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Development of a psychoeducational intervention for patients with cancer cachexia and their informal carers

by

Sally Wheelwright

Thesis for the degree of doctor of philosophy

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ABSTRACT

FACULTY OF MEDICINE

Cancer Sciences

Thesis for the degree of Doctor of Philosophy

DEVELOPMENT OF A PSYCHOEDUCATIONAL INTERVENTION FOR PATIENTS WITH CANCER CACHEXIA AND THEIR INFORMAL CAREGIVERS

Sally Jane Wheelwright

Cancer cachexia has a negative impact on patients and their informal caregivers but as there are no approved drug treatments for the condition, palliation of symptoms is the main therapeutic goal. This thesis describes the development and piloting of a workshop, the first small group psychoeducational intervention for cancer cachexia. The main objective of the workshop was to improve the quality of life (QOL) of patients and carers. A new questionnaire, the QLQ-CAX24 was developed to assess QOL in patients with cancer cachexia. A study to explore the feasibility of conducting a randomised controlled trial (RCT) using the workshop in a secondary care setting was conducted.

Workshop development was consistent with the MRC guidelines for developing and evaluating complex interventions and development followed the Coventry Intervention Development Process. A systematic review of the patient literature generated a comprehensive list of QOL issues and was used to develop a model of the patient experience of cancer cachexia. This model, along with the Integrated Theory of Health Behaviour Change provides the theoretical underpinning of the workshop. The patient systematic review supplemented interviews with patient and health care professional (HCP) interviews in the development of the QLQ-CAX24. A systematic review of the carer literature was limited by the available data but domains of experience were identified.

The intervention targets of the workshop were identified by carrying out interviews with patients, carers and HCPs and by consulting the patient and carer systematic reviews. The published literature and other cancer cachexia interventions informed the content of the workshop, both in terms of the information it provides and the methods used to deliver this information. Pilot and feasibility testing demonstrated that although the workshop was acceptable, a different recruitment strategy is required for the planned RCT.

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DECLARATION OF AUTHORSHIP

I, ... [please print name]

declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

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....

I confirm that:

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2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
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Date: ....

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Abbreviations

ACT	Acceptance and Commitment Therapy
AHP	Allied health professional
ATM	Antecedent Target Measure
BMI	Body mass index
CASP	Critical Appraisal Skills Program
CIDP	Coventy Intervention Development Process
CMH	Countess Mountbatten Hospice
CNS	Clinical nurse specialist
COSMIN	Consensus-based standards for the selection of health status measurement instruments
CQOLC	Caregiver Quality of Life Index-Cancer
CRF	Cancer-related fatigue
CRP	C-reactive protein
CT	Computerised tomography
ECOG	Eastern Cooperative Oncology Group
EMA	European Medicines Agency
EORTC	European Organisation for the Research and Treatment of Cancer
EPA	Eicosapentaenoic acid
EPCRC	European Palliative Care Research Collaborative
ERAS	Enhanced recovery after surgery
ERD	Eating-related distress
ESPEN	European Society for Clinical Nutrition and Metabolism
FAACT	Functional Assessment of Anorexia/Cachexia Therapy

FACIT	Functional Assessment of Chronic Illness Therapy
FAWE	Family Approach to Weight and Eating
FDA	US Food and Drug Administration
FRI	Family Relationships Index
GPS	Glasgow Prognostic Score
HCA	Healthcare assistant
HCP	Health care professional
HPN	Home parenteral nutrition
HRQOL	Health related quality of life
ITHBC	Integrated Theory of Health Behaviour change
L3	Third lumbar vertebra
MAWE	Macmillan Approach to Weight and Eating
MDCP	Macmillan Durham Cachexia Pack
MoSCoW	M– Must have; S – Should have; C – Could have; W– Would like if time permits
MRC	Medical Research Council
MS	Multiple sclerosis
NHS	National Health Service
ONS	Oral nutritional supplements
OS	Overall survival
OT	Occupational therapists
PANAS	Positive and Negative Affect Schedule
PCU	Palliative care unit
PG-SGA	Patient-Generated Subjective Global Assessment
PIS	Participant information sheet

PN	Parenteral nutrition
PPI	Patient and public involvement
PRISMA	Preferred Reporting Items of Systematic reviews and Meta-Analyses
PRO	Patient reported outcome
QOL	Quality of life
RCT	Randomised controlled trial
RT	Radiotherapy
SD	Standard deviation
SME	Self-management education
S-NIS	Secondary nutritional impact symptoms
WHO	World Health Organization
WRD	Weight-related distress

Part A: Introduction and aims

Chapter 1: Introduction

1.1 Overview

Cachexia is a common problem for cancer patients and can have serious consequences, negatively impacting response and tolerance to treatment, survival and health-related quality of life (HRQOL). The most obvious clinical manifestation is unintentional weight loss but the identification and management of the condition is challenging, and currently there are no approved drug treatments for cancer cachexia. Health care professionals (HCPs) may feel they are ill-prepared and under-resourced to support patients. Equally, informal caregivers, who often feel responsible for the patient's nutritional needs, can be unsure how best to help and their own quality of life (QOL) may worsen as a result of their loved one's condition. To encourage the self-management of the impact of cachexia, patients and their carers need information and support. This thesis describes the development and piloting of a workshop, the first small group psychoeducational intervention for cancer cachexia, and a study to explore the feasibility of conducting a randomized controlled trial (RCT) using the workshop in a secondary care setting. The workshop was devised with the aim of improving QOL by educating and supporting patients with unintentional weight loss and their carers.

The thesis is divided into five parts. Part A provides an introduction to relevant concepts, leading to the rationale for the decision to develop a workshop. An overview of the methods employed is then presented. In Part B, the impact of cancer cachexia on the QOL of both patients and carers is explored in two systematic reviews. These reviews establish the need for an intervention and contribute to the intervention targets. The patient review also informs the development of a questionnaire to evaluate QOL in patients with cancer cachexia. The development of the workshop is described in Part C, whilst preliminary testing is covered in Part D. Finally, a general discussion and conclusions are offered in Part E.

This chapter begins by describing what cancer cachexia is, why it can be difficult to identify in clinical practice and prevalence. Currently recommended treatments and management strategies are then described. This is followed by a discussion of the impact of cachexia, including the psychosocial impact for both patients and carers, and the reason that QOL needs to be considered and assessed. Finally, previously published psychoeducational interventions are introduced and the rationale for the development of a workshop is provided.

1.2 Cancer cachexia definition

Cachexia, from the Greek “kakos” and “hexis” meaning “bad condition”, has been defined as, “…a complex metabolic syndrome associated with underlying illness and characterized by loss of muscle with or without loss of fat mass” [1]. It occurs when there is an imbalance between catabolism and anabolism, independent of food intake. Commonly found in a number of chronic diseases, including chronic heart failure, AIDS and chronic obstructive pulmonary disease, cachexia is associated with poor prognosis and high morbidity. This thesis focusses on cancer cachexia.

Progress in the diagnosis, treatment and research of cancer cachexia has been hampered by the lack of an agreed definition of cachexia. There have even been problems in discriminating cachexia from other terms commonly used to describe wasting disease, such as anorexia, malnutrition and sarcopenia [2]. Following the publication of three different cancer cachexia definitions [1,3,4], representatives from the three groups met in December 2009 under the auspices of the European Palliative Care Research Collaborative (EPCRC) to reach a consensus definition for cancer cachexia specifically. Following a formal consensus process, including focus groups and two Delphi rounds, a consensus definition for cancer cachexia was produced [5]:

> Cancer cachexia is a multi-factorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. The pathophysiology is characterized by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism.

The consensus group also identified cancer cachexia as a continuum with three stages: pre-cachexia, cachexia and refractory cachexia (see Figure 1 [5]). In pre-cachexia, the early clinical and metabolic signs of cachexia (e.g. anorexia, impaired glucose tolerance) are present but involuntary weight loss is ≤ 5%. Patients with cachexia have >5% loss of stable body weight in the last 6 months, or have ongoing weight loss >2% and a body mass index (BMI) <20 kg/m^2 and sarcopenia, but have not entered the refractory stage. Refractory cachexia is associated with active catabolism, or the presence of factors that render active management of weight loss no longer possible and/or appropriate. Refractory cachexia is characterized by a low performance status (World Health Organization Score 3 or 4) and life expectancy <3 months. Although this consensus diagnosis defines the different stages of cancer cachexia, it did not describe how the different stages of cachexia should be assessed or operationalised and simple clinical indicators may not be sufficient for this purpose [6-8].

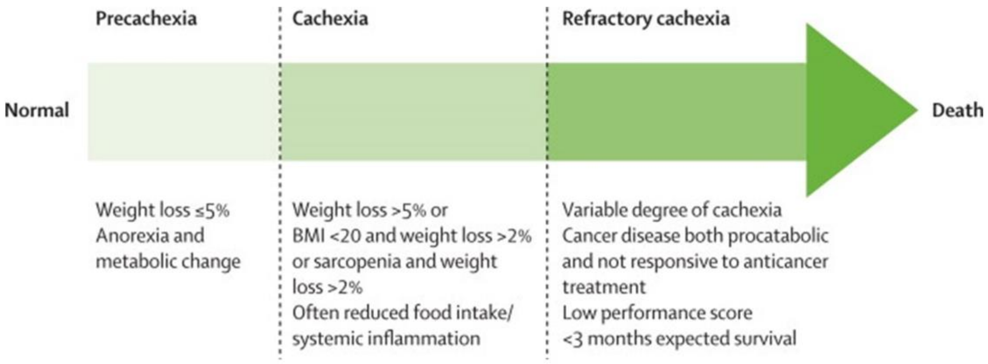


Figure taken from Fearon et al. (2011) [5] and reproduced with permission of the rights holder, Elsevier.

Figure 1: Stages of cancer cachexia.

The consensus definition provides a list of possible components for classifying cancer cachexia, but actual diagnostic criteria still need to be formulated [9]. These criteria must be clinically relevant, practical and acceptable. The key indicators are weight loss, sarcopenia (muscle depletion), food intake and abnormal metabolism. Each of these are discussed in turn.

The bivariate classification of weight loss (whether patients have lost 5% of their body weight or not) is generally accepted to be an oversimplification. Martin and colleagues have proposed a grading system based on current BMI and rate of weight loss which predicts survival independently of conventional prognostic factors [10]. Further research is required to establish what clinical interventions are most appropriate for each grade.

In the consensus definition paper, it was proposed that muscle mass could be assessed using computerised tomography (CT) cross-sectional images taken in the third lumbar (L3) region as these were routinely available [5]. A review of 53 CT L3 studies, including a total of 9128 patients, concluded that there was an association between muscle depletion and adverse outcomes including poor survival and chemotherapy toxicity [11]. However predefined clinical cut-offs need to be established, based on patient characteristics including sex, age, muscularity and tumour type, to identify those patients most in need of intervention.

For the concept of reduced food intake, there is a great deal of heterogeneity in methods of assessment and there is no consensus on which method is preferable. Similarly, for abnormal metabolism, there is no consensus on the most appropriate measurement system. C-reactive protein (CRP) is a commonly used index of systemic inflammation. The Glasgow Prognostic Score (GPS), which is based on CRP and albumen levels, has been proposed as providing an objective framework for the assessment and treatment of cancer cachexia [12]. The proposal is that patients with a GPS of 0 do not have cachexia; a GPS of 1 corresponds to either pre-cachexia if there is no weight loss or to cachexia syndrome if there is weight loss; and a GPS of 2 is indicative of refractory cachexia. In terms of treatment, if a patient was experiencing weight loss but had a GPS of 0, then cachexia would not be the cause and an alternative explanation, such as malabsorption or malnutrition, would be sought. However, the value of this classification system in clinical practice has not been evaluated.

The consensus group did not provide a definition for secondary cachexia, although this is important from a clinical perspective [4]. Primary cachexia refers to the tumour-induced metabolic component of the condition and in secondary cachexia, secondary nutritional impact symptoms (S-NIS) contribute to the progression of the primary cachexia [13,14]. S-NIS are factors which interfere with nutritional intake or uptake and include nausea and vomiting; localized pain, such as mouth ulcers or pain in general; taste and smell disturbances, such as those induced by chemotherapy; diarrhoea or constipation; shortness of breath; fatigue; depression; anxiety and mechanical obstruction, such as a tumour occluding the oesophagus [15,16]. Many of these are treatable using supportive care measures so it is important to consider S-NIS in the clinical management of weight losing cancer patients, to maximise nutritional uptake [17]. However, it can be clinically difficult to estimate the relative contribution of S-NIS and cachexia to the presentation of the anorexia and cachexia in the patient [18]. Whether there are cancer cachexia patients without any S-NIS at all remains an unanswered question. In one study including 151 patients attending a cachexia clinic, more than half had three or more S-NIS [19]. Unfortunately, it is not possible to extract data from that study to ascertain whether any patients presented without S-NIS.

1.3 Hidden cachexia

According to the World Health Organization (WHO), the worldwide prevalence of obesity more than doubled between 1980 and 2014 [20]. In 2014, about 39% of the world's adult population were overweight (BMI ≥ 25 kg/m^2) and 13% were obese (BMI ≥ 30 kg/m^2). In England, results from the Health Survey for England indicated that 61.7% of adults were overweight or obese [21]. Even in cancer patient samples, including those with metastatic disease, 40-60% are reported to be overweight or obese [22]. In the context of this obesity epidemic, there is a concern that cachexia may be under-recognised [14]. Obese patients with a chronic illness tend to survive longer, an effect known as the obesity paradox [23], and the same is true for patients with cancer cachexia [10]. Nevertheless, patients with cancer have a poor prognosis, regardless of overall body weight, if they have involuntary weight loss along with muscle depletion and low muscle attenuation [24]. Obese patients may perceive their initial involuntary weight loss as beneficial and fail to seek help for their cachexia, making them more at risk of a negative cancer outcome [25]. For the busy HCP, it can be harder to spot patients with cachexia who are overweight or obese because they do not have the wasted appearance typically associated with cachexia and there are no quick, easy-to-use and reliable tools available for assessing lean body mass in clinic.

Cancer cachexia may also be hidden in patients approaching the end of life who gain, rather than lose weight because of ascites, peripheral oedema, hepatomegaly, or increased tumour burden [26].

1.4 Prevalence of cancer cachexia

Cachexia has been estimated to be the immediate cause of death in 20-40% of cancer patients and it has been reported that more than 80% of patients with cancer develop cachexia before death [27,28]. However, estimating the prevalence of cachexia in cancer patients is not straightforward. Historically, the lack of a consensus definition of cachexia [29] meant that prevalence estimates could differ considerably: the proportion of patients with cachexia in a sample of 8541 cancer patients varied between 2.4% and 14.7% depending on which definition was used [30]. In addition, the type of cancer affects prevalence. In the classic study led by Dewys, weight loss was found in between 11% (favourable non-Hodgkin's lymphoma) and 87% (gastric) of over 3000 cancer patients about to have chemotherapy [31]. More recently, a study of 390 consecutive patients with advanced cancers found that 36% met the consensus definition for cancer cachexia [5], with lymphoma patients having the lowest prevalence and pancreatic cancer patients having the highest [32]. A preliminary report on 1000 outpatients with cancer found that 39.7% had significant weight loss (≥10%) [33] and a review of symptom prevalence in patients receiving active cancer treatment found that 45% of 3388 patients had anorexia or appetite changes whilst 40% of 321 patients had weight loss [34]. Taking all these data together, it is clear that eating problems and weight loss are common problems for patients with cancer, even if prevalence figures are not clear cut.

1.5 Treatment for cancer cachexia

The European Society for Clinical Nutrition and Metabolism (ESPEN) has recently published guidelines to improve the detection and management of malnutrition and metabolic disorders in adult cancer patients and survivors, at any stage of the disease. The guidelines, which were developed using the GRADE system [35], are summarised in Appendix A. The GRADE rankings for the quality of evidence range from very low to high, whilst strength of recommendation can either be weak or strong. Consensus was reached if 75% or more of the guideline group members agreed, with strong consensus if agreement was 100%. Although strong recommendations were made for 12 guidelines, the majority of these had a low or a very low level of evidence. The recommendations included the suggestion to regularly monitor nutritional intake, weight change and BMI from diagnosis onwards and to carry out quantitative assessments of nutritional intake, S-NIS, muscle mass, physical performance and systemic inflammation in patients with abnormal screening. The use of high dose micronutrients is not recommended but nutritional interventions, including dietary advice and the use of oral nutritional supplements is endorsed if required. Enteral nutrition should be offered if oral intake is inadequate and then parenteral nutrition if enteral nutrition is not sufficient. Only maintaining or increasing physical activity had a high level of evidence and was strongly recommended. The use of progestins, or corticosteroids for a short period, to increase appetite in anorectic patients with advanced cancer, had high levels of evidence but the strength of recommendation was weak. In general, there is a deficit of evidence relating to the topics covered by the guidelines.

The same problem of a lack of evidence was found when the European Palliative Care Research Collaborative (EPCRC) produced a consensus- and evidence-based clinical practice guideline for the management of cancer cachexia in advanced cancer patients, with a focus on refractory cachexia (see Appendix B) [36]. Overall, there was not enough evidence to recommend use of most of the treatments, or they are inappropriate for patients with refractory cachexia. However, it was suggested that megestrol and progestins, steroids and prokinetics could be of some benefit.

Four Cochrane reviews to examine treatments for patients with cancer cachexia have been completed. These reviews have found no evidence that eicosapentaenoic acid improves symptoms associated with cachexia in patients with advanced cancer [37] and inadequate evidence to recommend the use of thalidomide in clinical practice [38]. Whilst megestrol acetate was shown to offer a benefit in appetite, weight gain and QOL compared with placebo (but not other drugs), oedema, thromboembolic phenomena and deaths were more frequent in patients treated with megestrol acetate [39]. A review on the effects of exercise on lean body mass, a biomarker for cancer cachexia, found no trials that met the inclusion criteria [40]. The use of ghrelin in the management of cancer cachexia is the subject of a new Cochrane review, currently underway [41].

There are three issues which have been identified as contributing to the disappointing results with cachexia therapies: the lack of a consensus definition, unimodal clinical trials and initiation of therapy too late in the disease trajectory [14,42]. The lack of a consensus definition and staging framework means that clinical trials have not necessarily included comparable patients which impacts the possibility of carrying out meta-analyses, and compromises the comparison of the effectiveness of different treatments.

Although cachexia is universally acknowledged to be a multi-factorial syndrome, the vast majority of clinical trials have investigated single agents. Many of these trials have focussed on anorexia and have met with limited success [43]. The small number of published studies examining multiple interventions in cancer cachexia suggest that body weight and lean body mass may be increased [42] and one study found increased survival, increased body fat and a greater exercise capacity in patients given nutritional supplements along with medication to counteract metabolism and inflammation [44]. Results across trials are inconsistent, however, and positive results are typically not achieved for all outcome measures. Currently, there is no published study which has included all the modes of intervention which have been suggested as beneficial, that is nutrition, exercise, medication to counteract anorexia and systemic inflammation, and also psychosocial support. Indeed, examination of the WHO International Clinical Trials Registry (apps.who.int/trialsearch) indicates that this trend is set to continue as only one of the 18 cancer cachexia studies currently recruiting is using a multi-modal design, the MENAC trial [45]. The MENAC intervention comprises nutritional advice and an oral nutritional supplement containing eicosapentaenoic acid (EPA); a home-based physical exercise programme; and anti-inflammatory treatment (ibuprofen).

Prior to the refractory phase, cachexia may be reversible to some degree so if cachexia therapy was started early, and ran in parallel with antineoplastic therapy, patients' progression along the cachexia continuum might be curtailed. This is why it has been recommended that the focus of cachexia therapy research should switch to the point of cancer diagnosis [14]. For this to be possible, however, early clinical indicators of cachexia or ideally pre-cachexia need to be identified. MENAC addresses this issues by recruiting patients with a diagnosis of advanced lung cancer, pancreatic cancer or cholangiocarcinoma because they are likely to either already have cachexia syndrome or be in the pre-cachectic phase.

Based on current thinking, a treatment plan which advocates first targeting the tumour, then systemic inflammation, next normalising energy and substrate intake and finally encouraging exercise has been proposed [14]. This plan neglects to include a psychosocial component, which is important for cancer cachexia [13]. Although psychosocial support for cancer cachexia patients may address the consequences of the condition, such as distress, it may also help alleviate some of the causes of the condition and support treatment. For example, psychosocial support may help to maximize nutritional intake, and also support uptake and compliance with new therapies [13]. Communication between the patient, family and HCPs has been identified as important for the delivery of multimodal treatment [46] and psychosocial interventions can contribute to improvement in this area.

For patients who are already experiencing cancer cachexia, a multi-modal approach to clinical management is recommended but a number of barriers may prevent this occurring in practice [47]. Specialised cachexia clinics are a rarity (see section 0) so the responsibility to provide care usually falls to the oncologist and/or cancer nurse who may be constrained by time, resources and confidence to manage the condition [48]. Nevertheless, it has been suggested that there are practical ways that the non-cachexia specialist can and should provide multimodal care for cancer cachexia, using simple treatments (such as managing S-NIS, providing tailored advice on eating, and encouraging physical activity and exercise), as long as the patient, family and care team all buy in to the approach of supported self-management [47].

1.6 Impact of cachexia on cancer patients

Cachexia can have a profound impact on cancer patients. In a study including patients with a wide variety of cancer diagnoses, weight loss prior to chemotherapy was associated with lower response rates to treatment, decreasing performance and shorter survival [31]. A study including only patients due to receive chemotherapy for gastrointestinal carcinomas (n=1555) found that weight loss at presentation was an independent prognostic variable [49]. Weight loss was correlated with shorter failure free and overall survival, along with decreased QOL, performance status and response to treatment. Patients with weight loss had more frequent and more severe dose limiting toxicity and so they received less treatment.

Similar results were found in a sample of nearly 800 lung cancer patients: weight loss was associated with treatment toxicity and shorter survival [50]. In patients with advanced pancreatic cancer, who had all lost ≥5% of their body weight, weight loss alone (≥10% vs. <10%) did not predict functional aspects of self-reported QOL, inflammatory status or body composition, but there were differences in performance status and grip strength [51]. Using a three factor profile, incorporating weight loss, reduced food intake and systemic inflammation, differences were found on all variables, including measures of objective and subjective functioning, body composition and health status.

