion in the study, will be required to provide written consent to their medical/dietetic records being accessed and included in the study in this way.

All potential participants will be informed by the Research Dietitian that they are free to withdraw at any time from the study without giving reasons and without prejudicing further treatment.

Since this is a non-invasive, qualitative study we do not anticipate that any safety issues will arise during the conduct of the study. However, in the unanticipated event that they do, the PIS will be reviewed and updated accordingly. All participants who are actively enrolled on the study will be informed of the updated information and given a revised copy of the PIS in order to confirm their wish to continue on the study.

Since it is known that the management of malnutrition in the community is sub-optimal it is possible that the researcher will observe and document examples of neglect in the care of vulnerable adults during the data collection period. Should this occur, the Research Dietitian will inform her supervisors and will be responsible for reporting this to the appropriate authorities in accordance with local safeguarding policies.

8.1 Assessment and management of risk

Potential risks of the study will include:

1. As food/nutrition is an emotive subject, patients and key stakeholders may become upset when discussing aspects of the patient's nutritional care. Participants will be made aware that they can withdraw feely from the study at any time without consequence. The Research Dietitian will aim to ensure that the participant is comfortable and at ease at all times during the qualitative interviews. This will include prior to commencement of the interview and before more probing questions. The Research Dietitian will employ communication skills to establish a rapport with the patient and observe any cues from the participant during the interview indicative of distress including if they might be perceiving the questions to be intrusive. The Research Dietitian will respond by checking with the participant at several points within the interview whether or not they are happy to proceed with answering the questions and share their experience. The Research Dietitian will also remind the participant that it is perfectly acceptable to pause or stop at any time, at their discretion and without consequence.
2. There is the potential that whilst undertaking an interview the Research Dietitian might obtain information that the participant is at risk of potential harm or reveals an intention to harm others. The Safeguarding policies in place within the [redacted] Trust will be followed, including notification of all necessary parties. The Research Dietitian will make every effort to arrange to attend the Trust Safeguarding Training prior to commencement of the study to ensure knowledge of these policies is up-to-date.
3. The Research Dietitian lone working to conduct the various patient, dietitian and key stakeholder interviews. The location of these interviews will vary with each set of participants. The department's policy on Lone Working will be strictly followed and a Chief Investigator will be made aware at all times of the whereabouts of the Research Dietitian during the interview period of the study. Interviews will only be conducted in mutually agreed locations and where the Research Dietitian feels safe. In instances where the Research Dietitian is uncertain of the safety of the location, a Chief Investigator will accompany the Research Dietitian to the interview location. In the event that the Research Dietitian perceives a situation that puts her in imminent danger, she will not intervene but will instead remove herself from danger immediately and when clear, contact the police with the details. If she is in a situation where she is unable to leave, she will phone the Chief Investigator and alert her by using a pre-agreed coded statement question to indicate that she is in danger and needs the police urgently.

8.2 Research Ethics Committee (REC) review & reports

Before the start of the study, approval will be sought from an NHS REC for the study protocol, informed consent forms and other relevant documents. Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study. In addition,

approval of proposed amendments will also be sought from the [redacted] R&D department before their implementation.

All correspondence with the REC will be retained.

The Chief Investigators will be responsible for producing annual reports as required. The Chief Investigators will also notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigators will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigators will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Peer review

The study was intitially prepared as a research proposal for a funding application to The Dunhill Medical Trust. Through a competetive process the Research Dietitian was awarded a Research Training Fellowship from The Dunhill Medical Trust, which is funding the study. With some refinement, the research proposal has evolved into this study protocol which has been reviewed by two academic research supervisors, experts in Nutrition & Dietetics. The proposed study procedures have been reviewed in detail by the Research Dietitian's PhD Thesis Progress Committee which includes experts in Nutrition, Dietetics & Qualiative Research Methodology.

8.4 Patient & Public Involvement

Anecdotal evidence from direct patient communication during my previous clinical role helped to suggest the idea for the project. Unfortunately, due to the timing of the research design process and application for relevant approvals, it was not possible to formally involve patients, service users, and/or their carers, or members of the public in the research process so far.