Cachexia was also found to have an impact on the survival and performance status in a sample of pancreatic cancer patients which included both those undergoing tumour resection and palliative treatment [52]. Finally, in a sample of over 400 unselected palliative care cancer patients, those patients classified as cachectic using a variety of criteria, were found to have worse QOL, reduced functional abilities, more symptoms and shorter survival [53].

These studies included large samples of patients with different types of cancer, providing convincing evidence of the major implications that cachexia has for cancer patients. It is associated with decreased response and tolerance to treatment, functional abilities and performance status; more symptoms; reduced survival and perhaps inevitably given these other associations, worse HRQOL. The psychosocial impact of the condition is discussed in the next section.

1.7 Psychosocial impact

The importance of psychosocial factors for oncology patients has long been recognised [54] but with the increasing complexity of the medical management of cancer patients, clinics consistently overrun [55,56] and clinicians have little time to discuss psychosocial issues [57]. In addition, patients may feel that it is not the physician's role to deal with psychosocial issues or they may withhold information so as not to burden their physician [58].

Cancer also has a significant psychosocial impact on carers [59]. Informal carers or caregivers, who may or may not be family members, are non-professionals in a close supportive role who share in the illness experience of the patient and who undertake vital care work and emotion management [60]. In the UK, there was estimated to be almost 1.5 million people providing informal care for someone with cancer in 2016 [61].

A systematic literature search of the qualitative literature, including data from patients, carers and HCPs, informed the development of a model of the psychosocial effects of cancer cachexia [62]. The model conceives psychosocial effects as negative emotions. Mechanisms which lead to negative emotions are listed as inability to eat, awareness of weight loss, starving to death, changed cooking and eating habits, loss of "dinner hour", relationship changes, lack of attention to nutritional problems by HCPs and inappropriate or wrong information [63-68]. Adverse reactions like force feeding, patient withdrawal and hunger strike are associated with escalating psychosocial effects [64,65,69], whilst decreasing psychosocial effects are associated with coping strategies, specifically letting nature take its course, finding other ways to care and patient driven feeding [70,71]. The model does not make explicit the direction of causality in either of these two associations; for example whether the suggestion is that people are better able to cope because they have fewer negative emotions or that people experience fewer negative emotions because they are better able to cope.

Since the review included data from patients, carers and HCPs it is not clear to whom the negative emotions which are used to define psychosocial effects are associated with. Do the authors mean patients and carers together, or perhaps the psychosocial effects refer to either patient or carer? This is important because sometimes patients and carers have different responses. For example, in a study with 101 carers, 82% reported distress as a consequence of patient anorexia, more than the corresponding percentage of patients [72]. One reason for this distress is that patient rejection of food may induce feelings of rejection in carers, along with a sense of helplessness. One study found a significant correlation between the magnitude of patient weight loss and caregivers' distress [25]. Weight loss provides visible evidence of disease progression and may be perceived as symbolising the looming of death, adding to feelings of powerlessness and loss of control carers may experience [63,67,73,74]. Food and eating have a central role in everyday life so caregivers face these problems on a daily basis. Social interactions often include a food element and special occasions are frequently associated with special foods so there is an impact on social life, for both the patient and carer.

These cancer cachexia related problems for carers are in addition to the challenges associated with caring for someone with cancer in general. The shifting of primary care from hospitals and HCPs to the home and informal caregivers has increased the challenges faced by carers [75,76]: carers may take on the responsibility of symptom management, personal care and co-ordinating appointments, along with providing social and emotional support [77]. It has been suggested that the education and support required by caregivers should become part of the patient discharge plan [78]. Formalising this help could be beneficial as many caregivers report having difficulty accessing HCPs, and getting the information and support they need [75]. This would also be a practical step to back up governments', advisory bodies' and international agencies' rhetoric on the vital role played by caregivers and the importance of addressing their needs [60,79,80].

A comprehensive review on the effects of caring for a patient with cancer listed over two hundred problems and burdens related to cancer caregiving responsibilities including physical, social and emotional difficulties, need for information, and impact on daily life [59]. Given this wide range of potential problems, it is not surprising that being a cancer caregiver sometimes has a negative impact on QOL [81]. One way to evaluate whether carers are receiving the appropriate support and are coping with their caregiving role is to monitor their QOL because the multi-dimensional nature of QOL reflects the multi-dimensional problems faced by carers. Monitoring carer QOL can aid HCPs judge the amount of support which is required by carers and may help avoid crisis situations. These can arise when carers close to breaking point are assumed to be coping, because they do not request services [82]. At breaking point, whether this is by collapsing through physical exhaustion or injury, or by becoming overwhelmed by the carer responsibilities, carers can no longer carry on caring [83]. This can result in the need for emergency care for the patient.

Tracking carer QOL may also be important because of the interdependence between caregiver and patient QOL [84], with some studies providing evidence of a causal link, both from patient to carer and from carer to patient [85,86]. This suggests that if a carer's QOL declines, the same is likely to occur for the patient. Therefore, by meeting the needs of carers, and maintaining their QOL, patients could also benefit.

In the model described above, the psychosocial effects of cancer cachexia are defined in terms of negative emotions [62]. This could be considered too limiting since negative emotions are one aspect of the impact of a disease on an individual. A more expansive approach is to develop a model based on QOL or, for patients, HRQOL. HRQOL refers to those aspects of QOL which patients consider are affected by disease and treatment and includes physical, emotional, cognitive and social components [87]. By identifying very specific HRQOL issues, a more detailed understanding of how cancer cachexia affects patients can be obtained and this information can inform the content of interventions by pinpointing what concerns are most significant to patients with cancer cachexia. Similarly, understanding the factors which impact the QOL of carers of cancer patients with cachexia can contribute to the development of an intervention to help carers cope with the specific challenges associated with this condition. There have been no systematic reviews exploring how cancer cachexia impacts the HRQOL of patients or the QOL of carers.

1.8 Assessment of cancer cachexia related quality of life

As well as evaluating patient need, the assessment of HRQOL can improve patient care in a number of other ways, including complementing clinical outcomes in the evaluation of treatment benefit and harm, monitoring disease progression and aiding patient decision making [88]. In order to do this effectively, a reliable and valid HRQOL questionnaire is required. A systematic review carried out by SW found that most studies including weight losing or cachectic cancer patients used generic cancer HRQOL instruments [89]. This was also the case in a later systematic search of cancer cachexia clinical trials undertaken by SW [90]. Only one cancer cachexia specific HRQOL questionnaire, the Functional Assessment of Anorexia/Cachexia Therapy (FAACT), which is part of the Functional Assessment of Chronic Illness Therapy (FACIT) measurement system, was identified [89,91-93].

The FAACT was assessed by SW and a second judge using the consensus-based standards for the selection of health status measurement instruments (COSMIN) [94]. The COSMIN provides a methodological quality score for internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity and responsiveness. Each of these attributes is measured using a number of items which are rated excellent, good, fair and poor. The methodological quality score is obtained by taking the lowest rating of any of the items which make up each attribute. Content validity can be defined as "…the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose". Whilst the FAACT was found to have excellent content validity using the COSMIN, this checklist assesses content validity on the basis of whether 'experts' judge the items to be relevant and comprehensive. Since the development of the COSMIN, the central role of patient input in demonstrating content validity has become the standard [95]. Essentially this means that items should be derived from patient interviews or focus groups and since this is not documented for the FAACT, supplementary evidence of content validity is still required. In addition, the COSMIN checklist highlighted a number of weaknesses in the methodological quality of the study that reported its measurement properties. The evaluation of internal consistency, reliability, measurement error and structural validity were all rated as poor using the COSMIN.

There are no QOL tools aimed specifically at carers of patients with cancer cachexia and issues related to patient eating and weight loss are not adequately covered by the currently available carer QOL tools. In the four carer QOL instruments identified by a systematic review [96], there is only one item, in the Caregiver Quality of Life Index-Cancer Scale [97], related to patients' eating habits.

1.9 Psychoeducational interventions for cancer cachexia

Given the lack of effective treatment for cancer cachexia, it has been suggested that the focus of care should be on supported self-management [47]. Self-management can be encouraged by the use of psychoeducational interventions, which may be delivered alongside medical interventions. Psychoeducational interventions provide knowledge along with counselling or other supportive interventions [98]. There are very few such interventions specifically designed for patients with cancer cachexia [99]. The first psychoeducational intervention for patients with weight- and eating-related distress was the Macmillan Approach to Weight and Eating (MAWE) [100,101]. Weight-related distress (WRD) is defined as a negative emotion experienced because of self-perceived problems as a consequence of involuntary weight loss [102]. Similarly, eating-related distress (ERD) is defined as a negative emotion experienced because of self-perceived problems as a consequence of changing eating habits [101]. MAWE was developed to complement pharmacological and nutritional interventions for cancer cachexia. It is a nurse-delivered intervention for patients with the purpose of facilitating effective coping and thereby enhancing QOL. It comprises five components: breaking through the weight loss taboo, telling healing stories, managing conflict, support for eating well, and support for self-action. Nurses are trained for one hour a week for five weeks and then use their clinical judgment to select and offer appropriate components of the intervention during home visits. MAWE has been found to be feasible and acceptable, with both patients and their carers reporting benefits, even though the intervention was designed to be delivered only to patients [101]. However, further research, in the form of replica studies or a larger multi-centred trial would provide more confidence in the efficacy of MAWE.

Following on from MAWE came the Family Approach to Weight and Eating (FAWE), which was designed to support people with advanced incurable cancer who have weight loss and poor appetite, and their family caregivers [103]. FAWE provides information and advice on eating difficulties and weight loss, and supports the relationship between patient and carer. Further details are provided in Chapter 6.

Like MAWE, FAWE was found to be feasible and acceptable, and also the patient and family carers perceived it to be of some benefit. Also like MAWE, more research is required to demonstrate the efficacy of the FAWE.

MAWE and FAWE were developed to specifically address WRD and ERD but psychoeducational interventions can be incorporated into the more general management of cancer cachexia. A study which explored the use of a structured approach to the assessment and management of patients with cancer cachexia, employing both pharmacological and non-pharmacological management strategies, found that there was a significant impact on symptom burden [104]. Forty patients who had advanced cancer with a palliative diagnosis and were suffering from any of the symptoms commonly associated with cancer cachexia were assessed individually by one of the research team, a clinical pharmacist. The management strategies were developed for the project according to the published evidence at the time or if this was not available, best practice. The non-pharmacological strategies included self-management strategies for both patients and carers relating to the adaption of food, meals and lifestyle. Patients were reviewed at two weeks and four weeks, with new strategies introduced as necessary. Over the course of the study, twelve patients were lost to follow up when they either became too unwell or died. Nevertheless there were statistically significant improvements to symptom burden between each of the time points [104].

This study resulted in the Macmillan Durham Cachexia Pack (MDCP), a resource for HCPs to guide in the assessment and management of common problems seen in cachexia [105]. As well as providing dietary, exercise and management strategies, the pack contains a number of leaflets to help patients and their families deal with the emotional and psychological impact of the condition. The developers suggest that the MDCP should be used as a tool for specialists to improve awareness and management of cancer cachexia, and as an educational resource for generalists [106]. However, evidence about the efficacy of the pack as used by clinicians, rather than one dedicated individual in the context of a research project, has not been published.

The final published psychoeducational intervention is a DVD for patients with advanced cancer who have cachexia and their lay carers [107]. The intervention developers are currently trialling the use of the DVD, although there have been challenges in recruitment to the trial [108]. The intervention comprises a DVD, with a follow-up phone call to ensure the DVD has been received and the recipient can use it. The content of the DVD has been informed by qualitative research and provides information on cancer cachexia and how to cope with its physical, psychological and social impact, along with a mindfulness exercise. No data are available yet relating to the efficacy of this intervention.

There are pros and cons associated with each of the psychoeducational interventions described above, in terms of the chosen mode of delivery. A DVD or the leaflets included in the MDCP may be helpful for patients who could benefit from face-to-face psychosocial interventions but do not accept these, because of personal preference or barriers to access [109,110]. A self-directed format overcomes some of these barriers and for some interventions, can be equally efficacious [111]. One obvious disadvantage of using leaflets or a DVD format is the lack of interactivity. If an intervention is delivered face-to-face, participants can have their questions answered as they arise. MAWE and FAWE are nurse delivered interventions but as they are delivered to individuals or couples, they may have a high cost attached. In addition, they may only be offered to those families with very significant distress, even though they may be of more widespread benefit. An alternative approach is to deliver an intervention in small groups, which could minimise costs whilst maintaining interactivity. Group interventions also offer the opportunity of vicarious learning from others (modelling) and gaining comfort from sharing experiences [112]. The decision was therefore taken to develop a small group intervention, framed as a workshop.

Chapter 2: Aims and overview of methods

2.1 Introduction

The opening chapter described how cancer cachexia is a common problem for patients with cancer with profound implications for both patients and their carers. Currently there are no approved drug treatments for cancer cachexia in Europe and the US so palliation of symptoms is the main therapeutic goal. Psychoeducational interventions can contribute to the management of cancer cachexia by providing information and support. Previously, there have been no published small group interventions for patients and carers affected by cancer cachexia.

The term workshop was selected to describe the small group intervention developed in this PhD, to suggest that it would be an active rather than passively received intervention. Workshop was also considered a relatively neutral word, to avoid discouraging participants who could have negative associations with other terms which could have been used e.g. support group [113].

The workshop intervention was planned as a single session, rather than multiple sessions. This is important to reduce the burden of participation for this patient group, who can feel quite unwell. Single sessions have been shown to be effective in the management of other cancer-related symptoms. For the management of cancer pain, a systematic review and meta-analysis found that interventions with multiple exposures did not provide better outcomes than single exposure interventions [114]. However, this systematic review could not explore the effect of number of exposures with the same intervention. Nevertheless, the meta-analysis demonstrated that single exposure interventions had a significant effect on knowledge and attitudes and also maximum pain intensity, with the effect of average pain intensity approaching significance.

The creation of a workshop to provide advice and support for patients and their carers could also potentially serve as an alternative referral destination for patients who are not seen by a dietitian. A study that collected data on the dietetic referral of GI cancer patients from 2002-4 in a UK hospital found that few patients were referred at the start of their treatment for nutrition issues [115]. About one third of those patients who lost more than 10% of their body weight were not referred at all. More recently, an unpublished service evaluation at Southampton General Hospital indicated that very few, just 8%, of outpatient cancer patients who meet the consensus definition for cancer cachexia [5] were successfully referred to a dietitian. Anecdotal evidence suggests that some of the barriers include availability of dietitians, consulting room space and also clinicians' lack of confidence in the ability of dietitians to provide psychosocial as well as nutritional advice. In the future, the establishment of regular workshops would provide an alternative referral destination for those patients who may benefit from early intervention. The content of the workshop could also inform the development of a web site for families who are unable to attend a workshop.

As well as the mode of delivery for the intervention, it is important to consider whether the intervention should be delivered to patients and carers together, or in separate groups. Carers and patients are recognised to have important influences on each other. For example, the extent women psychologically adjust to the situation when one member of a married couple is diagnosed with cancer plays a key role in the wellbeing of both the woman and her spouse [84]. This is the case whether the woman is the patient (with breast cancer) or the caregiver of her husband (with prostate cancer). It is possible that psychosocial interventions for cachexia could benefit from working with both members of the patient-caregiver dyad simultaneously. Two reviews of couple-based psychosocial interventions for those affected by cancer both report encouraging results, but recognise that the current data are limited [116,117]. It therefore remains an empirical question whether a couple-based intervention for cancer cachexia will be more effective than individual-based interventions. The decision was taken to first develop a workshop for patients and carers together. If feedback from participants suggested this was an acceptable approach future research could compare the effect of delivering workshop to patients and carers together or separately.

The overarching aim of the workshop was to improve QOL in both patients with cancer cachexia and their carers. Recipients must perceive a benefit if an intervention is to be considered successful and QOL is considered an essential component in the evaluation of therapeutic interventions across the cachexia spectrum [14]. In order to improve QOL, an understanding of how it is affected by cancer cachexia is required. Although a previous review had explored psychosocial effects of cancer cachexia [62], there have been no previous systematic reviews focussing on the HRQOL of cancer patients with cachexia. A systematic review was therefore planned for this thesis (Chapter 3) which was intended to contribute both to the identification of the evidence base for the workshop and to the development of a model to underpin the workshop.

In order to evaluate whether the workshop was successful in improving HRQOL in patients with cancer cachexia, a validated instrument was required. Given the concerns described in Chapter 1 about the FAACT, the only published specific cancer cachexia instrument, the development of a new questionnaire was planned. This is described in Chapter 4.

A parallel stream of work was intended for carers. No published reviews of QOL in carers of patients with cancer cachexia had been published so a systematic review was carried out (Chapter 3). As described in Chapter 1, there is no QOL questionnaire specifically designed for carers of cancer cachexia patients and relevant issues are not well covered in the instruments aimed at carers of cancer patients in general. Ideally, a new instrument would have been developed for carers as part of this work package but this was not possible within the constraints of a PhD.

2.2 Aims

1. To carry out a systematic review of HRQOL in patients with cancer cachexia.
2. To carry out a systematic review of QOL in carers of patients with cancer cachexia.
3. To develop a model of the impact of cancer cachexia on patients.
4. To develop a model of the impact of cancer cachexia on carers.
5. To develop a psychoeducational workshop for cancer patients with unintentional weight loss and their carers.
6. To conduct a feasibility study to inform a future evaluation study. The feasibility study had the following objectives:
    i. to determine the acceptability and practicality of the intervention for patients and carers.
    ii. to assess the acceptability of the data collection process and inform the selection of measures for an evaluation study.

2.3 Ethical considerations

One reason for developing a single session workshop was to reduce burden for participants. The importance of reducing burden is a key component of the argument that patients approaching the end of their lives should not be invited to participate in research. Is it reasonable, as end of life approaches, for researchers to be inviting patients and carers to invest their time, energy and physical resources into an activity from which they may not directly benefit? This same question could be asked of research participants who are not approaching the end of life: the established ethical principles apply equally to patients who are and who are not expected to recover from their illness [118]. Informed consent is required before anyone can take part in research so this ensures that potential participants understand what they are committing to. The respect for autonomy within the ethical framework means that individuals, perhaps in consultation with their families, decide how they wish to spend their time and it is their choice whether to take part in research or not. Without research in palliative care interventions, it is not possible to be confident that outcomes such as QOL and symptom relief, are being optimised and that the interventions are not causing harm [119].

Although it is argued that palliative care research in the palliative care setting is as important as research in others settings, it is acknowledged that there may be additional considerations for conducting research in this patient group. In the UK, 16 recommendations for best practice palliative and end-of-life care research were developed by experts in these areas, including researchers, service providers, commissioners, members of ethics committees and policy makers [120]. It could be argued that most of their recommendations were equally applicable to non-palliative or end-of-life care research, however the importance of flexibility in terms of recruitment strategy and using wider inclusion criteria are particularly applicable to these populations.

2.4 Methods

The workshop was expected to feature several interacting components and was therefore considered to be a complex intervention. The Medical Research Council (MRC) has provided some general guidance for the development and evaluation of complex interventions as shown in Figure 2 [121]. This thesis is concerned with two of the boxes in Figure 2, development and, feasibility and piloting. Although further guidance has subsequently been published describing how to conduct and report process evaluation studies [122] and other research teams have tackled the issue of incoporating theory-driven approaches to evaluation [123], detailed instructions for the actual process of developing an intervention within the MRC framework have not been provided. Additional guidance was therefore sought.

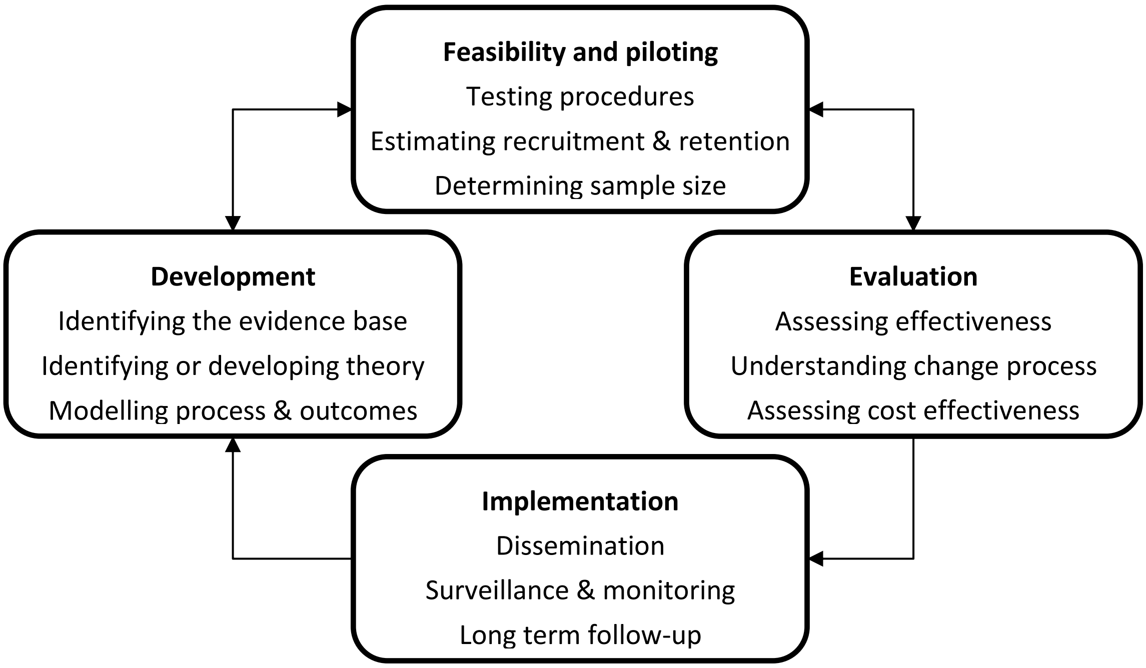


Figure 2: Key elements of the MRC development and evaluation process

Few published papers describe the process for developing interventions in sufficient detail to be able to utilise that process, and descriptions of the interventions themselves are not detailed enough to allow replication [124]. A search of the literature found only one published paper describing how to develop a workshop for self-management in cancer patients, the Coventy Intervention Development Process (CIDP) [125]. This process provides a very clear step by step guide, as summarised in Table 1 and and this approach was therefore selected to guide the development of the workshop in this thesis.

The preliminary step in the CIDP is to establish evidence of problem and need by reviewing the literature. For the workshop, this evidence was provided by the systematic reviews of the literature described in Chapter 3. Next, information on exisiting interventions is collated. This was introduced in section 1.9, with further details provided in section 6.3.

The next two steps in the process, which are described fully in Chapter 5, are based on the Antecedent Target Measure (ATM) approach to developing logic models [126]. Logic models consist of a sequence of cause and effect ('if-then') relationships. The process of logic modelling can be used to develop programmes or interventions and provides a method of understanding the rationale behind the resulting programmes. Logic models demonstrate the links between what needs to be changed, strategies to achieve these changes and what the expected outcomes are. ATM provides a method of mapping the problem which the intervention will address. It focuses on antecendents (root causes) to ensure that the intervention is aimed at the issues which lead to the problem rather than the symptoms of the problem [127].

There are two stages used in the ATM approach to identify what should be included in an intervention. The first stage is to identify the antecendents of the problem by clearly defining the problem and then interviewing individuals with content expertise in the area of the problem. By asking 'why does this happen?' questions, a visual map of the relationships between antecedents and the problem is developed. Maps from all the interviewees are integrated into a single summary map. In the second stage, a systematic prioritisation process is used to establish which antecedents the intervention will focus on.

Following the formation of intervention targets, literature reviews are conducted to identify intervention strategies and content-related evidence and a preliminary version of the workshop is produced. This step is described in Chapter 6. Finally the intervention is pilot tested (Chapter 8) and revised.

Table 1: Coventry Intervention Development Process

Step	**Tasks**
Preliminary work	Literature reviews & gather information on existing interventions
1. Antecedent (root causes) identification	Agree problem statement which will form basis of antecedent generation interviews
	Conduct interviews with patients, carers & healthcare professionals to identify antecedents
	Create summary map
2. Identify intervention targets	Rate importance and changeability through workshop attendance of each antecedent
	Select highest scoring antecedents
	Group antecedents to form intervention targets
3. Identify intervention strategies	Conduct literature review to establish strategies that address intervention targets
	Agree intervention strategies
4. Identify measures	Select outcome measures & plan evaluation framework
5. Produce and test intervention	Write workshop protocol
	Pilot workshop
6. Plan adoption, implementation & sustainability	Beyond the scope of this project

After the CIDP was followed to produce the workshop, a feasibilty study was carried out to explore whether it would be practical to conduct an RCT into the effectiveness of the workshop, whether the workshop was acceptable for patients and carers and whether the planned evaluation framework was appropriate (Chapter 9). Information from the pilot testing and feasbility study were used to produce the revised version of the workshop (Appendix S).

2.4.1 Advisory panel

An advisory panel was established to consult with during the development of the workshop. In an effort to recruit patients and carers to the project, a poster, shown in Appendix C, was put up in clinic waiting rooms, at the main entrance to Southampton General Hospital and at local supermarkets. There was no response to the poster. However one individual who had experience as both a patient and a carer and had advised on a previous project agreed to join the advisory panel. Patients and carers were also consulted on an ad hoc basis: SW discussed the project with patients and carers at support groups and outpatient clinics. HCPs were invitied by individual emails. Individuals with the following professions agreed to join the advisory panel: surgeon, professor of nursing, health economist, lecturer in health psychology, family therapist, consultant medical oncologist, dietitian, lecturer in cancer care, palliative medicine consultant, palliative care CNS, clinical psychologist and clinical research fellow in oncology. The advisory panel included the PhD supervisors. The panel was a ‘virtual’ committee in that members were emailed rather than convening as a group. They could choose to reply by email, phone or in person.

Part B: Establishing the need: the impact of cancer cachexia on quality of life

Chapter 3: Systematic literature reviews

3.1 Introduction

The first step in the CIDP is to review the literature to provide evidence of problem and need. In order to understand the impact of cancer cachexia on patients and carers, from their perspectives, systematic reviews of the QOL literature were carried out. By focussing on QOL, the concerns wich are most significant to patients and carers can be identified. These concerns not only provide evidence of the problem, but also inform the content of the workshop.

3.2 Methods

Separate systematic reviews of the literature were performed to help understand how cancer cachexia affects the QOL of patients and carers. The methods used in the reviews were informed by the Centre for Reviews and Dissemination guidance for undertaking systematic reviews[128], and the reporting follows the Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) guidelines[129]. SW carried out all steps of the review process with five colleagues sharing out the role of second judge and contributing to analysis.

3.2.1 Review questions

The patient review question was “What factors impact quality of life in patients with cancer cachexia?” The main aim of the review was to identify the relevant HRQOL issues and to develop a model of the impact of cancer cachexia on patients. A further research question addressed was whether opportunities for intervention could be identified in the model.

For the carer review, the review question was, “What factors impact quality of life in carers of patients with cancer cachexia?” and the main aim was to identify the relevant QOL issues for carers of patients with cancer cachexia. For the purpose of this review, QOL was conceptualised to be those aspects which carers consider are affected by the patient’s cachexia and included physical, emotional, cognitive and social components.

3.2.2 Search strategy and selection criteria

ISI Web of Knowledge, PubMed, EMBASE, Medline, CINAHL, PsychINFO and PsycARTICLES, were searched using relevant terms for papers written in the English language, published from 1980 onwards, which included direct quotes from adults, either patients with any cancer diagnosis who had cachexia or problems with weight loss or anorexia (for the patient review), or their informal carers (for the carer review). Because of the historical lack of a consensus definition for ‘cachexia’ [29], papers were accepted which described patients as having cachexia regardless of how this was defined and patients did not have to be described as cachectic to be included. Studies which focussed on the experience of using feeding tubes or which explored the end of life use of medically administered nutrition and hydration were excluded. Conference proceedings and abstracts were also excluded.

For both the patient and the carer review, two reviewers (SW and one other) screened all titles and abstracts. If either reviewer felt that the citation could match the inclusion criteria, the full paper was obtained. Full papers were also screened by two reviewers (SW and one other) and any disagreements about inclusion were resolved by discussion. Mindful of the difficulty of finding qualitative research papers [128], the references of all included papers were searched for additional papers and papers already known to the authors were also included.

For the patient review, online databases were searched from January 1980 to May 2012 whilst for the carer review, online databases were searched from January 1980 to February 2015. The search terms used are shown in Table 2. Terms were searched for in both subject headings, if available, and free text. The terms in italics were used in the carer review but not the patient review. The Boolean operator OR was used between the search terms whilst AND was used to combine the search term categories. All four categories were used for the carer review and the carer category was omitted for the patient review. The full search strategy as used in Medline for the carer review is shown in Appendix D. This was adapted as appropriate for the other databases.

Table 2: Systematic review search terms

Categories	**Terms**
Cancer	neoplasm, cancer, palliative, tumour, tumor, malignancy
Cachexia	cachexia, anorexia, weight loss, systemic inflammation, food, wasting syndrome, appetite, malnutrition, sarcopenia, muscle wasting, eating, nutritional assessment, emaciation, nutrition, *anorexia-cachexia*

Categories	Terms
Quality of life	quality of life, QOL, QL, HRQOL, HRQL, subjective health status, reported outcome, psychosocial, qualitative research, interview, questionnaire, emotion, emotional impact, *distress*, anxiety, fear, manage, experience*, impact*, perception*, belief*, fight*, response*, concern*, challenge**
Carer	carer, caregiver, family, partner, spouse, husband, wife, brother, sister, sibling, daughter, son, parent, mother, father, friend, relative

3.2.3 Quality assessment

Assessing the quality of qualitative studies is the subject of a number of on-going debates, including whether it is even apposite [128]. One reason for this concern is that qualitative research from different traditions has different theoretical perspectives and this influences design, analysis and interpretation. Combining different types of qualitative research, based on different theoretical assumptions and methods, could be considered inappropriate. Alternatively, it could be considered a strength. Although these debates continue, the vast majority of qualitative evidence syntheses do carry out critical appraisal [130] and the focus of debate has shifted to how to carry out the appraisal, what criteria to use for quality and what to do with studies which do not meet these criteria [131]. In the reviews reported here, the methodological quality of the studies was appraised and reported on using the Critical Appraisal Skills Program (CASP) tool for reviewing qualitative studies [132]. It was decided, *a priori*, to retain all the identified studies, whatever the quality, because it was anticipated that there would be very few.

3.2.4 Thematic synthesis

There are a large number of methods available to synthesise qualitative research findings [133]. Thematic synthesis, as described by Thomas and Harden [134], was selected because this method was developed to address questions relating to health interventions, including need. Following the approach, two judges (SW and one other) extracted direct participant quotes from each paper. Five judges for the patient review and three for the carer review, independently judged whether the quotes included any information about QOL, with any disagreements resolved through discussion. They then coded the content of each QOL quote for meaning, using as many codes as was necessary. The judges met to discuss and agree the coding system. Each quote was checked to ensure that all concepts had been coded and the wording for the codes was finalised. SW then relabelled the quotes using the agreed codes and the same judges identified themes within the codes, again independently. The judges met to discuss the themes until consensus was reached. Finally, themes were tested against the original quotes to ensure the thematic framework which had been developed was adequate.

In the case of the patient review, meta-themes were developed through discussion. A model of the patient experience of cancer cachexia was produced, again through discussion, based on the meta-themes, which led to a final revision of the meta-themes. The model was developed using a synthesis approach to theory building, where the meta-themes were considered to be concepts and relationships between those concepts were demonstrated graphically [135].

3.3 Patient review results

The patient systematic review found 18 relevant studies. A flow diagram of the review process is provided in Figure 3 and the characteristics of the 18 selected studies are shown in Table 3. Most of the studies were conducted in the UK (n=11), with five studies from North America and one each from Sweden and Switzerland. The studies included interviews with a total of at least 252 patients. It is not possible to compute the exact number of patients included because some of the papers report on the same interviews: Hopkinson and colleagues used the same patient interviews in three reports [64,136,137] and these interviews were later used again in combination with interviews from a pilot trial [138]. However, across these studies, there was only one repeated quote (see Figure 3). Similarly, the patient interviews described in one paper by Reid and colleagues [68] were drawn from those reported in another[74]. Since the focus of these two papers was different, there was no overlap in patient quotes.

As can be seen in Table 3, a variety of qualitative methods were used, and a number of data collection and data analysis techniques were employed across the studies, which it could be argued improves the richness of the data set (triangulation)[139]. Only one study scored the CASP maximum of ten [140]. All the 15 studies which scored nine lost a point for the reflexivity criterion because they did not consider the relationship between researcher and participants. The two low scoring studies were the oldest study [73] and a very concise report of some results from a study [138], the methodology of which has been more fully described elsewhere [64,136,137].

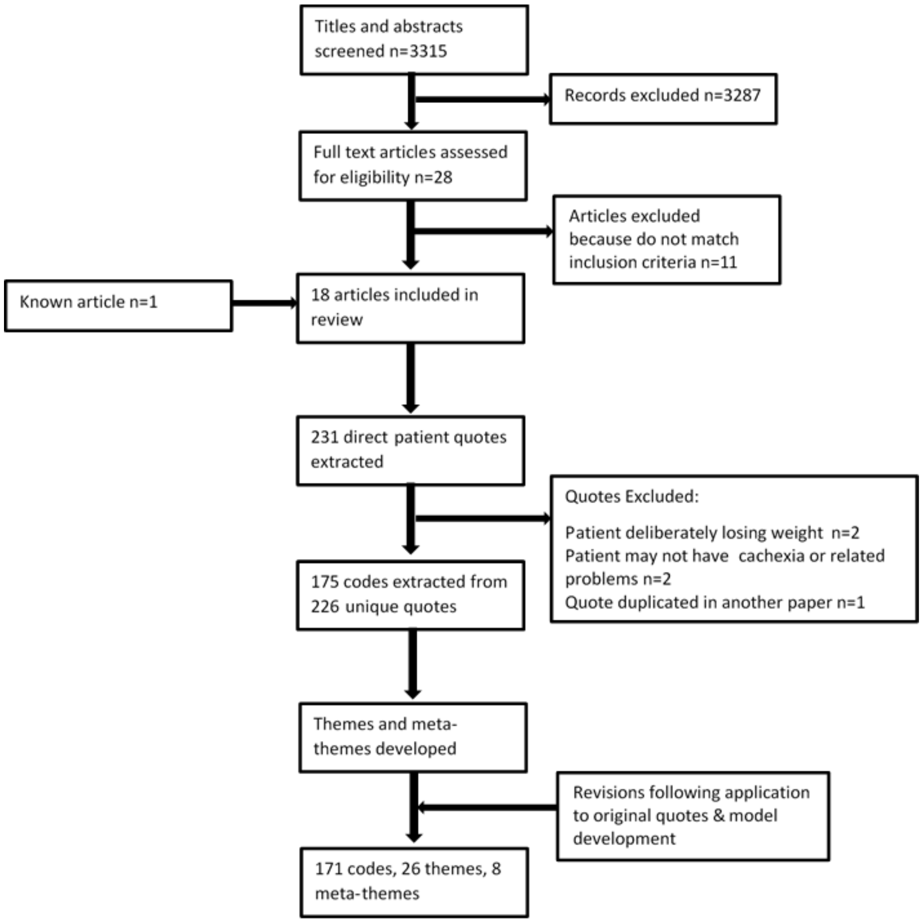


Figure 3: Flow diagram of the patient systematic review

The flow diagram in Figure 3 shows that eventually 171 codes were extracted from the data and these contributed to 26 themes, which can be grouped into eight meta-themes. Most of the 171 issues were included in just one theme but nine issues contributed to two themes. The high number of themes demonstrates the wide-ranging concerns of patients with cancer cachexia. The multi-dimensional nature of these concerns is confirmed by examination of Table 4 which lists the codes included in each theme and Table 5, which lists the themes along with a patient quote to illustrate each theme.

Table 3: Characteristics of studies included in patient review

Study	Country	Aim	Patient Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP total score
Hinsley and Hughes, 2007 [141]	UK	How does altered body image arising from cachexia impact on people's emotions, social functioning & relationships? How do other people's reactions to an altered body image impact on people's lived experience of the illness?	6 males & 6 females with cancer related weight loss.	Not specified	In-depth conversational style interviews	Thematic	Not specified	9
Holden, 1991 [73]	USA	To explore the ways in which terminally ill cancer patients and their primary caregivers view and respond to the patient's loss of appetite	9 males & 5 females randomly selected from 4 hospice programs.	Not specified	Semi-structured interviews	Not specified	Not specified	6

Study	**Country**	**Aim**	**Patient Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP total score**
Hopkinson and Corner, 2006 [136]	UK	To develop an understanding of the manifestations, management, and meaning of eating changes in patients with advanced cancer	16 males & 14 females with advanced cancer & a change in eating habits since they first perceived they were unwell.	Hermeneutic phenomenology	Semi-structured interviews	Mixed strategy for cross-case analysis	Dialogue with cancer patients, clinicians and academics. Search for disconfirming evidence	9
Hopkinson et al., 2006 [64]	UK	To explore the experience of and concern about weight loss in people with advanced cancer, their caregivers & nurse specialists	16 males & 14 females. All but 1 with reported weight-loss.	Humanistic nursing theory	Semi-structured interviews	Mixed strategy for cross-case analysis	Search for disconfirming evidence. Discussion with academics & clinicians	9
Hopkinson, 2007 [137]	UK	To explore the management of changing eating habits in people with advanced cancer	16 males & 14 females with advanced cancer	Hermeneutic phenomenology	Semi-structured interviews	Mixed strategy for cross-case analysis	Dialogue with cancer patients, clinicians and academics. Search for disconfirming evidence	9

Study	**Country**	**Aim**	**Patient Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP total score**
Hopkinson, 2008 [138]	UK	To examine a specific cause of distress (healthy-eating messages) & the implications for nursing practice	23 males & 9 females	Hermeneutic phenomenology	Not specified	Not specified	Not specified	5
Locher et al., 2009 [142]	USA	To examine the social factors that may contribute to under eating in older adults with cancer.	13 male & 17 female patients >70 years.	Constructionist perspective & grounded theory approach	Semi-structured interviews	Thematic with constant comparative method	Not specified	9
Locher et al., 2010 [143]	USA	To analyse the social organisation of caring as gendered work as it relates to meal preparation & consumption activities surrounding older adult cancer patients & their caregivers	13 male & 17 female patients >68 years. NB no criterion that participants had to be experiencing difficulty with food or eating activities.	Constructionist perspective & grounded theory approach	Semi-structured interviews	Constant comparison	Not specified	9

Study	**Country**	**Aim**	**Patient Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP total score**
McClement et al., 2003 [70]	Canada	To develop a beginning substantive theory aimed at uncovering the social processes inherent in family interactions with patients and health care providers around the issue of nutritional care in a palliative context.	3 male & 10 female patients on palliative care unit (PCU).	Grounded theory	Semi-structured interviews	Constant comparison	Prolonged engagement on PCU, triangulation, systematic checking of emerging model with participants & external colleagues	9
Muir and Linklater, 2011[144]	UK	To explore patients' views of nutrition, to begin to understand their concerns & to determine whether such standards meet the needs of patients in the palliative care setting.	4 male & 2 female inpatients in specialist palliative care unit.	Qualitative approach	Semi-structured interviews	Miles & Huberman's framework for qualitative data analysis [145]	Not specified	9

Study	Country	Aim	Patient Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP total score
Orrevall et al., 2004 [67]	Sweden	To investigate the nutritional situation prior to the introduction of home parenteral nutrition (HPN) from the perspective of patients with advanced cancer and their family members in order to understand the factors contributing to their decision to accept HPN.	8 male & 5 female patients with advanced cancer receiving palliative care.	Qualitative methods	Semi-structured interviews	Constant comparison	Input from the multi-disciplinary research group	9

Study	Country	Aim	Patient Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP total score
Reid et al., 2009a [74]	UK	To explore the lived experience of cachexia for patients with advanced cancer and their family members	8 males & 7 females with advanced, incurable cancer living at home, >10% weight loss in previous 6 months, weight loss progressive, involuntary & problematic & not due to reduced oral intake.	Heideggerian phenomenological philosophy	Inductive format interviews with non-directive, open-ended questions	Thematic for whole sample. Interpretative phenomenological analysis on a sub-set of 8.	All authors contributed to the analysis	9
Reid et al., 2009b [146]	UK	To explore the experience of cachexia & its effect on food & feeding	4 male & 4 female patients with advanced, incurable cancer living at home, >10% weight loss in previous 6 months, weight loss problematic, no secondary causes of cachexia.	Heideggerian phenomenological philosophy	Unstructured interviews	Thematic & interpretative phenomenological analysis	Not specified	9

Study	**Country**	**Aim**	**Patient Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP total score**
Reid et al., 2010 [68]	UK	To investigate the perceptions of patients and family members with regard to care received for cancer cachexia	8 males & 7 females with advanced, incurable cancer living at home, >10% weight loss in previous 6 months, weight loss problematic & not due to explainable clinical cause.	Heideggerian phenomenological philosophy	Qualitative unstructured interviews	Thematic for whole sample. Interpretative Phenomenological analysis on a sub-set.	Not specified	9
Shragge et al., 2007 [147]	Canada	To investigate the process that explains how patients with advanced cancer compensate for anorexia & manage the emotional and social consequences of declining intake.	7 male & 2 female patients with advanced cancer & self-report loss of appetite.	Grounded theory	Up to 3 unstructured interviews per participant	Constant comparison	Verification strategies based on Morse et al., 2002[148]	9
Souter, 2005 [66]	UK	To explore the experience of loss of appetite for cancer patients and their carers	7 patients who were supported by a specialist palliative care team in the community.	Phenomenological	Semi-structured interviews	Hermeneutical analysis & poetic transcription	Double coding of a subset of text.	9

Study	**Country**	**Aim**	**Patient Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP total score**
Stamataki et al., 2011 [140]	UK	To acquire a deeper understanding of cancer patients' experiences with the physical manifestations of weight loss or gain, the consequences of these changes on their psychosocial life and their self-management strategies	54 cancer patients with weight-change issues.	A longitudinal qualitative approach used to obtain in-depth exploratory descriptive data	Semi-structured interviews	Thematic with constant comparative method	Followed criteria established by Lincoln and Guba, 1985 [149] and Chiovitti and Piran, 2003 [150]	10
Strasser et al., 2007 [63]	Switzer-land	To discover and describe elements of eating-related distress in male patients with advanced cancer & their female partners	19 males with advanced cancer with weight loss (≥5%, 6 months) or appetite problems.	Qualitative methodology supported by related quantitative data	Focus groups for couples, one couple interviewed individually	Grounded theory coding and constant comparison methods	Results approved by patients, partners and professional, to whom findings were presented	9

Table 4: Codes included in each theme in the patient review

Theme	**Codes**
Acceptance & adaptation	Acceptance. Acceptance of home parenteral nutrition. Accepted can't eat. Accepting appetite limitations. Adapting. Impact on daily activities. Not bothered about not eating. Pleased with weight loss. Proud of past achievements. Realising eating won't stop weight loss. Things will never be the same again.
Appetite	Appetite preserved. Can't eat. Doesn't want to eat. Fluctuating appetite. Food cravings. Never satiated. No appetite. Reduced appetite. Small appetite.
Body image	Body image. Clothes don't fit. Clothes too big. Embarrassment. Others' reactions to visible weight loss. Weight loss.
Carer conflict	Anger with carer. Carer conflict. Carer imposing. Carer makes feel like not trying. Carer's approach unhelpful. Dissatisfied with carer. Feeling pressured. Lack of carer understanding. Unwelcome advice. Wanting others to understand eating limitations. Wants care. Wants carer to listen. Wants consideration.
Change in experience of eating	Change to types of food can eat. Eating causes vomiting. Eating habits. Eating is a chore. Eating meaningless. Eats less. Excess food intake. Forgetting to eat. Frustrated by meals taking long time. Meals take long time. Missing past food experience. No enjoyment from food. No hunger. No interest in food. No pleasure from food. No taste. Small mouthfuls. Taste changes. Texture change.
Change in identity	Change in identity. Shifting roles.
Concern for others	Concern for carer. Eating to please others. Empathy for carer's efforts. Protecting carer. Recognises carer worried. Withholding information.
Continuum of hope	Given up the fight. Helpless. Hopelessness. Hoping for a miracle. Nothing works. Progression to death. Wanting death. Weight loss evidence of approaching death.