As the project will be conducted on a small scale for the requirements of a PhD, patient and public involvement will be incorporated at the earliest possible stage and any feedback generated will be used to refine any relevant study tools (e.g. interview topic guide, observational pro forma, patient letters), any subsequent plans for the project, if necessary, or inform future research projects, as appropriate. This involvement may take the form of a series of presentations to members of the public or patient groups given by the Research Dietitian including conference presentations, speaking to patient/support groups or presenting study findings to service providers (including healthcare professionals). Results of the study will be fed back to study participants in an appropriate format as well as those who were consulted or collaborated in the project. Patient groups or charities will be consulted for information about relevant groups and forums with potential interest, to which the study can be presented.

8.5 Regulatory Compliance

Before patients are recruited to the study, the Research Dietitian/ Chief Investigators will apply for NHS permission from the site management organisation, HEI or NHS Research & Development (R&D).

For any amendment that will potentially affect a site's NHS permission, the Research Dietitian/ Chief Investigators will confirm with that site's R&D department that NHS permission is ongoing.

8.6 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigators and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.7 Data protection and patient confidentiality

As 'custodian' of all data collected during this study, the Chief Investigator(s) will ensure that patient anonymity is protected and maintained at all times by the Research Dietitian, and will also ensure that participant identities are protected from any unauthorised parties. All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. In addition, all information relating to study participants will be kept confidential and managed in accordance with the NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval.

Upon recruitment, all participants will be issued with a unique non-identifiable participant code/number which will be recorded on all proformas relating to the study. A master list of the unique identifiers, together with the name, date of birth, NHS number and home address of each study participant, will be kept in a password-protected database securely on a Trust/ University computer, separate from the rest of the data. Only the research team will have access to the database.

The following identifiable data will be collected for each study participant as relevant:

- Name – required in order to contact study participants to arrange qualitative interviews. This will apply to all participants.
- Date of Birth, Gender and Ethnicity – required in order to confirm study eligibility as part of the inclusion criteria and/or maximum variation sampling requirement.
- Address and postcode – required in order to contact study participants to arrange qualitative interviews and/or to send study information by post. This will apply to patients and key stakeholder participants only and not to dietitian participants.
- Contact phone numbers – required in order to contact study participants to arrange qualitative interviews. This will apply to all participants.
- NHS number – to permit access to dietetic records in relation to the consultation observed. This will apply only to the patients included in the study, and not to the dietitians or key stakeholder participants.

- GP/Consultant details – This will apply to patients only to ensure that the participant's GP or Consultant is aware of their participation in the study.
- Relationship with patient – This will apply to the key stakeholders only. Relations might include parent, child, spouse, civil partner, other relation, friend, carer, or healthcare professional. This information is required to record the link to the patient for the purpose of data interpretation. This will apply to all participants.

For the key stakeholders, identifiable data required for the arrangement of qualitative interviews i.e. name, address, contact details and relationship with patient, will be entered on a password-protected database securely onto a Trust/ University computer and will be accessed only by the Research Dietitian.

Patient-identifiable data required to permit access to electronic health records i.e. NHS number, will be entered on a password-protected database on a computer and will be accessed by the Research Dietitian for the purposes of data analysis and interpretation alone.

As part of the consenting procedure all participants will be requested to give their consent to the use of their data and will be directed to confirm this in writing on the informed consent form.

All participants will be informed during the recruitment process of their right to revoke their authorisation for the use of their data. All participants will be anonymised with regards to any future publications relating to this study. Pseudonyms may be used for the purpose of publication, if more appropriate but participants will remain unidentifiable at all times. In addition to previously stated measures to ensure the anonymity of participants, the Trust will not be identified in any reports, presentations or publications generated from the study. Furthermore, any staff, wards, treatment units involved in the study will also remain unnamed. Any contextual information which is not relevant to the research question being answered will not be included in any direct participant quotes used in any reports, presentations or publications generated from the study. No recognisable labels will be used to describe any aspect of the study in publication which would make participants identifiable.

Observation data at each site will be collected by the Research Dietitian using a standard pro forma designed for use in this study. The pro forma for the observation protocol will not contain any patient-identifiable data and will carry the unique non-identifiable participant code/number assigned to that patient.

All interview transcripts and notes will be labelled with the unique non-identifiable participant code/number assigned to that patient. The transcripts will be checked for identifiable information and edited accordingly to remove such data without adversely affecting the data collected.