Theme	**Codes**
Eating as pleasure	Enjoys food variety. Food pleasurable. Food preferences. Likes eating with others. Motivated by food.
Food aversion	Aversion to thought of food. Can't face healthy food. Food appearance unappealing. Food aversions. Food smell aversion. Large portion size off putting.
HCP input	Being ignored. Dietitian advice unhelpful. GP unhelpful. Lack of acknowledgement. Lack of care. Nurse helpful. Unhappy with dietitian approach.
Isolated	Isolated.
Knowledge to understand	Lack of advice. Lack of information. Wants diet advice. Wants explanation for weight loss. Wants to know prognostic value of weight loss. Weight loss as health barometer.
Loss of control of body	Eating and weight unrelated. Vomiting causing weight loss. Weight loss out of control.
Loss of independence	Loss of autonomy. Loss of independence. Maintaining independence.
Negative emotions	Depressed. Desperate. Disappointed with being thin. Frustration. Illness tough. Scared. Stressed. Upset. Worried. Worried about intake. Worried about weight loss.
Nutritional support	Nutritional supplements. Parenteral feeding helpful.
Sense of failure	Can't eat enough to regain weight. Eating stupid things. Feels useless. Not eating enough. Organic food too expensive. Scared about unhealthy diet. Self-blame. Self-harm.

Theme	**Codes**
Significance of weight loss	Amount of weight loss surprising. Pleased with weight loss. Wants explanation for weight loss. Wants to know prognostic value of weight loss. Weight loss. Weight loss as health barometer. Weight loss evidence of approaching death. Weight loss out of control. Worried about weight loss.
Social life	Eating to be sociable. Eats alone. Embarrassed by process of eating. Enjoying social occasions. Prefers eating alone. Spoiling social occasions.
Social support	Appreciative of others efforts. Carer understanding about appetite loss. Eating easier with others.
Symptoms	Dry mouth. Early satiety. Fatigue. Mobility. Nausea. Sore mouth. Stomach sensation. Weakness.
Taking control	Advising carer. Eating for strength. Eating for well-being. Eating to live. Eating to survive. Fighting. Forcing self to eat. Keeping positive. Maintaining normality. Managing stoma. Monitoring intake. Monitoring weight. Self-management. Struggling to eat. Trying. Trying to cope. Wanting to live.
The ostrich phenomenon	Avoiding thinking about problem. Avoids mirrors. Disguising weight loss. Hiding quantity eaten from family.
The unexpected	Amount of weight loss surprising. Can't understand changes in eating. Change in appearance shocking. Change in eating alarming. Weight loss unexpected consequence of cancer.
Waste	Food preparation waste of effort. Food waste of money.

Table 5: Themes identified in patient review

Theme	**Example patient quote**
Acceptance & adaptation	I'm accepting what I've got and I'm quite happy with it. Whether that's correct in dietary terms is another matter. Doesn't mean a thing to me [144].
Appetite	You want to eat but you can't eat. I could go with a wee taste of soup of something, but I've no real appetite [74].
Body image	My sport is swimming… I'm embarrassed to go swimming because I look at my body and say what the hell has happened to me? [140]
Carer conflict	She worries too much. She tries to force me to eat when I don't want to. It is really a source of conflict and it is driving me nuts [73].
Change in experience of eating	I take soups but I don't enjoy anything... I have no feeling of hunger at all and no appetite [136].
Change in identity	See when I look in the mirror and see [myself] the face that looks back at me, it's not me! [74]
Concern for others	I am glad she does this for me (i.e. brings me two to three meals a day)...I worry about her, though [143].
Continuum of hope	I know I am going to die soon; there is nothing anybody can do to help me [64].
Eating as pleasure	Yes, food is important as a source of pleasure, as a pleasurable experience [144].
Food aversion	It's just you cannot force it inside you because I know if I force it I will be sick – you don't want to see it or smell it. In fact, sometimes I go in the kitchen and its horrible [137].

Theme	Example patient quote
HCP input	Nobody mentioned it to me at the hospital, I do get weighed at the hospital though, one time ten stone seven, the next ten stone four, but no talk of the weight loss from them [68].
Isolated	I don't feel comfortable meeting people. . . [puts heads down and looks at floor] you know what their reactions are gonna be [74].
Knowledge to understand	No one explained why you lose weight. You would then not have to destroy yourself psychologically with: I must eat, even if I am not hungry, if I don't like the taste [63].
Loss of control of body	I know the cancer is eating away at me…I always felt I was in control. You know you are not going to be in control but subconsciously you don't believe it, then you get the physical evidence. You can see you are losing weight fast… [64]
Loss of independence	You got no control. Basically, it's like being a kid again [137].
Negative emotions	I'm getting fed up with myself. It gets you down, you think, "Oh my God! How much longer am I going to be like this?" You know, like this. And it doesn't seem possible. And you can't see any way at the end of the tunnel. Strange, strange how your life could come to this [141].
Nutritional support	One thing that (my specialist nurse) put me on to was this energy drink. That's absolutely magic. (..) I feel as though I couldn't do without it. I have one of those every day [136].
Sense of failure	I feel that I'm useless because I can't eat, and I feel quite weak as well [140].
Significance of weight loss	I suppose it's all tied up with the cancer thing, which is very scary, very scary. So I think it's all tied up with that 'cos I can't bear the thought of cancer. When I look at myself, it reminds me of why I'm looking, why I've lost weight [141].

Theme	**Example patient quote**
Social life	Taking liquidized food is not the sort of thing you want to do with family and friends [136].
Social support	Almost everybody brought their version of chicken soup—and, it was wonderful [143].
Symptoms	Also, I have lost the ability to walk....But, not eating is not allowing me to gain my muscle strength back [142].
Taking control	You know you are doing something yourself, as well as other people helping. It enables you to keep going. You know you are looking after yourself [137].
The ostrich phenomenon	I'm trying to cope with it. . .put it out of my mind [74].
The unexpected	I always thought cancer patients lost weight because they had it in the stomach and they couldn't eat [64].
Waste	Well, in the end there was no point in it. It was meaningless to eat. Cooking every day and eating just to go and put it down the toilet is a waste of effort, I think, a waste of money [67].

The 26 themes were organised into eight meta-themes: 'food and eating', 'loss of control', 'physical decline', 'emotions', 'identity', 'knowledge', 'relationships' and 'coping' as shown in Figure 4. Each theme contributes to a single meta-theme. The meta-themes were used to develop a model to conceptualise the patient experience of cancer cachexia and to inform the development of the workshop (Figure 5). The starting point for the model is 'food and eating' and the endpoint is emotional well-being, characterised by 'loss of control' and 'emotions'. Problems with food and eating contribute to the physical decline experienced by patients which in turn affects the patient's identity (both in terms of physical appearance and role played in life). The physical decline and identity changes both impact the patient's emotional well-being. 'Identity' and 'emotions' are also directly affected by 'food and eating'. The extent to which this occurs is mediated by the patient's relationships, how they cope with the situation and their knowledge of cachexia.

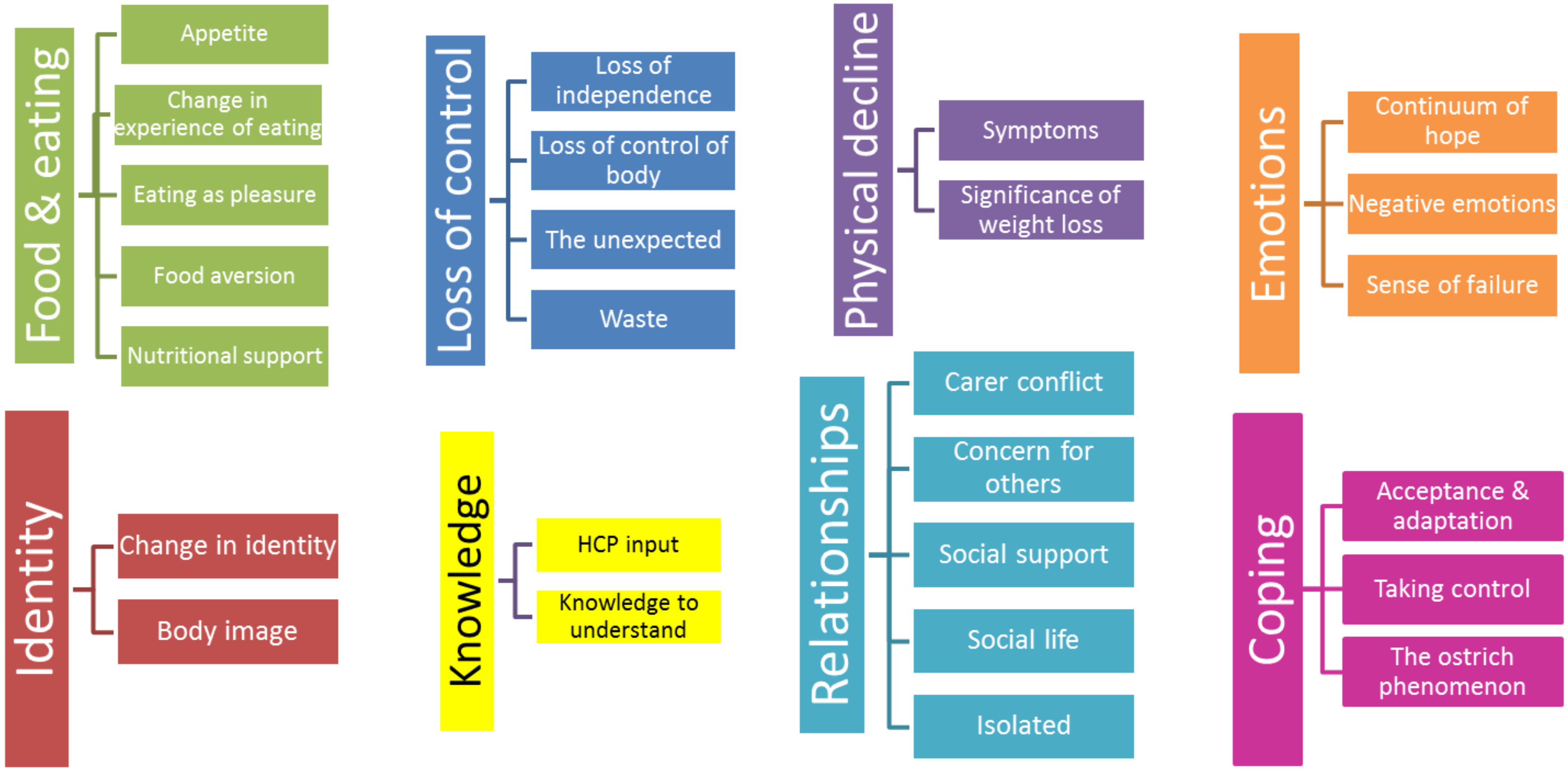


Figure 4: **Meta-themes and themes identified in patient review**

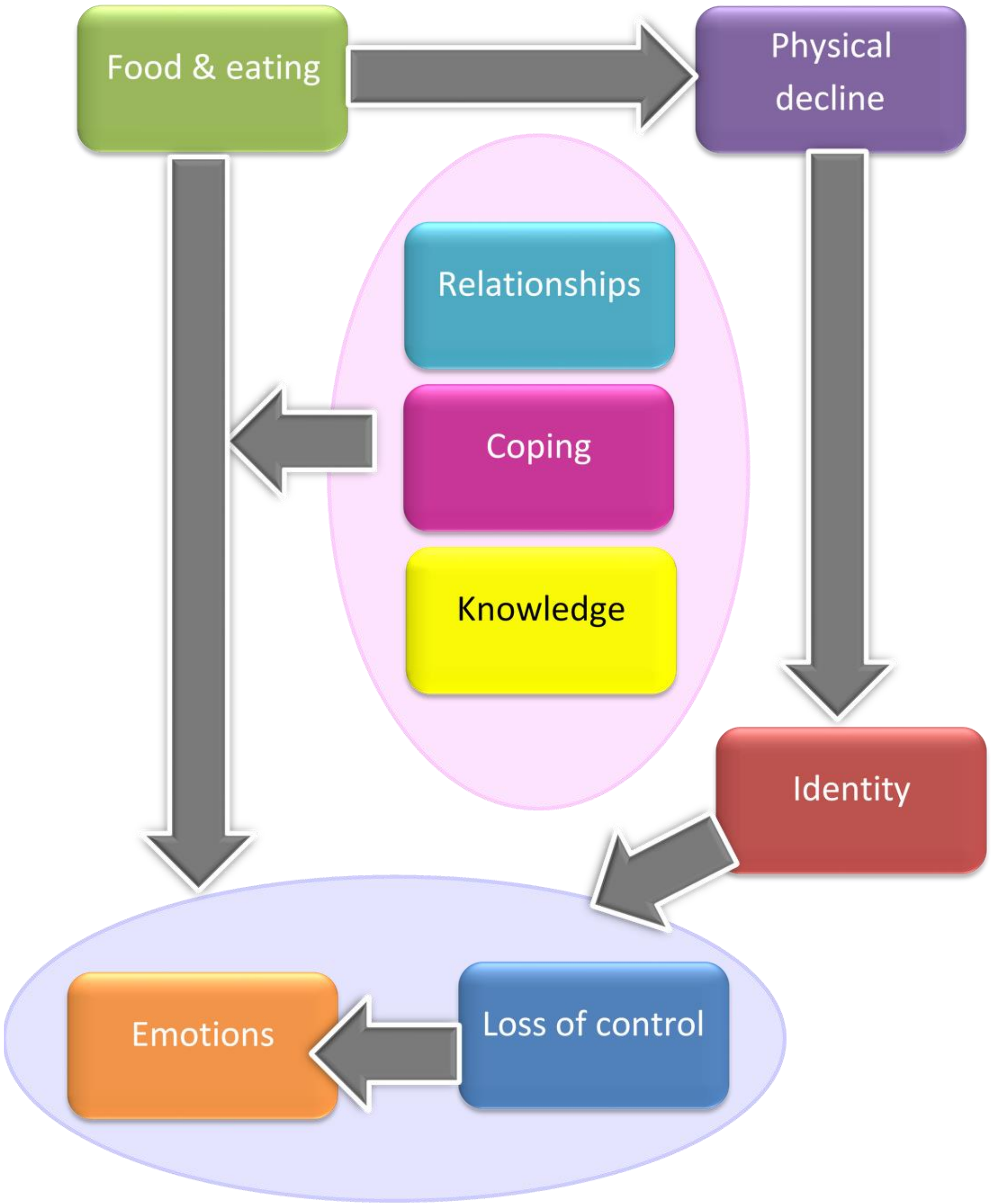


Figure 5: **Model of the patient experience of cancer cachexia**

Interventions could be developed to act at any stage of the model. For example, between ‘food and eating’ and physical decline, the focus of an intervention could be on maximising the nutritional intake using appropriate interventions such as appetite stimulants, nutritional supplements and psychosocial interventions to increase consumption. It is suggested that interventions between ‘food and eating’, and emotional well-being (‘emotions’ and ‘loss of control’) should focus on improving knowledge of cachexia, coping strategies and family relationships.

3.4 Patient review discussion

This synthesis of 18 primary qualitative studies identified 26 themes (or HRQOL domains) and eight meta-themes which describe the experience of cancer patients affected by cachexia and related problems. The meta-themes were used to develop a psychosocial model to conceptualise the patient experience of cancer cachexia.

In the discussion of the model which follows, the details were obtained from the codes and themes in Table 4, Table 5 and Figure 4. The model starts with ‘food and eating’. Most patients with cachexia report that they have a poor appetite and eat relatively little. Along with alterations in the taste and texture of food, preferences may have changed, sometimes to the extent that there is a strong aversion to formerly enjoyed foods. Eating is no longer a pleasurable activity but rather a chore with meals taking too long. All these food and eating problems contribute to the physical decline experienced by patients. They describe issues with weight loss, fatigue and weakness. The physical decline can have a negative impact on body image and patients sometimes struggle to recognise themselves in the mirror, or they may even avoid mirrors altogether. These issues contribute to the identity meta-theme, which also encompasses the idea that patients’ role in life may change as a result of their condition. For example, patients who were previously responsible for the provision of family meals may no longer be able to fulfil that responsibility. Following on from the identity meta-theme are the two connected meta-themes of ‘loss of control’ and ‘emotions’. ‘Loss of control’ refers to both body – the patient feels that eating and weight are unrelated and weight loss is out of control – and mind, with the loss of autonomy and independence. Some patients feel a sense of failure at not being able to control their weight loss and eating, both in terms of quantity and the types of food they are able to consume. Negative emotions, such as fear, depression and frustration are commonly experienced. Some patients describe their situations as hopeless whereas others cling on to the chance of a miracle.

Along with the link between problems with food and eating and negative emotions as a result of physical decline, there is also a direct link. This implies that even if the physical decline could be minimised, there would still be negative emotions associated with the cachexia. This is because the role of food is more than just nourishment [144]: the preparation and sharing of food has a central role in daily life, special occasions are often associated with special foods and providing food can be an expression of love or caring. The model identifies three meta-themes which have a significant impact on whether difficulties with food and eating lead to negative outcomes: ‘relationships’, ‘coping’ and ‘knowledge’. Looking at the themes which are included in the relationships meta-theme illustrates how relationships may be both beneficial and harmful to the patient’s well-being. For example, conflict with carers, such as feeling pressured, and feeling isolated have a negative impact, whereas feeling supported and maintaining a social life result in positive emotions.

The knowledge meta-theme underlines the importance of health care professionals taking the time to explain more about the condition and how to deal with it. Patients want advice and information. Sometimes the knowledge they want is not available, e.g. precise prognostic predictions based on weight loss, so it is important to be aware of this and manage expectations. Sometimes all that is required is acknowledgement of the weight loss by health care professionals.

The coping strategies patients use can also influence the impact of food and eating on emotions. Some patients are able to accept and adapt to their new situation, others ignore it (“ostrich phenomenon”) and others cope by trying to control the effects of cachexia, by forcing themselves to eat for example.

The necessity of taking a biopsychosocial approach to cancer cachexia has previously been emphasised [13] and the model developed in this review summarises how this approach mirrors the patient experience. In the biopsychosocial approach, health concerns are framed in terms of the functional interdependence between physical, psychological and social functioning [151]. The limitations of the biomedical model have long been recognised, with the fundamental criticism that in this approach, it is assumed that ‘disease’ can be fully accounted for by biological or somatic abnormalities, and the disease is therefore treated in isolation from the patient [151]. The shift from the biomedical to the biopsychosocial approach throughout medicine, which is already demonstrable in the USA [152], has partly been driven by a change in the leading causes of death from infectious diseases to chronic disease, with the consequent augmented role of behaviour in disease aetiology, prevention and management.

The model emphasises that even if the physical aspects of cachexia are treated successfully, it is likely that there would still be a psychosocial impact of the condition. This is because eating plays such a significant part in everyday life and food has very significant emotional, social and cultural roles [66]. It is therefore vital to develop effective interventions to address the emotional impact of the condition. This may be particularly important for patients with refractory cachexia, for whom the primary treatment goal is the overall increase of well-being and the alleviation of cachexia-related symptoms [36]. The model presented here suggests that there are three elements which contribute to the emotional welfare of the patient: their relationships, how they cope and their knowledge of the syndrome. These three elements should be incorporated in any psychoeducational intervention for patients with cancer cachexia.

There is considerable overlap between the psychosocial model of cachexia described in section 1.7 [62] and the model of the patient experience of cancer cachexia developed in this chapter. This is not surprising given the extensive overlap of the literature used in the construction of both models. The methods used to generate the psychosocial model are not clearly described so it is difficult to understand exactly how the analysis was carried out. Nevertheless, both models use negative emotions as an outcome, with the addition of loss of control in the patient experience model. Whilst both models suggest that coping will have an effect on outcome, the patient experience model additionally highlights the importance of relationships and knowledge.

3.5 Carer review results

The systematic review found 16 relevant studies. A flow diagram of the review process is provided in Figure 6 and the characteristics of the 16 selected studies are shown in Table 6. Most studies were conducted in the UK and North America, with one in Sweden and one in Switzerland. The studies included interviews with a total of at least 169 carers. The precise number of carers cannot be calculated because some of the papers reported on the same interviews: the three McClement papers [69-71]; the three Hopkinson papers [64,136,138]; and the three Reid papers[68,74,146]. Despite this overlap, just two quotes were duplicated across the papers.

As can be seen in Table 6, a variety of qualitative methodologies was used, and a number of data collection and data analysis techniques were employed across the studies, which may improve the richness of the data set (triangulation)[139]. Most of the papers rated well on the CASP but all failed the reflexivity criterion because they did not report on the relationship between researcher and participants. The lower rated studies were the oldest study[73] and two papers reporting results from studies, the methodology of which has been more fully described elsewhere[69,138].

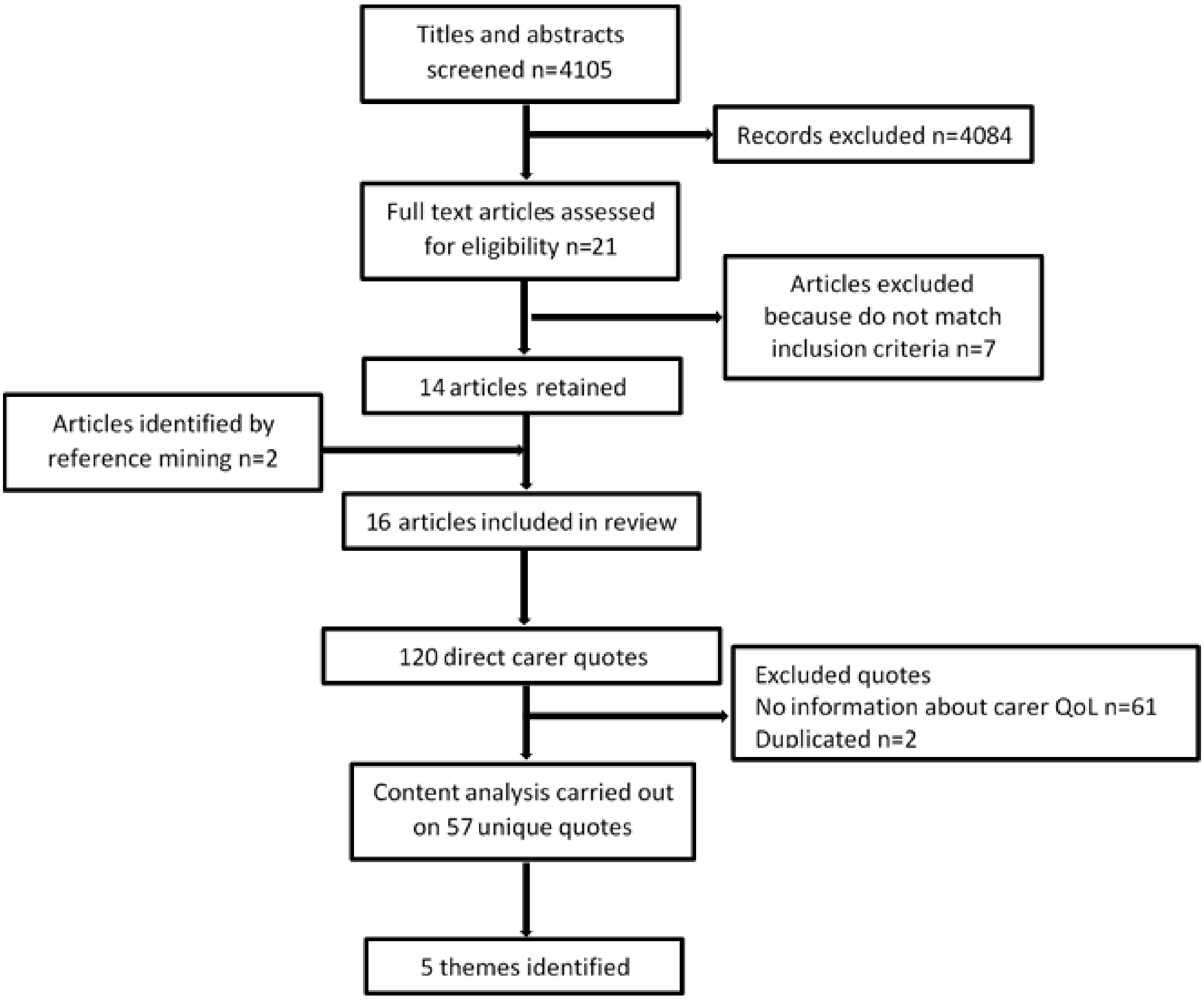


Figure 6: Flow diagram of the carer review process

Figure 6 shows that more than half the quotes were excluded because they did not contain any information about carer quality of life. Rather they covered topics such as beliefs about the importance of food and descriptions of patient's symptoms, appearance and eating habits. Given the limited data, it became apparent that the review would identify domains of experience rather than specific QOL issues. The themes which were extracted from the 57 quotes which included information about the effect of the patient's illness on carers themselves were impact on everyday life, taking charge, need for outside help, conflict with patient and emotions. Each of these themes is described in turn.

Table 6: Characteristics of studies included in carer review

Study	Country	Aim	Carer Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP criteria met
Holden, 1991 [73]	USA	To explore the ways in which terminally ill cancer patients and their primary caregivers view and respond to the patient's loss of appetite	9 female & 5 male caregivers of patients randomly selected from 4 hospice programs	Not specified	Semi-structured interviews	Not specified	Not specified	6
Meares, 1997 [65]	USA	To explore the meaning of nutrition cessation in adult in-home hospice patients with cancer as described by women primary caregivers during the first year of bereavement	12 women who had cared for terminally ill cancer patients who had ceased oral intake	Van Manen's method for researching the lived experience [153]	Semi-structured interviews	Themes and essences were identified using Van Manen's method [153]	Double coding of half the transcripts. Themes approved by 3 participants.	9

Study	Country	Aim	Carer Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP criteria met
Wilson, 2002 [154]	UK	To investigate the needs of people with cancer, and their lay carers during discharge from hospital to home, and identify the role of district nurses in meeting these needs.	18 carers of cancer patients discharged from hospital to home	Not specified	Semi-structured interviews	Thematic analysis	Critical examination and comparative interpretation of transcripts by the research team. Presentation of copious data extracts in paper	8
McClement, 2003 [70]	Canada	To develop a beginning substantive theory aimed at uncovering the social processes inherent in family interactions with patients and health care providers around the issue of nutritional care in a palliative context.	13 family members of adult palliative inpatients, 10 bereaved family members whose relative had been an inpatient on the same palliative care unit (PCU) in the last year	Grounded theory	Semi-structured interviews	Constant comparison	Prolonged engagement on PCU, triangulation, systematic checking of emerging model with participants & external colleagues	9

Study	**Country**	**Aim**	**Carer Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP criteria met**
McClement, 2004 [69]	Canada	To provide a more detailed description of one of the major sub-processes of a model regarding family responses to declining oral intake and weight loss in a terminally ill relative	13 family members of adult palliative inpatients, 10 bereaved family members whose relative had been an inpatient on the same PCU in the last year	Grounded theory	Semi-structured interviews	Not specified	Not specified	7
Orrevall, 2004 [67]	Sweden	To investigate the nutritional situation prior to the introduction of home parenteral nutrition (HPN) from the perspective of patients with advanced cancer and their family members in order to understand the factors contributing to their decision to accept HPN.	7 female and 4 male family members of patients with advanced cancer receiving palliative care	Qualitative methods	Semi-structured interviews	Constant comparison	Input from the multi-disciplinary research group	9

Study	Country	Aim	Carer Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP criteria met
Souter, 2005 [66]	UK	To explore the experience of loss of appetite for cancer patients and their carers	7 carers of patients supported by a specialist palliative care team in the community	Phenomenological	Semi-structured interviews	Hermeneutical analysis & poetic transcription	Double coding of a subset of text.	9
Hopkinson, 2006a [136]	UK	To develop an understanding of the manifestations, management, and meaning of eating changes in patients with advanced cancer	23 caregivers of patients with advanced cancer & a change in eating habits since they first perceived they were unwell	Hermeneutic phenomenology	Semi-structured interviews	Mixed strategy for cross-case analysis	Dialogue with cancer patients, clinicians and academics. Search for disconfirming evidence	9

Study	Country	Aim	Carer Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP criteria met
Hopkinson, 2006b [64]	UK	To explore the experience of and concern about weight loss in people with advanced cancer, their caregivers & nurse specialists	23 caregivers of patients with advanced cancer & a change in eating habits since they first perceived they were unwell	Humanistic nursing theory	Semi-structured interviews	Mixed strategy for cross-case analysis	Search for disconfirming evidence. Discussion with academics & clinicians	9
Strasser, 2007 [63]	Switzer-land	To discover and describe elements of eating-related distress in male patients with advanced cancer & their female partners	19 female partners of males with advanced cancer and weight loss (≥5%, 6 months) or appetite problems	Qualitative methodology supported by related quantitative data	Focus groups for couples, one couple interviewed individually	Grounded theory coding and constant comparison methods	Results approved by patients, partners and professional, to whom findings were presented	9
Hopkinson, 2008 [138]	UK	To examine a specific cause of distress (healthy-eating messages) & the implications for nursing practice	32 carers of patients recruited from community palliative care team clients	Hermeneutic phenomeno-logy	Not specified	Not specified	Not specified	5

Study	**Country**	**Aim**	**Carer Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP criteria met**
McClement, 2008 [71]	Canada	To provide a more detailed description of one of the major sub-processes of a model regarding family responses to declining oral intake and weight loss in a terminally ill relative	13 family members of adult palliative inpatients, 10 bereaved family members whose relative had been an inpatient on the same PCU in the last year	Grounded theory	Semi-structured interviews	Constant comparison techniques and open, axial and selective coding procedures.	Prolonged engagement on PCU, triangulation, systematic checking of emerging model with participants & external colleagues	8
Reid, 2009a [146]	UK	To explore the experience of cachexia & its effect on food & feeding	6 female & 2 male family member carers of patients with advanced, incurable cancer & cachexia living at home	Heideggerian phenomeno-logical philosophy	Unstructured interviews	Thematic & interpretative phenomenological analysis	Not specified	9

Study	**Country**	**Aim**	**Carer Sample Characteristics**	**Qualitative Methodology**	**Data Collection Method**	**Method of data analysis**	**How was trustworthiness ensured?**	**CASP criteria met**
Reid, 2009b [74]	UK	To explore the lived experience of cachexia for patients with advanced cancer and their family members	10 female & 2 male carers of patients with advanced, incurable cancer & cachexia living at home	Heideggerian phenomenological philosophy	Inductive format interviews with non-directive, open-ended questions	Thematic for whole sample. Interpretative phenomenological analysis on a sub-set of 8.	All authors contributed to the analysis	9
Locher, 2010 [143]	USA	To analyse the social organisation of caring as gendered work as it relates to meal preparation & consumption activities surrounding older adult cancer patients & their caregivers	21 carers of cancer patients attending outpatient clinic. NB no criterion that patients had to be experiencing difficulty with food or eating activities	Constructionist perspective & grounded theory approach	Semi-structured interviews	Constant comparison	Not specified	9

Study	Country	Aim	Carer Sample Characteristics	Qualitative Methodology	Data Collection Method	Method of data analysis	How was trustworthiness ensured?	CASP criteria met
Reid, 2010 [68]	UK	To investigate the perceptions of patients and family members with regard to care received for cancer cachexia	10 female & 2 male carers of patients with advanced, incurable cancer & cachexia living at home	Heideggerian phenomenological philosophy	Qualitative unstructured interviews	Thematic for whole sample. Interpretative Phenomenological analysis on a sub-set.	Not specified	9

3.5.1.1 Impact on Everyday Life

Food and eating are part of everyday life for most people so when someone is having difficulty in this area, those around them are confronted with the problems on a daily basis. Carers may be constantly 'watchful' or aware of the patient's appetite loss and its effects [66] as they feel a profound sense of responsibility for the patient's nutritional care [65,67].

> Every time you go shopping you look and wonder if mother'd fancy that. If we're having something different I think I wonder if mother'd like that [66].

Carers can spend a lot of time and energy selecting and preparing food [73], worrying about whether they are getting this right [63] and what the best strategies are to improve intake[67]. Carers' time may also be taken up by going out of their way at mealtimes to make sure the patient eats.

> I came to the hospital and the trays were already gathered up. And I looked at his tray and I could see he hadn't eaten… After that I was there every day to feed him his breakfast [69].

This underlines the responsibility carers may feel for ensuring that patients' nutritional intake is adequate.

The ongoing concern about food and eating adds to the daily stress experienced by carers. For many people, shared mealtimes provide an opportunity to talk over the day's events but this may not be possible for carers of patients with cancer cachexia. Whereas before the onset of cachexia, patient and carers may have enjoyed eating together, carers may now eat alone because patients find it difficult to be around food.

In the extreme case, when patients cannot even tolerate cooking smells [66,147] caregivers may no longer be able to cook at home.

> He couldn't take the smell of the food. So I was going to my sister's place to eat. I wasn't cooking anything. He felt sick. He didn't like the smell of anything… [my] brother-in-law would come sit. So I would go quick, eat, come back [154].

Eating may therefore be reduced to nothing more than refuelling with a loss of the mealtimes which previously punctuated the day.

> ...and dinner hour, I didn't realize until he stopped eating that there was a dinner hour, and then there was none, and it was so difficult to get through the day because what to do you do from 5 to 7? That part of your day is empty. [65]

Without mealtimes, carers may feel there is a void, time and space to be filled. Along with the loss of mealtimes, carers’ diet may also be affected, with some mirroring the decline seen in the patient.

> …We always ate together…He wouldn't eat if I didn't eat, so I stopped eating when he stopped eating... [65].

Other carers eat unhealthily or eat for comfort.

> Oh yes, I've gained 30 pounds. I never cook anymore. I eat my main meal at work at noon and then I just snack at home. I'll eat a half gallon of ice cream in front of the TV... You know, I eat like I did when I was a little girl. My mother would always feed me when I was anxious. (This brought on a flood of tears.) [73].

Whether carers eat too little or too much, worry about the patient can result in a change in their diet.

3.5.1.2 Taking Charge

Some carers cope with the difficult situation they face by trying to control what is happening. They recognise that patient weight loss is a problem and set themselves the target of ensuring the patient gains weight, even if they are not sure what is achievable [138]. Taking charge of food and eating may help carers assuage feelings of powerlessness and may create an outlet for the love and care that caregivers want to provide.

> I really did fuss with the food issue and it wasn't that I didn't trust them [the staff], it was more control. It was a thing that I could control. It was the one thing I could say that wasn't being done. Yeah, I could intervene. It was a power thing. I was aware of the power in me, but I was also aware that it was something I could do for her…[69].

For the carer in the quote above, taking responsibility for the patient’s nutritional care was a positive aspect of the caregiving experience. By ensuring the patient has, what the carer perceives to be, adequate nutrition, the carer is protecting the patient. Other carers protect patients and take charge by controlling conversations.

> If I were to go out to eat somewhere, to try out a new restaurant, I wouldn’t bring it up in conversation because I don’t want to make her feel ill at ease in case she was thinking about a time when she could eat and enjoy food more… [71].

Food-related topics of conversation may become taboo if carers are concerned that patients will find them upsetting. Monitoring conversation topics can be effortful and caregivers may miss the opportunity to share enjoyable experiences, a common feature of human communication [155].

3.5.1.3 Need for outside help

Many carers talk about their need for external support, specifically from HCPs. There can be a sense of frustration when HCPs are perceived as failing to acknowledge weight loss as a problem.

> I get angry at times, you know of the idea of it happening. He said to the doctor . . . [about his weight loss] but they didn't take it in, didn't do anything…the doctor knew about it – but he was very lackadaisical [68].

By appearing to ignore weight loss issues, HCPs can isolate carers through the failure to develop a common agenda for patient care. This can make carers feel powerless. If HCPs are thought to be failing to acknowledge the condition, carers may also conclude that they are not willing to help with weight loss and eating difficulties.

> We were in limbo, . . .nobody cared, we couldn't turn to anybody. . .nobody seemed to help us. . .we just had to cope on our own. . .when he wasn't eating and that we didn't known whether to call for a doctor or what or who to turn to [74].

When HCPs are considered to be failing to meet the carer's need for information about the condition, carers can feel angry and isolated. Without the appropriate information and support, carers find themselves in the unenviable position of trying to deal with a very difficult situation for which they feel ill-prepared.

> We were panicking because he wasn't eating and we didn't know what to do. . .we felt it was our fault, because he wouldn't eat and we couldn't get him to eat [74].

Carers want and need the support of HCPs, and they expect them to provide the information required to enable the best patient care. If this expectation is not met there can be a negative effect on the quality of the relationship between the HCP and the family.

3.5.1.4 Conflict with patient

Conflict and tension can arise when what a patient is able or willing to eat diverges from what the carer thinks the patient should be eating. Sometimes this relates to food quantity: family members are determined to make the patient eat more whilst the patient is unable to do so [70,74]. For other carers, it is the quality and type of food that is important.

> I do go into battle sometimes…He'll eat sweet biscuits, cakes, you name it, but when it comes to actual meals, even things he used to be passionate about, he just won't eat [138].

Carers may have an expectation that patients should be following the healthy diet which is recommended for the general population, and will express their disapproval when this is not the case. The disagreements between patient and carer, both in terms of the quality and quantity of food consumed by the patient, can be viewed in terms of a clash between the carer taking charge and patient autonomy. Carers may recognise that their attempts at encouragement can have the reverse effect.

> I give her food and then she doesn't eat it, then I feel guilty that she isn't getting anything inside her - I was worried and sad that she wouldn't eat and she got angry with me for nagging about food and it almost went the opposite way you see, that she would simply refuse to eat any food. [67]

This can cause feelings of guilt at both the failure to get the patient to eat enough and for upsetting the patient. In some families, carers find it hard to deal with the patient's rejection of their efforts leading to hurtful and upsetting arguments.

> I said, 'All right let's get you better and [then you leave] or I'll [leave], please yourself'. And she didn't like that. I think she said something that really got at me… [154]

Carers feel guilty about the arguments, partly perhaps because they feel that the family should pull together in times of adversity. They may think that the patient may not have much time left and that this time should not be filled with arguments.

> And then when we did have [arguments over food], you felt terrible in yourself [participant's eyes welled up, looks to the side, clears throat, and then re-establishes eye contact] . . . because you know why should we be having these bust ups?[146]

Nevertheless, carers may be unable to suppress the anger which arises when their care is rejected.

> I made dinner, made what he liked, what he always liked. . . He said he didn't like it, didn't want it, which I was quite angry at [74].

3.5.1.5 Emotions

Caregivers describe a number of negative emotions which are caused by the impact of caring for a loved one with cachexia. As illustrated in the quote directly above, they may feel anger when food they have spent a long time preparing is rejected. Worry and fear about the patient's condition and the future are common emotions, which may be compounded by feelings of helplessness.

Sadness is often provoked by feelings of loss: carers are mourning for how things used to be.

> … we've always liked going out to eat and enjoying our food. But this last year there have been very few occasions when he has enjoyed his food and since he hasn't enjoyed eating it isn't any fun to invite people for dinner either, if they are going to sit and eat for several hours and he just thinks it's a hard time and it starts to taste bad.[67]

Carers can miss being in the kitchen together, going out to eat or simply eating a meal at home together.

3.6 Carer review discussion

This synthesis of 16 primary qualitative studies identified five themes which describe the experience of caring for cancer patients affected by cachexia and related problems.

The five extracted themes were 'impact on everyday life', 'taking charge', 'need for outside help', 'conflict with patient' and 'emotions'. Cachexia has an impact on everyday life above and beyond the impact of being a caregiver *per se*. This is because human beings need to eat to survive. It can be gruelling to face the daily challenge of thinking of foods to tempt the patient with, shopping and preparing food, and then having that carefully prepared food rejected, whilst watching the patient quite literally wasting away. Some carers adopt a problem-focussed coping strategy [156] by 'taking charge' of meals, even if the patient is in hospital, or they take on the role of the patient protector, ensuring nothing is said that might upset the patient. Nevertheless, many caregivers will want and need the help of HCPs so that they can be reassured that the care they are providing for their patient is as good as possible. As a minimum, carers want HCPs to acknowledge patient weight loss so they can feel confident that the problem is being taken seriously and it is a topic which is open for discussion.

Patient rejection of food is a common occurrence and carers may interpret this as a personal rejection of their love, care and attention [63,74]. This is because of the many roles food plays beyond that of providing nourishment to the body [157]. The potential conflict at the heart of the carer-patient relationship is important for cachexia: carers are determined to make their patient eat and patients struggle to eat. Conflict with patients was not one of the problems or burdens included in the comprehensive review of cancer caregiving responsibilities, described in section 1.7 [59]. If this conflict is being driven, to some extent, by different expectations of the amount and types of food which the patient should be consuming, better education for both patient and carer may help to avoid this conflict.

Anger, worry, fear, guilt, and helplessness are just some examples of the difficult emotions carers have to contend with, both as a direct result of conflict with the patient and because of the other pressures of caregiving. For example, if a patient is not eating, the carer may have no dining companion so the social aspect of eating is gone and this may induce a sense of loss. This loss may also reflect anticipatory grief, which encompasses both current losses and the loss of future plans [158].

Much of the impact of cachexia on carers is mirrored in other cancer symptoms. For example, a review of family caregivers and cancer pain management described how carers can experience negative emotions as a consequence of their lack of confidence in their knowledge and skill to assess patient pain and to identify appropriate use of medication [159]. Conflicting guidance from HCPs contributes to the problem of pain management. In the same way that weight loss can be viewed as a health barometer, carers of patients in pain see this as a sign of approaching death and this impacts mood, distress levels and burden. Although there are many parallels with the experience of carers of patients with cancer cachexia, the difference is that, in general, the immediate goal of both patient and carer is to relieve the pain. Patients and carers coping with cancer cachexia may not share the same immediate goal: carers may want the patient to eat more, whilst patients may not want to eat at all. This mismatch in objectives can lead to conflict.

Given the limited data available, these findings must be considered provisional and it would be inappropriate to use them to develop a conceptual model of the experience of caring for a patient with cancer cachexia. However, domains of experience have been identified and future studies will need to identify more specific QOL needs and issues.

All the studies included in this review are cross-sectional so there is no consideration of trajectory. Future research could explore the effects of caregiving longitudinally, perhaps mirroring a patient study in which cancer patients were interviewed two to three weeks after diagnosis with follow up interviews at three, six and twelve months after diagnosis [140]. In this way, changes in the QOL of carers could be tracked, along with changes in the eating, weight and HRQOL of patients. This would help establish whether there are any triggers which have a particular impact on carer QOL.

Another future research avenue would be to shift from considering the caregiver as an individual, and instead to conceptualise the caregiver-patient dyad as the unit of analysis. In this approach, the importance of the effect that carer and patient have on each other is recognised [160]. For example, the extent women psychologically adjust to the situation when one member of a married couple is diagnosed with cancer plays a key role in the wellbeing of both the woman and her spouse. This is the case whether the woman is the patient (with breast cancer) or the caregiver of her husband (with prostate cancer) [84]. Although all but one of the studies included in this review feature interviews with both carers and patients, findings are not generally presented in terms of the caregiver-patient dyad. The 'conflict with patient' theme illustrates why the caregiver-patient dyad approach is useful. An alternative approach would be to conduct paired depth interviews (also known as paired or joint interviewing) with patients and carers, a qualitative method which was developed over forty years ago [161]. Through this method, relational factors as well as the individual components can be explored. However, there may be concerns associated with this method, such as whether interviewees feel able to express their thoughts freely if someone else is present and the concern that one member of the pair will dominate the interview [162].