Participants may be informed of the study findings in a specially designed newsletter or invited to a presentation. Study results will be available at the participant's request only after they have been published. This will require the retention of the participant's name and contact information beyond the end of the research project, until study findings have been published. These details will be securely stored in a password-protected file only accessible by the research team. Participants will be offered

the opportunity to opt-in to notification of the study findings by any of the means specified. If they chose to be notified, their name and contact details will need to be retained for that purpose only, under the conditions of valid consent. Equally, participants will be given the option to not be contacted after the study ends in which case no identifiable information will be kept for up to 3 years beyond the study's end.

The Research Dietitian will abide by the information governance policies in place within the various clinical settings.

8.8 Indemnity

Arrangements for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research will be the responsibility of the study sponsor(s). Arrangements for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research will also be the responsibility of the study sponsor(s).

Arrangements for insurance and/ or indemnity to meet the potential legal liability of investigators/ collaborators arising from harm to participants in the conduct of the research in the NHS settings proposed will be covered by the NHS indemnity scheme, where appropriate. Activity within the other clinical settings proposed, will be covered under the professional indemnity of the Research Dietitian (Michelle Gibbs), provided by the British Dietetic Association.

8.9 Amendments

Once study approvals have been obtained, all subsequent amendments (substantial or non-substantial) will be notified to the [redacted] NHS R&D department as a first port of call, to assess whether the amendment affects the NHS permission. R&D will be responsible for the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial. Any substantive changes will be communicated to relevant stakeholders.

If the sponsor(s) wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor(s) will submit a valid notice of amendment to the REC for consideration. It will be the sponsors' responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendment history will be tracked by identifying the most recent protocol versions as "Protocol Amendment Version 1,2,3" and so on.

8.10 Access to the final study dataset

The Research Dietitian (Michelle Gibbs), the Chief Investigators (Christine Baldwin & Peter Emery) and any additional members of the research team will have access to the full dataset.

Any secondary analysis will only be undertaken with the consent of the participants. All patient documentation will reflect any proposed future use of these data in research.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Data arising from the study will be owned by [redacted]. On completion of the study, the data will be analysed and a Final Study Report prepared. While the study progresses, oral poster presentations may be given and abstracts produced on preliminary results within the Diabetes & Nutritional Sciences department at [redacted] in fulfilment of the Research Dietitian's PhD registration. A full study report will be produced at the end of the study in the form of a PhD thesis and accessible in line with [redacted] academic regulations. The Research Dietitian intends to publish the study data in (an) appropriate academic peer-reviewed journal(s) for which all participating investigators will be named authors. The funding body (The Dunhill Medical Trust) will be acknowledged within any publications. The [redacted] teams involved will specifically remain unnamed to preserve the anonymity of all participants. Participants will be notified of the outcome of the study by provision of the publication or by other means as appropriate (e.g. via a specifically designed newsletter or presentation). If participants specifically request results of the study, these will be provided to the participant after the results have been published. The study results may also be presented to the [redacted] NHS Trust and oral poster presentations maybe given and abstracts produced for professional conferences, as relevant. The study protocol, full study report, anonymised participant level dataset, and statistical code for generating the results will not be made publicly available. Patient and public involvement will also be incorporated during dissemination of findings.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be granted to individuals who have made a significant academic contribution to the study.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

The following documents are attached separately:

- CV of study co-ordinator / PhD Student – Mrs Michelle Gibbs
- CV of primary research supervisor / Chief Investigator 1 - Dr Christine Baldwin
- CV of secondary research supervisor / Chief Investigator 2 – Professor Peter Emery
- Consent form for Patients on headed paper
- Consent form for Dietitians on headed paper
- Consent form for Key Stakeholders on headed paper
- Participant Information Sheet for Patients on headed paper
- Participant Information Sheet for Dietitians on headed paper
- Participant Information Sheet for Key Stakeholders on headed paper
- GP letter template with notification of patient participation in study

11.2 Appendix 2 – Schedule of Procedures

Procedures	**Visits**	
	Screening	**Data collection days**
Informed consent	x	
Observation of treatment (Group 1)		x

Interview (Group 2)		x
Document review (Groups 1 & 2)		x

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.8	1.6.18	Michelle Gibbs	Changes to the research design, question, study procedures and study documents.
2 (Minor)	1.8	1.6.18	Michelle Gibbs	Study end date extension by 12 months (executed December 2019). No changes made to protocol.
3 (Minor)	1.9	21.2.19	Michelle Gibbs	Updated study dates in light of extension above. Changes to Transcription Service provider from [redacted] to [redacted] Research Support.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor(s) for approval prior to submission to the REC committee.