Future psychosocial interventions for cachexia could profit from working with both the patient and the carer together. This approach has been found to have some benefit in, for example, patients with advanced cancer and their spousal caregivers [163] and also in women with recurrent breast cancer and their family caregivers [164]. These studies were evaluating therapy based interventions which were delivered over eight and five weeks respectively. In the first study, marital functioning scores improved and depression scores reduced between the start and end of the therapy session. Patients in the second study reported significantly less hopelessness and less negative appraisal of illness than controls receiving usual care and their family caregivers reported significantly less negative appraisal of caregiving. However, there was no influence on QOL and the intervention effects were no longer evident at six months. Further development is therefore required to improve the impact and sustainability of the effects of the therapy intervention.

For families affected by cancer cachexia, this review has demonstrated that patient symptoms can impact the QOL of their carer. The impact on QOL is in ways that may be amenable to intervention. For example, it may be possible to facilitate conflict resolution. There is potential for improving carer, and in turn, patient experience of cancer cachexia through attention to cachexia-related factors that impact carer QOL.

3.7 Limitations

Both reviews only included direct quotes. Although this approach is not reliant on the authors' interpretation, it has the disadvantage that the number of quotes available for analysis is limited and selected. The aim of the studies which contributed quotes was not to uncover all the QOL issues faced by patients with cancer cachexia or patients, and, particularly in the carer review, many of the quotes did not include any content which could unambiguously be considered relevant to QOL. The themes identified in the carer review should therefore be considered provisional because the data set was relatively small, more than half the extracted quotes from carers did not contain any information about their own QOL and there is no indication that data saturation has been reached.

A second limitation is that, because cancer patients (or carers of patients) with cachexia, eating or weight loss problems, were included, the samples were not homogeneous. In addition, the studies identified in our searches were all European or North American in origin so the cultural generalizability is limited. Although there is a lack of primary evidence from the rest of the world concerning the impact of cancer cachexia on individuals or the impact of caring for a loved one with cancer cachexia, it is likely that there will be some overlap with the themes identified in the reviews. This is because of the central role food and eating play in human existence [157].

3.8 Conclusion

Patients with cancer cachexia describe many HRQOL issues, drawn from a wide range of domains. The model of the patient experience of cancer cachexia underlines the importance of clinicians tackling both the physical decline associated with cachexia and its emotional consequences in order to maximise QOL. For carers, although the complexity of caring for a cancer patient with cachexia translates into a range of problems and experiences, they can sometimes be reluctant to report on how their lives are affected. This may be because they do not want to detract from the patient's needs [165,166]. Focussed research with carers is therefore required to provide a complete list of the relevant QOL issues. By recognising and addressing the impact of caring for a patient with cancer cachexia on the carers, both carer and patient QOL may improve.

The two reviews presented in this chapter suggest that relationships, coping and knowledge of the condition are important components for cancer cachexia psychosocial interventions for both patients and carers.

Chapter 4: Development of a health-related quality of life questionnaire for patients with cancer cachexia

4.1 Introduction

The overarching aim of the workshop developed in this thesis was to improve the QOL of both patients and carers. The impact of cancer cachexia is multi-dimensional and QOL reflects this because it includes physical, emotional, cognitive and social components. Future evaluation studies of the workshop would therefore require robust measures of patient and carer QOL. As discussed in Chapter 2, the concerns about the only available cancer cachexia specific HRQOL questionnaire and the lack of a specific carer instrument suggested that new measures for both patients and carers should be developed. However, because of the limitations of a PhD, there was only time to develop a HRQOL questionnaire for patients with cancer cachexia. It was anticipated that this questionnaire would be the primary endpoint in a future RCT evaluation study.

Traditional RCT endpoints rely on changes in clinical outcomes measured and reported by the researcher, for example, overall survival or time to tumour progression. Usually, the gold standard primary endpoint in cancer RCTs is overall survival (OS) i.e. the time to death from any cause. However, the primary endpoint should reflect the most important aspect of the research being addressed and OS is an inappropriate primary endpoint if survival is not the main goal of the intervention. Factors which need to be considered include what the intervention actually is, what the anticipated treatment effects are and the clinical setting. Most importantly, the primary endpoint should provide direct evidence of clinical benefit to patients. Both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) advise that a patient reported outcome (PRO) measure should be used when "…measuring a concept best known to the patient or best measured from the patient perspective." [95,167]. PROS are data reported directly by patients, without interpretation from anyone else.

The European Organisation for the Research and Treatment of Cancer (EORTC) provides an alternative measurement system to FACIT (the system which includes the FAACT). The core EORTC instrument, the QLQ-C30, which is applicable to all cancer patients, is one of the most widely used measures of HRQOL in patients with cancer [168,169]. The QLQ-C30 comprises 30 items, with five multi-item scales to assess physical, role, cognitive, emotional and emotional functioning, three multi-item symptom scales (fatigue, pain, and nausea and vomiting), six single symptom items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties) and a global health and QOL scale. Additional modules are developed to assess particular diseases or patient groups in conjunction with the QLQ-C30. The development of new EORTC Quality of Life Group modules follows four phases [170]. In Phase 1, HRQOL issues are generated through interviews with patients and health care professionals (HCPs), and a literature search. These HRQOL issues are reviewed and revised in Phase 2 and questionnaire items are formulated. In Phase 3, the questionnaire items are pilot tested and a provisional version of the module is developed. The questionnaire may be used in clinical trials and research once Phase 3 has been completed, with the understanding that there may be some modification following Phase 4. In Phase 4, the new module undergoes extensive international field testing. Phases 1-3 are described in this chapter. The Phase 4 work is ongoing, with a target sample of 650 and an expected completion date of December 2017.

4.2 Method

The Phases 1-3 study protocol was approved by the EORTC Quality of Life Group. Ethical and research governance approvals were obtained at each centre in accordance with local requirements and all patients provided written informed consent. The study was coordinated from Southampton by SW with additional centres in France, Germany, Greece, Italy, Norway, Poland, Sweden and Switzerland. Collaborator meetings were held every six months, with regular email discussion and teleconferences between these times. SW carried out all the Southampton interviews and led the data synthesis and analysis. Researchers based at each study site carried out the interviews at these locations.

4.2.1 Phase 1: Generation of relevant HRQOL issues

The literature review described in Chapter 3 was used to generate an initial list of HRQOL issues. Semi-structured interviews (Phase 1a interviews) were conducted in four countries (Italy, Norway, Switzerland, UK) by experienced QOL researchers. Content analysis of the interviews was carried out locally to identify novel issues, that is issues which had not already been identified by the literature review. In the interviews, patients were asked to describe their experience of weight loss, with prompts relating to eating difficulties, weight loss and personal relationships if required (see Appendix E for interview schedule). Novel issues identified outside the UK were written in English by the local researcher and were sent to the co-ordinating centre along with the relevant section of the interview translated into English. SW evaluated the novelty of each proposed issue and added any new issues generated in the patient interviews to those already collected in the literature review as they were received.

Interviews were carried out until data saturation was achieved, defined as when three consecutive interviews produced no new issues [171]. The full list of issues was distributed to the project collaborators for feedback and to check for missing issues. Based on this feedback, SW revised the list by combining and modifying issues where appropriate and removing issues with obvious overlap with the QLQ-C30.

This revised list was used in a second round of patient interviews (Phase 1b interviews) and also interviews with HCPs who were all experienced in cancer cachexia. The aim of the Phase 1b interviews was to check whether any issues should be removed and if any issues were missing, based on the feedback provided by patients and HCPs. Interviewees rated the importance of each issue on a four point scale ranging from not at all (1 point) to very much (4 points) and selected the ten issues which they considered the most important. They were then asked to identify any issues which they thought should not be included. Finally, participants were asked to consider whether any issues were missing.

4.2.2 Phase 2: Construction of the provisional questionnaire

Following EORTC guidelines, the collaborators provisionally planned to remove issues from the list where the mean patient importance score was two or less and >5% patients rejected the issue. New issues would be included if ≥10% of participants (patients or HCPs) mentioned the issue [170].

Issues were operationalised by SW into items with a response format and time frame compatible with the QLQ-C30. To aid this process, as is usual practice, existing full questionnaires (including an unpublished weight loss and eating habits questionnaire which had been used in several Macmillan trials and the FAACT), were consulted as well as items in the EORTC QOL group item library. The EORTC translation centre co-ordinated the translation of all the items into the languages required for Phase 3 (French, German, Greek, Italian, Norwegian, Polish and Swedish), following the EORTC translation procedure guidelines[172].

4.2.3 Phase 3: Testing the questionnaire for relevance and acceptability

The provisional questionnaire was piloted with patients in eight European countries: France, Germany, Greece, Italy, Norway, Poland, Sweden and the UK. After providing informed consent, patients completed the QLQ-C30 followed by the provisional questionnaire. They were then asked to indicate the relevance (yes or no) and importance (1, not at all; 2, a little; 3, quite a bit; 4, very much) for each item on the provisional questionnaire. Participants were encouraged to 'think aloud' during this process, to indicate if they found any question difficult, annoying, confusing, upsetting or intrusive, and to make any other comment they wished about the questionnaire. In order to check the patients taking part were representative of the range of patients who experience cancer cachexia, sociodemographic and clinical data were recorded, along with the Charlson Comorbidity Index[173], ECOG Common Toxicity Criteria and ECOG Performance Status [174].

The final questionnaire patients completed was the Symptom Checklist, a measure of S-NIS created for this study. A new measure was required because the only published S-NIS questionnaire available at the start of the study was aimed specifically at patients with head and neck cancer [16]. The Symptom Checklist created for this study combines items from the Patient-Generated Subjective Global Assessment (PG-SGA) [175] and the Nutrition Impact Symptoms (NIS) Checklist [17] (which was kindly shared by the authors at the start of the study, prior to publication) to produce a checklist of 17 items which is applicable to patients with any type of cancer (Appendix F). Neither of the instruments contributing items to the Symptom Checklist have validated thresholds to distinguish patients with many and few S-NIS. The symptom checklist in the PG-SGA contributes to an overall score rather than being considered in isolation. Each item on the NIS Checklist is scored on a four point scale (1=none to 4=a lot). Based on the authors' clinical experience and patient interviews, a threshold of three or more items scoring ≥3 was considered significant in the paper describing the NIS Checklist [17]. However, no data were presented to justify this threshold. For the Symptom Checklist used in this study, a pragmatic approach to identifying a threshold for high and low scores was devised. Patient scores were scaled to give a range of possible scores of 0 to 100, with higher scores indicative of more S-NIS. A scaled score of 25 on the Symptom Checklist was chosen to differentiate patients with high or low symptom scores. Patients with a scaled score below 25 (Group A) answered most questions 'not at all' whereas patients scoring above 25 (Group B) had at least some degree of symptom for most questions or they were more severely affected by some of the listed symptoms.

One of the objectives of Phase 3 was to reduce the number of items in the questionnaire. A provisional set of decision rules was agreed by the collaborators, based on the module development guidelines [170]. Items were rejected if <60% patients rated the item as relevant and important (quite a bit or very much); or <50% patients reported the issue applies quite a bit or very much; or if there were floor or ceiling effects (<10% patient responses for both response options one or two and three or four). In addition, patient comments about each item were reviewed.

It was anticipated that the eight domains identified by the HRQOL review described in Chapter 3 would inform the first attempt to identify scales for the new module. A statistician carried out multitrait scaling to examine whether the hypothesised scales demonstrated convergent validity i.e. whether each item within the scale correlated ≥0.4 (corrected for overlap) with its own hypothesised scale [176].The internal consistency of the scales was tested using Cronbach's alpha. A Cronbach's alpha of ≥0.70 is often considered to provide evidence of adequate internal consistency [176]. Analyses were carried out using Stata Statistical Software, release 13 [177].

4.2.4 Participants

For the Phase 1a interviews, sample size was determined by the number of interviews required to reach data saturation. For Phase 1b and Phase 3, sample size was based on the module development guidelines [170]. The guidelines suggest that a minimum of ten patients and five HCPs should review the issue list in Phase 1b. For Phase 3, a minimum of 15 patients in each cell of the recruitment matrix is suggested.

Eligible patients had a confirmed cancer diagnosis and met the consensus definition of cancer cachexia [5]. In order to include a representative sample of cancer cachexia patients, patients with different cancer diagnoses were recruited, at different stages of cachexia and with varying amounts of S-NIS. In Phase 1, a 2x2 recruitment matrix was used with patients categorised according to cachexia stage (syndrome vs. refractory cachexia) and many or few S-NIS, as assessed by the local researcher using their clinical judgement. Patients with many S-NIS were required to have been treated for these symptoms for at least two weeks.

For the Phase 3 interviews, the recruitment matrix became 3x2. Patients with an ECOG performance status of 3 or 4 were recorded as having refractory cachexia. The remaining patients were classified according to when they had been diagnosed with cancer (greater than or less than 100 days before the interview) to ensure patients with different experiences were included. Scores on the Symptom Checklist were used to categorise patients into those with fewer S-NIS symptoms (Group A) and more S-NIS symptoms (Group B).

All participants were 18 years or over. Patients unable to take part in interviews and complete self-report questionnaires were excluded.

4.3 Results

Module development is summarised in Figure 7.

4.3.1 Phase 1

Twenty one patient interviews were required to achieve data saturation in Phase 1a. The characteristics of the participants are shown in Table 7. The patients included twelve men and nine women, with a variety of primary diagnoses. Most had advanced cancer. There was a good spread of patients with many and few S-NIS, and of syndrome and refractory cachexia.

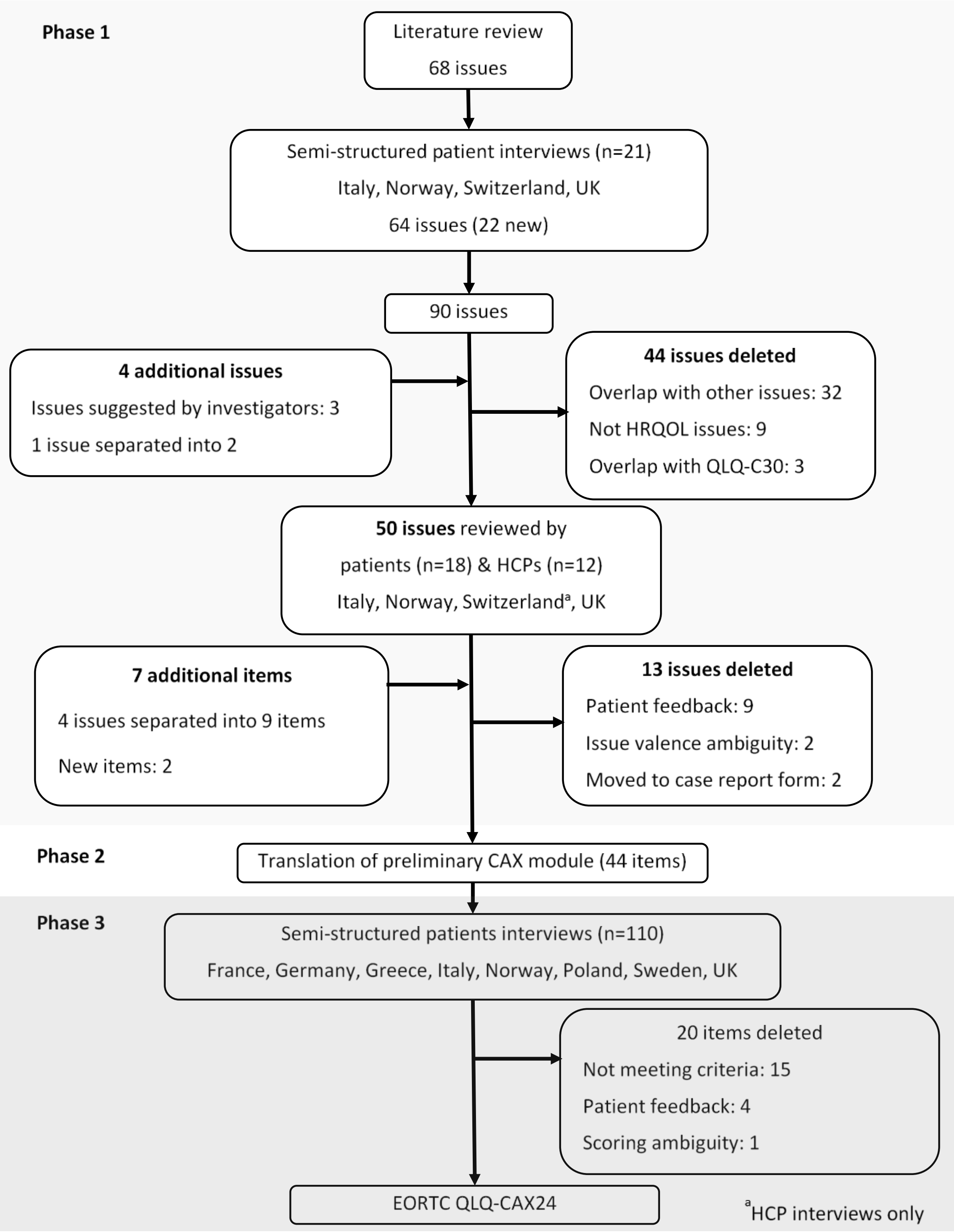


Figure 7: **Summary of EORTC QLQ-CAX24 development**

Table 7: Characteristics of patients participating in Phase 1

	Phase 1a participants	**Phase 1b participants**
Age (years) Mean (SD) Range	 63.5 (11.2) 43-87	 60.7 (11.9) 31-82
Number of males	12 (57.1)	9 (50.0)
Country Italy	 6 (28.6)	 6 (33.3)
Norway	3 (14.3)	6 (33.3)
Switzerland	7 (33.3)	-
UK	5 (23.8)	6 (33.3)
Primary tumour lung	 2 (9.5)	 2 (11.1)
head & neck	1 (4.8)	2 (11.1)
upper GI	5 (23.8)	5 (27.8)
breast	4 (19.0)	1 (5.6)
colorectal	3 (14.3)	2 (11.1)
gynaecological	1 (4.8)	-
lymphoma	3 (14.3)	1 (5.6)
male cancer	-	1 (5.6)
melanoma	-	1 (5.6)
thyroid	2 (9.5)	-

	Phase 1a participants	**Phase 1b participants**
unknown origin	-	2 (11.1)
brain	-	1 (5.6)
Disease stage local	1 (4.8)	2 (11.1)
local advanced	5 (23.8)	4 (22.2)
metastatic	15 (71.4)	12 (66.7)
Cachexia type syndrome, few S-NIS	5 (23.8)	5 (27.8)
refractory, few S-NIS	3 (14.3)	3 (16.7)
syndrome, many S-NIS	8 (38.1)	8 (44.4)
refractory, many S-NIS	5 (23.8)	2 (11.1)

Values in parentheses are percentages unless indicated otherwise

From the 21 patient interviews, 22 new issues were identified. These were added to the 68 issues which were extracted from the literature review, resulting in a total of 90 issues (Appendix F). These 90 issues were reduced to 50 following review for repetition and overlap with the QLQ-C30.

The 50 issues were reviewed in Phase 1b by 18 patients from three countries (UK, Norway, Italy). As can be seen Table 7, the patients included nine men and nine women, with a variety of primary diagnoses. Most had advanced cancer but had not yet entered the refractory stage of cachexia. There was a good spread of patients with many and few S-NIS. Patient importance scores, the number of patients rejecting an issue and the number of patients including issues in their top ten are tabulated inTable 8. The list was also shown to 12 HCPs, three each from Norway, Italy, Switzerland and the UK, including one palliative care doctor, four palliative/cancer care nurses, four dietitians and three oncologists for feedback.

Table 8: Phase 1b patient (pt) quantitative scores

Issue	Number of pts rejecting item	Mean importance score	Number of pts rating issue as top 10
1. A change in food preferences	1	2.67	2
2. Appetite very changeable	0	3.06	5
3. Binge eating	5	1.65	1
4. Does not feel the need for food	0	2.78	5
5. Feeling too full to eat	0	2.39	2
6. No pleasure from eating	1	2.94	6
7. Not eating as much	1	3.06	10
8. Strong negative reaction to food	0	2.39	2
9. Thinks a lot about food and eating	1	2.06	1
10. Willing but not able to eat	0	3.11	8
11. Use of feeding tube	1	2.00	2
12. Use of nutritional supplements	0	2.61	2
13. Difficulty drinking	0	2.22	1
14. Dribbling	3	1.44	2
15. Dry mouth	3	2.50	3
16. Eating is uncomfortable	0	2.17	1
17. Problems with stomach/bowel	1	2.44	4
18. Smell changes	2	2.00	2
19. Taste changes	1	2.61	5
20. Texture of food unpleasant	1	2.44	3

Issue	**Number of pts rejecting item**	**Mean importance score**	**Number of pts rating issue as top 10**
21. Choosing not to think about weight loss	3	2.44	2
22. Effect of weight loss on ability to do things	1	3.17	6
23. No control over weight	2	2.69	3
24. Self-monitoring weight	1	2.28	0
25. Weight as illness indicator	1	2.39	2
26. Worried about weight loss	0	2.89	3
27. Acceptance of change in eating	2	2.61	3
28. Change in self-identity	0	2.53	1
29. Completely focussed on self	4	1.61	2
30. Embarrassed by eating or weight loss	2	2.39	4
31. Missing past experiences	2	2.86	3
32. No sense of hope	0	2.00	2
33. Thinking about the ultimate result of weight loss	1	2.17	3
34. Waste of food distressing	4	1.94	0
35. Worry about food costs	7	1.72	2
36. Concern about burdening others	1	2.17	4
37. Eating to please others	3	1.67	1
38. Eating with others	1	2.24	3
39. Feeling pressured by others	1	1.89	3
40. Feeling socially isolated	2	1.67	1

Issue	**Number of pts rejecting item**	**Mean importance score**	**Number of pts rating issue as top 10**
41. Feeling supported by others	0	3.11	7
42. Mealtimes not pleasurable	1	2.39	4
43. Protecting others from effects of weight loss	5	1.67	0
44. Keeping things normal	1	2.67	7
45. Staying independent	1	2.56	5
46. Bothered by appearance	2	2.17	3
47. Feeling physically less attractive	0	2.39	3
48. Uncomfortable with sexual intimacy	1	2.00	2
49. Lack of knowledge about weight loss	1	2.33	0
50. Lack of support from health care professionals	3	2.17	2

4.3.2 Phase 2

Most of the comments made by patients were either general (e.g. “The questionnaire includes all fields that I think are important,”) or were suggestions for issues which are already included (e.g. “I have a lot of problems swallowing,”). However, two patients suggested including being too tired to eat as an item. Although the QLQ-C30 has ‘Were you tired?’, being too tired to eat goes beyond this concept and it was agreed to include this issue. Similarly, HCPs made mostly general comments (e.g. “The issues should be unambiguous,”) but two HCPs suggested that patients in a lot of pain would be unable to eat. The QLQ-C30 has “Have you had pain?”, but the suggested issue is very specifically looking at pain having an effect on the ability to eat. It was therefore decided to also include this issue.

Application of the agreed decision rules, described in section 4.2.2, led to the removal of nine issues (acceptance of change in eating, binge eating, dribbling, smell changes, completely focussed on self, waste of food distressing, worry about food costs, eating to please others, protecting others from effects of weight loss). Two further issues (self-monitoring weight and weight as illness indicator) were also removed, because it was not clear whether these were positive or negative in terms of HRQOL. Two issues about the use of feeding tubes and nutritional supplements were considered not patient reported outcomes and were removed. One issue, 'strong negative reaction to food' became three items to distinguish whether the negative reaction was due to the thought, smell or sight of food. 'Embarrassed by eating or weight loss' became two items to differentiate the two sources of embarrassment. As a result of all these modifications, the questionnaire for Phase 3 comprised a total of 44 items and is shown in Appendix H.

4.3.3 Phase 3

A total of 110 patients was recruited. The sampling matrix and number of patients in each cell is shown in Table 9. The module development guidelines recommend a minimum of 15 patients in each cell [170]. However, within the time frame of the project, it proved difficult to find patients with refractory cachexia and a low score on the Symptom Scale and also patients with a high score on the Symptom Scale within the first 100 days of diagnosis. These two cells both contain 13 and 12 patients respectively.

The characteristics of the patients taking part in this phase are shown in Table 10. There were slightly more men than women, but a good spread of primary cancer diagnoses. Group A (low Symptom Checklist score) and Group B (high Symptom Checklist score) were similar across most variables. The mean BMI across the whole sample was in the normal range, with just 25% of patients in the underweight category (BMI<18). Twenty percent of patients were classed as overweight (BMI≥25), including three obese patients (BMI≥30). The mean weight loss was considerably more than the 5% in six months stated in the consensus definition of cancer cachexia [5], but there was much variation, with some individuals even reporting weight gain at some points during their illness.

Table 9: Number of patients in each cell of the Phase 3 sampling matrix

	Cachexia syndrome: Interview within 100 days of cancer diagnosis	**Cachexia syndrome:** Interview >100 days after cancer diagnosis	**Refractory cachexia**: ECOG performance status 3 or 4
Group A: Symptom Checklist scaled score ≤25	25	17	13
Group B: Symptom Checklist scaled score >25	12	20	22

NB. Total is less than 110 because one patient with cachexia syndrome, interviewed in the first 100 days after cancer diagnosis, did not complete a Symptom Checklist

Table 10: Characteristics of patients participating in Phase 3

		Whole Sample	**Group A**	**Group B**
Age (years)	Mean (SD)	62.9 (13.7)	62.5 (13.2)	63.4 (14.4)
	Range	20-93	40-93	20-84
Number of males		63 (57.3)	31 (56.4)	31 (56.4)
Primary tumour				
	lung	25 (22.7)	10 (18.2)	14 (25.9)
	head & neck	17 (15.5)	11 (20.0)	6 (10.9)
	upper GI	16 (14.5)	7 (12.7)	9 (16.4)
	breast	13 (11.8)	7 (12.7)	6 (10.9)
	colorectal	13 (11.8)	8 (14.5)	5 (9.1)
	gynaecological	8 (7.3)	5 (9.1)	3 (5.5)

	Whole Sample	**Group A**	**Group B**
lymphoma	6 (5.5)	3 (5.5)	3 (5.5)
male cancer	4 (3.6)	1 (1.8)	3 (5.5)
kidney	3 (2.7)	1 (1.8)	2 (3.6)
melanoma	3 (2.7)	1 (1.8)	2 (3.6)
thyroid	1 (0.9)	0 (0.0)	1 (1.8)
unknown origin	1 (0.9)	1 (1.8)	0 (0.0)
One or more comorbidities	32 (29.1)	17 (30.9)	15 (27.3)
Symptom Checklist scaled score			
Mean (SD)	25.9 (15.4)	13.9 (7.5)	38.2 (10.9)
Range	0-74.5	0-23.5	25.5-74.5
BMI			
Mean (SD)	21.3 (3.9)	21.9 (3.9)	20.8 (3.8)
Range	15.5-31.2	16.0-31.2	15.5-28.4
n	109	55	53
% weight loss in last 3 months			
Mean (SD)	7.7 (6.6)	8.0 (5.6)	7.4 (7.5)
Range	-7.3-23.4	-6.7-22.1	-7.3-23.4
n	96	46	50
% weight loss in last 6 months			
Mean (SD)	12.9 (7.6)	12.8 (6.6)	12.7 (8.4)
Range	-9.6-32.6	-9.6-25.7	-8.3-32.6

	Whole Sample	**Group A**	**Group B**
n	102	51	50
% weight loss from premorbidity			
Mean (SD)	18.2 (7.5)	17.4 (7.4)	18.7 (7.6)
Range	-6.9-45	6.3-45.0	-6.9-37.6
n	92	43	48
ECOG performance status			
0	7(6.4)	3 (5.5)	4 (7.3)
1	25 (22.7)	13 (23.6)	12 (21.8)
2	42 (38.2)	25 (45.5)	16 (29.1)
3	29 (26.4)	11 (20.0)	18 (32.7)
4	6 (5.5)	2 (3.6)	4 (7.3)
Missing	1 (0.9)	1 (1.8)	0 (0.0)
Toxicity level			
None	45 (40.9)	25 (45.5)	19 (34.5)
Mild	36 (32.7)	20 (36.4)	16 (29.1)
Severe	29 (26.4)	10 (18.2)	19 (34.5)
Living alone	21 (19.0)	13 (23.6)	8 (14.5)
Carer easily available	85 (77.3)	39 (70.9)	46 (83.6)
Education beyond secondary school	46 (41.8)	24 (43.6)	22 (40.0)
Previous employment level			
Unskilled	23 (20.9)	7 (12.7)	15 (27.3)

	Whole Sample	Group A	Group B
Skilled manual	45 (40.9)	26 (47.3)	19 (34.5)
Administrative	22 (20.0)	8 (14.5)	14 (25.5)
Professional	17 (15.5)	12 (21.8)	5 (9.1)
Missing	3 (2.7)	1 (1.9)	1 (1.8)

Values in parentheses are percentages unless indicated otherwise. Number of patients in Group A and Group B added together is less than Whole Sample because one patient did not complete a Symptom Checklist and so could not be classified.

Application of the item decision rules would have resulted in the removal of 25 items leaving 19 items in the module. Collaborator review of these items raised the concern that many of the items related to function had been lost, which are important for patients more affected by S-NIS. The item decision rules were therefore applied to Group A and Group B separately resulting in one additional item to consider from Group A and ten from Group B (Table 11). Any patient comments for each of the 30 surviving items were carefully reviewed which led to the removal of five items (marked as ‘removed’ in the final column of Table 11). The wording of one item (issue 39) was changed from ‘Have you worried that you might lose your independence?’ to ‘Have you worried about becoming more dependent on others?’ as some patients pointed out that they were already somewhat dependent on others. The collaborators at each centre translated this item into their own language and then checked with 5-10 patients that the new version was acceptable. Item 31, ‘Have you felt hungry?’ (issue 1) was also removed because it is ambiguous whether this is positive or negative with respect to HRQOL. Appetite loss is covered by the QLQ-C30.

Table 11: Decisions about items

Issue	**Samples meeting relevance & importance criteria**	**Samples meeting floor & ceiling criteria**	**Samples meeting prevalence criterion**	**Deletion vs. Retention**
1. No hunger	All 3	All 3	All 3	Delete (scoring ambiguity)

Issue	**Samples meeting relevance & importance criteria**	**Samples meeting floor & ceiling criteria**	**Samples meeting prevalence criterion**	**Deletion vs. Retention**
2. Willing but not able to eat	All 3	All 3	Whole sample & Group B	Retain
3. Taste changes	All 3	All 3	Whole sample & Group B	Retain
4. Texture of food unpleasant	Whole sample & Group B	All 3	Whole sample & Group B	Retain
5. Put off eating by thought of food	None	All 3	Group B	Delete
6. Put off eating by food smells	Whole sample & Group B	All 3	Group B	Retain
7. Put off eating by quantity	Group B	All 3	All 3	Retain
8. Change in food preferences	None	All 3	Whole sample & Group B	Delete
9. Changeable appetite	None	All 3	All 3	Delete
10. Missing past experiences	Group B	All 3	Whole sample & Group B	Delete (patient comments)
11. Weight loss preventing usual activities	All 3	All 3	All 3	Retain
12. Too tired to eat	Whole sample & Group B	All 3	Group B	Retain

Issue	**Samples meeting relevance & importance criteria**	**Samples meeting floor & ceiling criteria**	**Samples meeting prevalence criterion**	**Deletion vs. Retention**
13. Unable to eat because in pain	All 3	All 3	Group B	Retain
14. Feeling too full to eat	All 3	All 3	All 3	Retain
15. Difficulty drinking	All 3	All 3	Group B	Retain
16. Dry mouth	All 3	All 3	All 3	Retain
17. Difficulties chewing	Whole sample & Group A	All 3	None	Delete
18. Difficulties swallowing	All 3	All 3	Group B	Retain
19. Indigestion/heart burn	All 3	All 3	Group B	Retain
20. Not eating as much	All 3	All 3	Whole sample & Group B	Retain
21. Worried about weight loss	All 3	All 3	All 3	Retain
22. Thinks a lot about food and eating	None	All 3	Whole sample & Group B	Delete
23. Outlook on future worsened	Whole sample & Group A	All 3	All 3	Delete (patient comments)
24. Thinking about the ultimate result of weight loss	All 3	All 3	All 3	Retain

Issue	Samples meeting relevance & importance criteria	Samples meeting floor & ceiling criteria	Samples meeting prevalence criterion	Deletion vs. Retention
25. Mealtimes as social events	Group A	All 3	All 3	Delete (patient comments)
26. Feeling supported by others	All 3	Whole sample & Group B	None	Delete
27. Feeling pressured by others	Whole sample	All 3	Whole sample & Group B	Retain
28. Concern about being a burden	All 3	All 3	All 3	Retain
29. Problem eating with others	None	All 3	None	Delete
30. Embarrassed by eating	None	Whole sample & Group B	None	Delete
31. Embarrassed by weight loss	Whole sample	All 3	None	Delete
32. Change in self-identity upsetting	None	All 3	All 3	Delete
33. Bothered by appearance	All 3	All 3	All 3	Retain
34. Change in role in life upsetting	All 3	All 3	All 3	Delete (patient comments)
35. Feeling physically less attractive	Group B	All 3	Whole sample & Group B	Delete (patient comments)

Issue	Samples meeting relevance & importance criteria	Samples meeting floor & ceiling criteria	Samples meeting prevalence criterion	Deletion vs. Retention
36. Uncomfortable with sexual intimacy	None	All 3	None	Delete
37. No control over weight	All 3	All 3	All 3	Retain
38. Keeping things normal	All 3	All 3	All 3	Retain
39. Staying independent	All 3	All 3	Whole sample & Group B	Retain
40. Forcing self to eat	All 3	All 3	All 3	Retain
41. Avoiding thinking about weigh loss	None	All 3	Whole sample & Group B	Delete
42. Acceptance of change in eating	Group B	All 3	None	Delete
43. Inadequate information	All 3	All 3	Group B	Retain
44. Lack of support from health care professionals	All 3	All 3	None	Delete

Samples: Group A - fewer secondary nutritional impact symptoms (S-NIS); Group B - more S-NIS symptoms; Whole sample - Group A and B combined. Relevance and importance criteria: ≥60% patients rated the item as relevant and important (quite a bit or very much); floor and ceiling criteria: ≥10% patient responses for both response options one or two and three or four; prevalence criteria ≥50% patients reported the issue applies quite a bit or very much

The provisional module therefore has 24 items and is called the EORTC QLQ-CAX24. Five multi-item scales are proposed – food aversion, eating and weight-loss worry, eating difficulties, loss of control and physical decline. These are shown in Table 12. The scales are based on the domains identified in the patient review described in Chapter 3 but with some modifications. The food and eating domain is split into two scales – food aversion and eating difficulties; the emotions domain becomes eating and weight-loss worry; loss of control subsumes identity and relationships; and items from the coping domain were removed during the Phase 3 item reduction process. A single item covers the knowledge domain and three other single items check for dry mouth, indigestion/heartburn and forced eating.

Table 12 also includes Cronbach's alpha values (as a measure of internal consistency) and the range of values for within scale item correlations (as a measure of convergent validity). Adequate internal consistency and convergent validity was demonstrated for three of the five scales (food aversion, eating and weight-loss worry, loss of control). For the other two scales, eating difficulties and physical decline, the values fell slightly below the desired levels. However, the figures of 0.7 for Cronbach's alpha and 0.4 for within scale item correlations are only provided as guidance and the proposed scales will be fully evaluated in the planned validation study.

Table 12: Issues included in the EORTC QLQ-CAX24 and hypothesised conceptual scales

Conceptual Scale	**Issues**	**Cronbach's alpha**	**Item correlation with scale (range)**[a]
Food aversion	Taste changes Texture of food unpleasant Put off eating by food smells Put off eating by quantity Feeling too full to eat	0.72	0.41 to 0.53
Eating and weight-loss worry	Worried about weight loss Worried not eating enough Worried about ultimate result of weight loss	0.74	0.52 to 0.60
Eating difficulties	Willing but not able to eat	0.62	0.32 to 0.49

Conceptual Scale	Issues	Cronbach's alpha	Item correlation with scale (range)[a]
	Difficulty drinking Difficulties swallowing		
Loss of control	Feeling pressured by others Concern about being a burden Bothered by appearance No control over weight Keeping things normal Staying independent	0.79	0.43 to 0.66
Physical decline	Weight loss preventing usual activities Too tired to eat Unable to eat because in pain	0.62	0.39 to 0.52
4 single items	Dry mouth Indigestion/heartburn Forcing self to eat Inadequate information	N/A	N/A

[a] corrected for overlap

4.4 Discussion

The EORTC QLQ-CAX24 has been developed to be used in conjunction with the EORTC QLQ-C30 to assess HRQOL in cancer patients with cachexia. The development process followed a predefined set of guidelines and decision rules for inclusion of relevant issues. The module was developed with the help of cancer patients from nine countries at different stages of the cancer disease trajectory, from relatively soon after diagnosis to those approaching the end of life, and with differing numbers of S-NIS. Item selection was primarily based on the results and feedback from the patient participants. This study has shown that the QLQ-CAX24 is relevant, acceptable and applicable to patients with cancer cachexia.

The issues included in the QLQ-CAX24 are consistent with the model developed from the patient review described in Chapter 3, with some modification of the domain structure. The provisional module contains five scales and four single items. Further assessment of the scale structure, using multi-trait scaling and factor analyses, will occur when Phase 4 data collection is complete.

A challenge for any cancer cachexia HRQOL measure is that it should be appropriate for patients at all stages of cachexia. The patients contributing to the development of the QLQ-CAX24 were therefore deliberately selected to include patients with both cachexia syndrome and refractory cachexia. As well as including patients with cachexia syndrome and patients with refractory cachexia, the development of the QLQ-CAX24 drew on the experience of patients with either many or few S-NIS. For the Phase 3 data collection, it was agreed to use number of S-NIS as identified by the Symptom Checklist to stratify patients rather than asking centres to classify patients in order to have a more objective measure. The cut point selected for the Symptom Checklist was chosen to contrast patients answering ‘not at all’ to most questions (mean item score close to one) with those with at least some experience of most symptoms or some more severe symptoms (mean item score close to or >2). This threshold appeared to work well in, but further work will be required to validate this cut point.

A striking finding in Phase 3 was that the number of items meeting the item decision rules was, perhaps not surprisingly, fewer for Group A (low Symptom Checklist score) than for Group B (high Symptom Checklist score). To ensure important items were not lost at Phase 3, items were considered for inclusion as long as they met the item decision rules in either Group A, Group B or the sample as a whole. It may be that the module is shortened following Phase 4, which will include a much larger sample of patients, if some items are not applicable across all patients.

Interestingly, the Phase 3 sample contained four patients who had a scaled score of zero on the Symptom Checklist, perhaps suggesting that there are some patients who have no S-NIS at all. However, the Symptom Checklist only asks patients about symptoms in the last two weeks. Patients’ S-NIS, which did contribute to their weight loss, may have been successfully treated in this time.

There are a number of limitations to the study including, possible participation bias. This bias could arise from HCPs in terms of who they invited to participate. As a formal cachexia assessment instrument is not currently available [178], patients were selected based on clinical judgement and because they met the consensus definition of cancer cachexia [5]. Bias could also arise based on which patients agreed to participate. Although the use of a recruitment matrix ensured that the views of patients at different stages of cachexia, some of whom were nearing the end of life, were included, in two of the Phase 3 subgroups, fewer than the 15 patients recommended by the EORTC guidelines could be recruited in the time frame of the project [170]. Extra efforts will be needed to recruit to these two subgroups in Phase 4, the validation phase of the project.

Although there may be some modification to the QLQ-CAX24 after Phase 4, through a reduction in length and adjustment to the scale structure, it is now available for use in clinical trials and other research. Whether clinicians and researchers should choose to use the QLQ-CAX24 or the FAACT, the only other instrument for the assessment of HRQOL in patients with cancer cachexia, will partly be determined by which of the core questionnaires from the EORTC and FACIT measurement systems is most applicable to their requirements [168,179]. An additional consideration is that the FAACT is a single scale whereas the QLQ-CAX24 comprises scales allowing more precise hypothesis testing. In the context of an outcome measure for the future RCT planned for the workshop, this is important because it is unlikely that all aspects of HRQOL can be improved through a psychoeducational workshop. For example, it could be hypothesised that the workshop will improve the ‘loss of control’ and the ‘eating and weight loss worry’ scales, along with the ‘inadequate information’ and ‘forcing self to eat’ items, whereas it may not help with ‘physical decline’. This, along with its demonstrable content validity, means that the QLQ-CAX24 is a better choice than the FAACT, for the primary outcome measure in the future workshop RCT.

Part C: Developing a workshop for cancer patients with unintentional weight loss and their carers

Chapter 5: Identification of workshop intervention targets

5.1 Introduction

This chapter describes steps one and two of the CIDP [125], antecedent (root causes) identification and intervention target identification. The systematic reviews described in Chapter 3 identified how cancer cachexia affects the QOL of both patients and carers. Improving QOL is a key goal for the workshop. In order to achieve this, it is important to identify the root causes, i.e. the antecedents, of why QOL is negatively impacted. Using this approach, the focus of the workshop will therefore be on the prevention, rather than the treatment, of the negative consequences associated with cancer cachexia. After identification and rationalisation, the antecedents were grouped together to form the workshop intervention targets.

5.2 Method

As described in Chapter 2, the CIDP employs the ATM approach to logic modelling. In essence, this approach first involves producing a written statement which describes the problem that the intervention will address. This is then followed by interviews with people who have experience with the problem, with the goal of identifying all the reasons that the problem occurs. The problem statement and reasons are written in boxes and arrows are drawn between boxes to represent the causal relationships between the reasons, culminating with the problem to be addressed by the intervention.

The project advisory panel was asked to agree on a problem statement, which encapsulates the reason the workshop is needed, using the personalised email shown in Appendix J. The proposed statement was:

> People with cancer often have unintentional weight loss. The person with cancer and their carer may find this difficult.

The email explained that the statement would be used in interviews with patients, carers and HCPS who would be asked to suggest reasons for the problem. The phrase ‘unintentional weight loss’ was used rather than cachexia to ensure that all interviewees would understand the statement. Panel members were invited to suggest alternative wording for the statement. Ten members of the advisory panel commented on the initial formulation of the problem statement. Six members were happy with this statement. Other comments received were:

> I prefer family, friends, loved ones, to carer (myself). Carer implies they need care, which they don’t always. Also I think 'difficult' is a bit weak. [Consultant medical oncologist]

> Clear & open statement. However, do you want to gauge how much they understand the causes of weight loss (see your point about root causes) and/or the emotional/psychological impact of not eating, being nourished, etc. and visibly losing weight? Your follow up question (what they think the root causes are) might direct them to searching for factual explanations about unintentional weight loss (a test of knowledge), rather than a more reflective questioning of why they find it difficult ('reasons for the problem and why it is difficult for them'). [Family therapist]

> I suggest, "People with cancer often have unintentional weight loss. The person with cancer and their carer may find this a distressing and challenging problem." [Palliative care consultant]

> I suggest, "People with cancer often have unintentional weight loss. This can be difficult for the person with cancer and their carer." [Lecturer in cancer care]

These comments were discussed with a new set of four advisory panel members. The problem with using the word ‘carer’ was acknowledged but a definition was included in the participant information sheet. This issue was also discussed with patients and carers at a support group. Patients said that they did not find the term ‘carer’ offensive and would be quite happy to describe their carer as such. Although carers were also happy to be labelled with that word, it was not a term that they used for themselves and most did not think of themselves as a carer. For example, one lady said, "I'm old school. Marriage is for life. He's just my husband.” No-one could think of an alternative word to use.

It was agreed to retain the relatively weak phrasing of the problem as ‘difficult’ so that interviewees would think broadly about the problem and be open to mentioning reasons which they may think could be perceived as trivial. The comments from the family therapist were noted but it was felt the interviewer could address this problem if it arose by explaining that it was not the interviewee’s knowledge of why cancer cause weight loss that was of interest, but rather why this was a difficult experience. Following the discussion, the problem statement to present to participants was chosen to be:

> People with cancer often have unintentional weight loss. This can be difficult for the person with cancer and their carer.

5.2.1 Recruitment and participants

The ATM approach suggests carrying out about 12 interviews with ‘content experts’, that is individuals who may be able to provide insight as to why the problem occurs [126]. The content experts for this study were identified as patients, carers and HCPs. Five interviews from each group were planned to allow for the earlier interviews being lower quality than the later interviews [126].

Patients were required to have both a confirmed cancer diagnosis and cachexia as defined by the consensus definition [5]. They were aged 18 years or over and able to read and write in English. Patients were excluded from the study if they were unaware of their cancer diagnosis or if they had no concerns about eating or weight loss as this would mean that they could not draw on their own experiences and could not be considered as content experts. Participating patients were asked to nominate an informal carer, ideally someone living in the same home, but as a minimum, carers were required to have face-to-face contact with the patient at least five times a week. This requirement has been applied in previous research exploring the experience of cancer cachexia in families [74]. Carers were also required to be aged 18 years or over and able to read and write in English.

Potential participants were informed of the study by an HCP. Anyone who was interested was asked to give their permission for SW to initiate contact. SW checked eligibility and then provided participant information sheets for patients and carers and answered any questions about the study. All participants were required to provide written informed consent. Basic sociodemographic data was collected for all participants, along with basic clinical data for patients. All patient and carer interviews took place in their own home. Patients and carers were interviewed separately.

HCPs from a range of professions within the Southampton University Hospitals NHS Trust were approached about the study. SW provided a participant information sheet and answered any questions. All HCPs taking part were required to provide written informed consent. Interviews were conducted at a location convenient for the HCP.

5.2.2 Procedure

After the advisory panel agreed on the problem statement, SW carried out interviews with patients, carers and HCPs to create a map to identify the antecedents to the problem. After the first two interviews, it became clear that separate maps for patients and carers were required because there were too many antecedents to include on one map. Therefore, for the remaining interviews all participants were asked to create one map for patients and one map for carers. The interview template is shown in Appendix J.

Microsoft PowerPoint was used to map out each participant's understanding of the problem for patients and carers separately. A text box with the problem statement was placed on the right hand side of the screen. SW typed each reason the interviewee identified as a cause of the problem in a separate text box and used connectors to link the boxes, as directed by the participant. This allowed participants to edit the content and causal linkages in their map. Interviewees were encouraged to keep thinking of reasons and were able to flip between the two maps they were creating until fully satisfied with both maps.

Two summary maps, one for patients and one for carers, were produced by integrating the maps of all the participants. Each summary map was created by selecting the most comprehensive map created in the interviews, systematically comparing the other maps to this template and then adding in any additional antecedents [126]. The summary maps were supplemented with data from the systematic reviews of the patient and carer literature described in Chapter 3 and also the semi-structured interviews with patients and HCPs carried out as part of the development of the QLQ-CAX24, described in Chapter 4. The list of HRQOL issues which was generated from the literature reviews and interviews was compared with the summary map and any missing issues were added in.

Two lists of antecedents were created from the two summary maps and presented to members of the project advisory panel, who were asked to rate the importance of each antecedent and also its changeability in the context of the planned workshop. It was important to include a changeability rating because it was anticipated that there would be some high scoring antecedents which the workshop would not be able to address (e.g. lack of dietitians). Panel members were invited to fill out a survey on iSurvey, a web-based survey platform, hosted by the University of Southampton. The instruction given was

> This survey contains reasons why it can be difficult for a person with cancer to have unintentional weight loss and reasons why it can be difficult caring for a person with cancer who has unintentional weight loss. Please rate the importance and changeability through workshop attendance of each of the issues.

The patient and carer antecedents were presented separately. Panellists were asked to score each reason on a five point Likert scale for importance ('not important' to 'very important') and changeability (‘not changeable’ to ‘very changeable’). The importance and changeability rating exercises were presented in blocks so that all the importance ratings were carried out before moving on to changeability.

The mean scores for importance and changeability for patient and carer antecedent were calculated separately. Following the CIDP, antecedents which scored above the mean for both importance and changeability were selected. A combined list of patient and carer antecedents, which were important and changeable was produced. Thematic analysis was used to group similar antecedents together. Intervention targets for the workshop were then formed on the basis of these themes.

5.3 Results

5.3.1 Participants

Most of the patients, carers and HCPs who expressed an interest in the study were happy to take part after reading the participant information sheet (PIS). However two families declined: one couple felt they were too old to take part and did not feel they could make a useful contribution. The other family did not give a reason.

All the patients who took part had advanced cancer and most were male. The patients had all lost a considerable amount of weight since developing cancer. At the time of the interview, all were off cancer treatment. Patient characteristics are summarised in Table 13.

Table 13: Characteristics of patients participating in antecedent identification interviews

ID	**Age (years)**	**Sex**	**Cancer site**	**% weight loss from premorbid weight**	**ECOG performance status**	**Education level**	**Occupation level**	**Lives with**
Pat1	88.0	male	pancreas	29.1	2	university	professional	nephew & his wife (moved in temporarily)
Pat2	78.8	male	prostate	12.9	3	compulsory school	middle	wife
Pat3	60.9	male	pancreas	38.1	2	university	professional	wife

ID	Age (years)	Sex	Cancer site	% weight loss from premorbid weight	ECOG performance status	Education level	Occupation level	Lives with
Pat4	71.7	male	head & neck	14.9	2	university	professional	wife
Pat5	66.1	female	lung	18.3	2	compulsory school	middle	husband

The carer characteristics are summarised in Table 14. Patient/carer pairs are indicated by the number in the ID. Most of the carers were female and most were the spouse of the patient. Car1 was a breast cancer survivor, Car5 had cardiovascular problems and type 2 diabetes requiring insulin, but the other carers had no major medical problems.

Table 14: Characteristics of carers participating in antecedent identification interviews

ID	Age (years)	Sex	Relationship to patient	Education level	Occupation Level
Car1	67.5	female	wife of patient's nephew	college	middle
Car2	72.1	female	wife	compulsory school	middle
Car3	61.0	female	wife	college	middle
Car4	68.2	female	wife	compulsory school	middle
Car5	70.2	male	husband	compulsory school	middle

The HCPs who contributed were a palliative care clinical nurse specialist, a specialist registrar medical oncologist and two dietitians specialising in cancer patients. One of the PhD supervisors, JH (Professor of Nursing) was also interviewed. Although this could be viewed as a confounding factor, it was felt that this was outweighed by the experience JH has in the field of cancer cachexia.

5.3.2 Antecedents

The number of antecedents included in each map ranged from 8 to 30, with an average of 14. The patient composite map is shown in Figure 8, with antecedents colour-coded by QOL domains, and the carer composite map is shown in Figure 9, with antecedents colour-coded into categories (effects on own life, relationship with patient, uncertainty, negative emotions) to aid viewing. These composite maps include the supplementary data from the literature reviews and the QLQ-CAX24 development interviews. A total of 54 antecedents were identified for patients and 65 for carers.

Eight members of the advisory committee completed all the importance and changeability ratings. The mean scores for each antecedent are shown in Figure 8 and Figure 9. For the patient antecedents, the mean importance score was 4.1 and the mean changeability score was 3.2. There were 15 antecedents which scored above the mean for both importance and changeability. For carers, the mean importance score was 3.9, changeability was 3.3 and 14 antecedents scored above the mean on both measures. The high scoring antecedents are shown in Table 15. By examining both the patient and carer lists of high scoring antecedents, six themes were identified. The themes common to both patients and carers were not knowing what to do for the best, conflict with each other and negative emotions. For patients, an additional theme was forcing self to eat. Food provision and managing patient's dependency were the additional carer themes.

5.3.3 Intervention Targets

On the basis of the identified themes, three intervention targets were chosen. 1) Providing information about eating well with cancer. This addresses the themes of not knowing what to do for the best, forcing self to eat and food provision. 2) Addressing patient-carer conflict. This target is for the 'conflict with each other' theme. 3) Addressing negative emotions associated with eating and weight loss difficulties. This covers the negative emotions and managing patient's dependency themes.

Table 15: Antecedents identified as important and changeable

Themes	**Patient antecedents**	**Carer antecedents**
Not knowing what to do for the best	trying to balancing eating with consequences e.g. bowel problems, not knowing what to do for the best, uncontrolled symptoms (e.g. nausea, appetite, pain, poor taste, dry mouth)	lack of understanding about disease process & decreased need for food, not knowing what food to offer, difficult to know whether to 'fight' back against the cachexia or let nature take its course, uncertainty about how best to help patient, knowing what should be doing is different to actually putting into practice
Conflict with each other	losing control of decision making, conflict with carer	wants patient to eat more, conflict with patient,
Negative emotions	fear, fear of the unknown, anticipating pain and suffering, frustration, anxiety, depression	fear that patient is going to die if s/he doesn't eat, having to accept things have changed, feeling rejected when patient doesn't eat prepared food
Forcing self to eat	forcing self to eat for strength, forcing self to eat for energy, forcing self to eat to maintain normality, forcing self to eat to keep things under control,	
Food provision		trying to find things patient will eat, wanting to provide normal meals, wanting to provide balanced diet
Managing patient’s dependency		managing patient's dependency

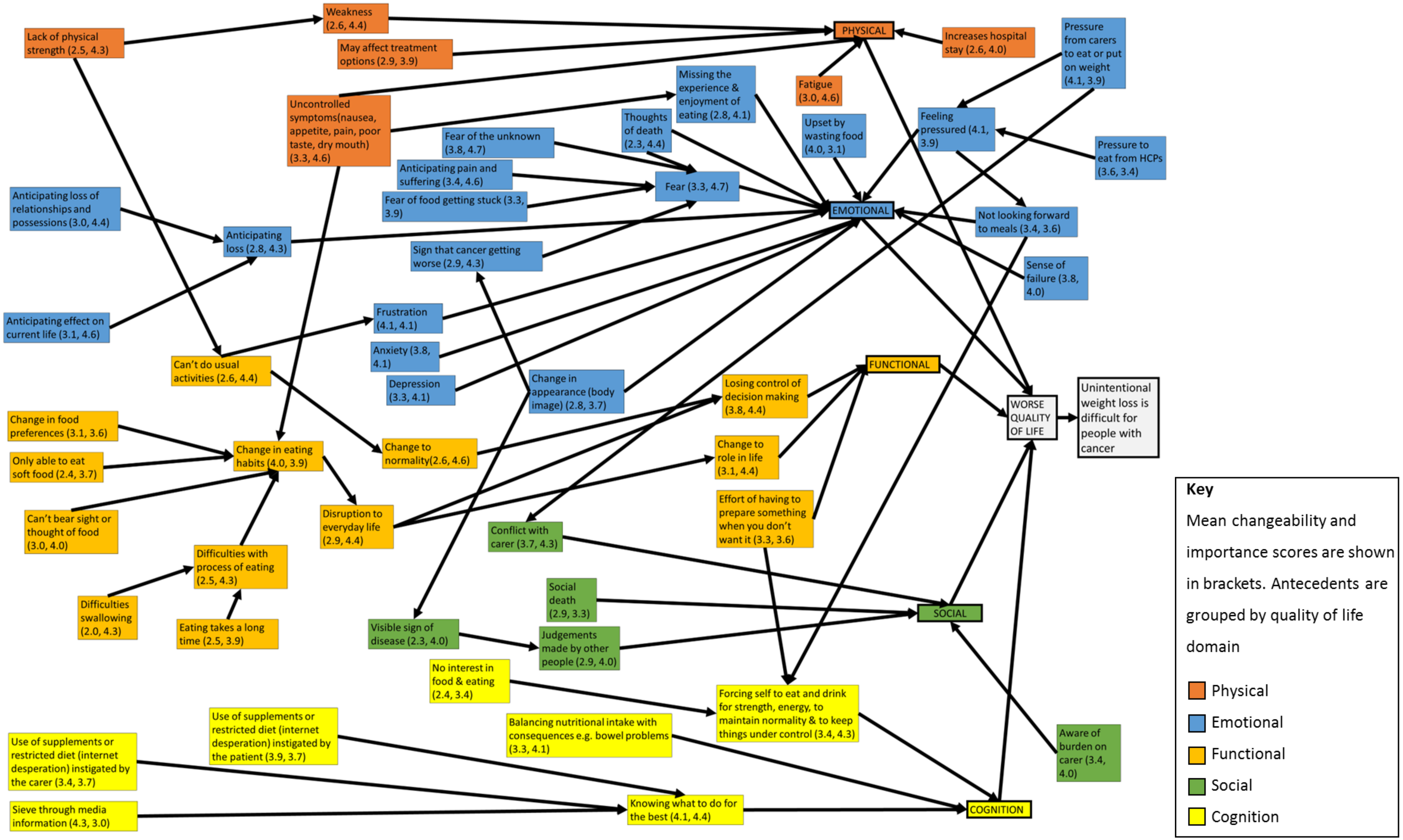


Figure 8: Composite map identifying why unintentional weight loss is difficult for cancer patients

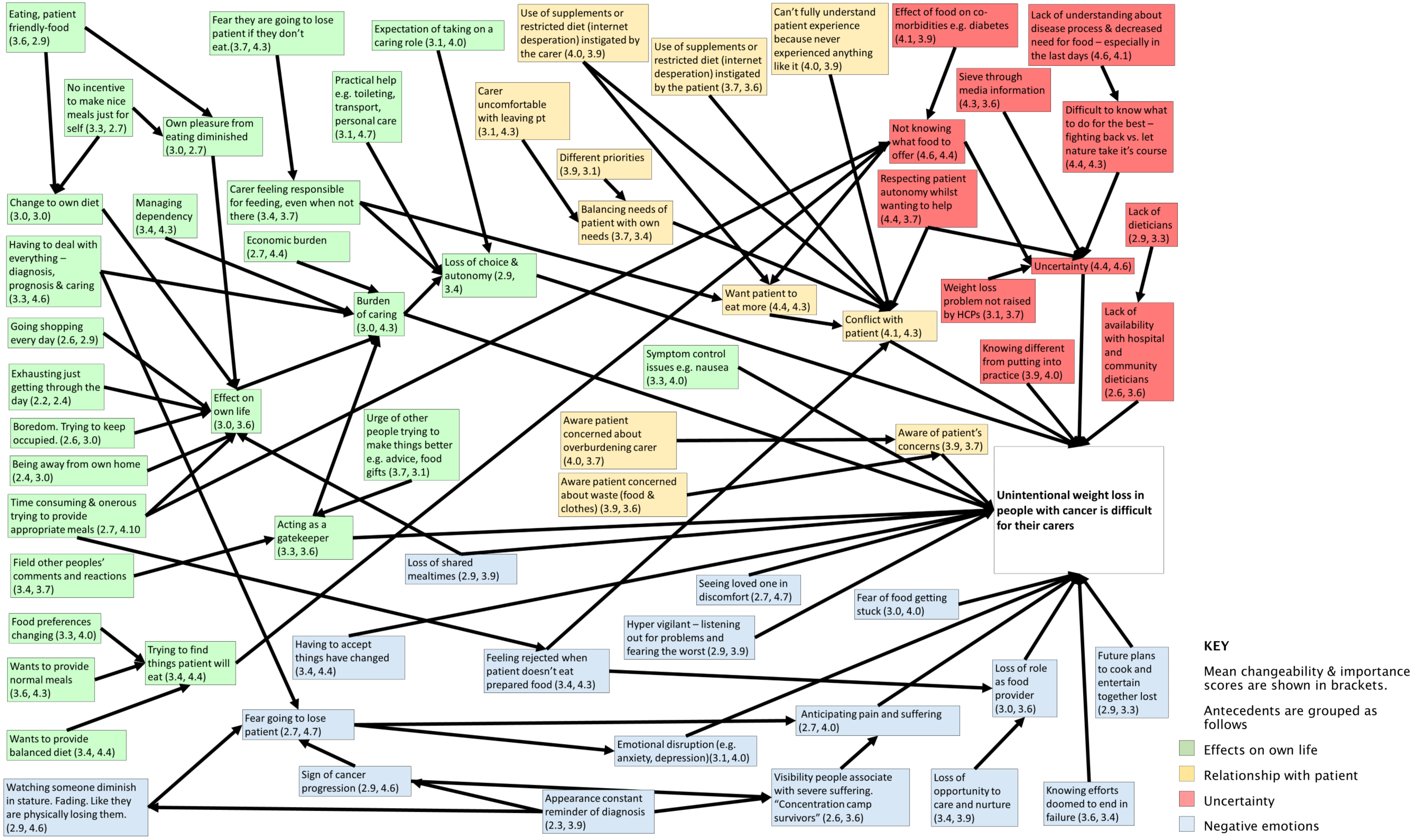


Figure 9: **Composite map identifying why unintentional weight loss in patients is difficult for carers**

5.4 Discussion

This chapter described how intervention targets for the workshop were identified, following the CIDP [125]. The advisory panel agreed on a problem statement which encapsulated the reason the workshop is needed. This statement formed the basis of interviews with patients, carers and HCPs, who were asked to identify and map the reasons why cancer cachexia can be difficult for the person with cancer and their carer. The advisory panel selected which antecedents were most important and amenable to change and these antecedents were then grouped together to form the three workshop intervention targets: providing information about eating well with cancer, addressing patient-carer conflict and addressing negative emotions. These targets were used to guide the development of the workshop protocol, which is described in the next chapter.

Maps were created using the ATM approach to developing logic models [126]. Most participants found this process relatively straightforward although it was easier for patients and carers to think of reasons if they found the weight loss more troubling. For some of the HCPs who participated, there was a slight wariness at the start of the interviews as if they were under professional scrutiny. However this soon disappated when SW emphasised that they were being asked to contribute ideas based on their own experience. One advantage of the ATM approach is that interviewee's responses are mapped during the interview itself so that they can edit and approve their own maps. This member checking process, also known as respondent validation or participant validation, enhances the trustworthiness of the results [180]. Another advantage of the ATM process is that it acknowledges the limitation of an intervention, in terms of the number of issues which can be addressed and provides a systematic method to select the issues to focus on.

All participants were asked to develop maps for both patients and carers about why unintentional weight loss in cancer patients is difficult. More reasons were identified for carers than patients, although more patient reasons were retained when selecting antecedents based on importance and changeability ratings. These ratings were made by the advisory panel which only included one person who was not an HCP. It would have been advantageous to seek ratings from more patients and carers, particularly for the importance scores. For the changeability ratings, it could be argued that professional experience is more relevant.

For both patients and carers there were a number of reasons which scored highly for importance but did not score above cut off for changeability. Antecedents related to weight loss being a barometer for cancer progression fell into this category for patients and carers. In addition, for patients, physical symptoms, disruption to everyday life and missing enjoyment associated with eating were all rated as important but not changeable in the context of a workshop. For carers, the antecendents which were not rated as changeable despite being important were related to the burden associated with caring and concern for the patient's discomfort. It may be that some of these issues would be amenable to change using different interventions, or it may be that patients and carers need to find a way of living with some distressing experiences. For example, Acceptance and Commitment Therapy (ACT), a third wave behavioural and cognitive therapy, is concerned with teaching people how to live with troubling events without being dominated by them [181,182].

Consultation with the advisory panel about the problem statement resulted in some discussion about the using the term 'carer'. The use of the term 'carer' in a range of conditions has been criticised because people fail to recognise themselves as a 'carer', believing that they are simply doing what is appropriate based on their relationship. It has also been suggested that the description is invalid because caring is often reciprocal within a relationship [183]. Similar findings have been reported when focussing on people caring for patients with cancer - carers often fail to self-identify as such, despite taking on many responsibilities [184-186]. These issues were reflected in the informal discussion SW had with a support group. Members of the support group were not able to suggest an alternative term and this is also true of the literature. The best approach seems to be to use the term 'carer' but to provide an explanation of exactly what is meant by the term [183]. This tactic was used in all the participant documents for the workshop studies where the following descriptions was used:

> A carer is anybody who provides unpaid support and care to a family member, partner or friend. You can take part whether or not you receive Carer's Allowance.

In verbal discussions with patients and carers, the inadequacy of the term was always acknowledged but patients were generally happy to identify someone as their carer.

Chapter 6: Workshop development

6.1 Introduction

The work described in the previous chapter, step two of the CIDP, identified three intervention targets: providing information about eating well with cancer, addressing patient-carer conflict and addressing negative emotions. In this chapter, the third step of the CIDP, the identification of intervention strategies is presented. However, the chapter starts with a description of the theoretical foundations to the workshop. The MRC guidance for developing and evaluating complex interventions emphasises the importance of using appropriate theory and the best available evidence [121]. Existing evidence and theory should be drawn upon to develop a theoretical understanding of the intervention, supplementing this with new research if necessary. The Integrated Theory of Health Behaviour change (ITHBC) [187] was selected as the most appropriate theory to underpin the workshop, supplemented by the model of the patient experience of cancer cachexia described in Chapter 3. After describing how the theories contributed to workshop development, the literature searches which were carried out to inform the content of the workshop, both in terms of the information it provides and the methods used to deliver this information are presented.

6.2 Theoretical frameworks

Although the MRC guidelines recommend the use of theory in the development and assessment of complex interventions, the evidence on whether interventions based on theory are more effective is equivocal [188]. Where interventions based on theory have been unsuccessful, inappropriate theories may have been selected or incorrectly applied. The advantages of using theory to develop interventions include aiding the identification of intervention targets and providing a better understanding of how the intervention works, and how or if it is transferable to other contexts and problems.

For the workshop, intervention targets had already been identified using ATM so theory was required more to describe and understand how the intervention would work. In order to find the most suitable theory to underpin the workshop, the 82 theories of behaviour and behaviour change identified by a scoping review were assessed [188] and the ITHBC was selected as the most apposite based on the workshop intervention targets [187]. The ITHBC is a midrange nursing theory. Midrange nursing theories bridge the gap between the more abstract, broader in scope, grand nursing theories and the narrower nursing practice theories. ITHBC was developed by integrating concepts identified in successful interventions, including the concept of self-efficacy [189]. Self-efficacy refers to an individual’s confidence that they can complete tasks or achieve specific goals. Those with high self-efficacy are theorised to experience less negative consequences and to be more successful in their role [190]. As can be seen in Figure 10, ITHBC purports that engagement in self-management behaviours are encouraged when individuals have sufficient knowledge about a condition and perceive this to be the case, fostering self-regulation skills. These self-regulation skills are also enhanced through social interaction and support. Engagement in self-management behaviours is seen as the proximal outcome which in turn influences the long-term outcome of improved health status.

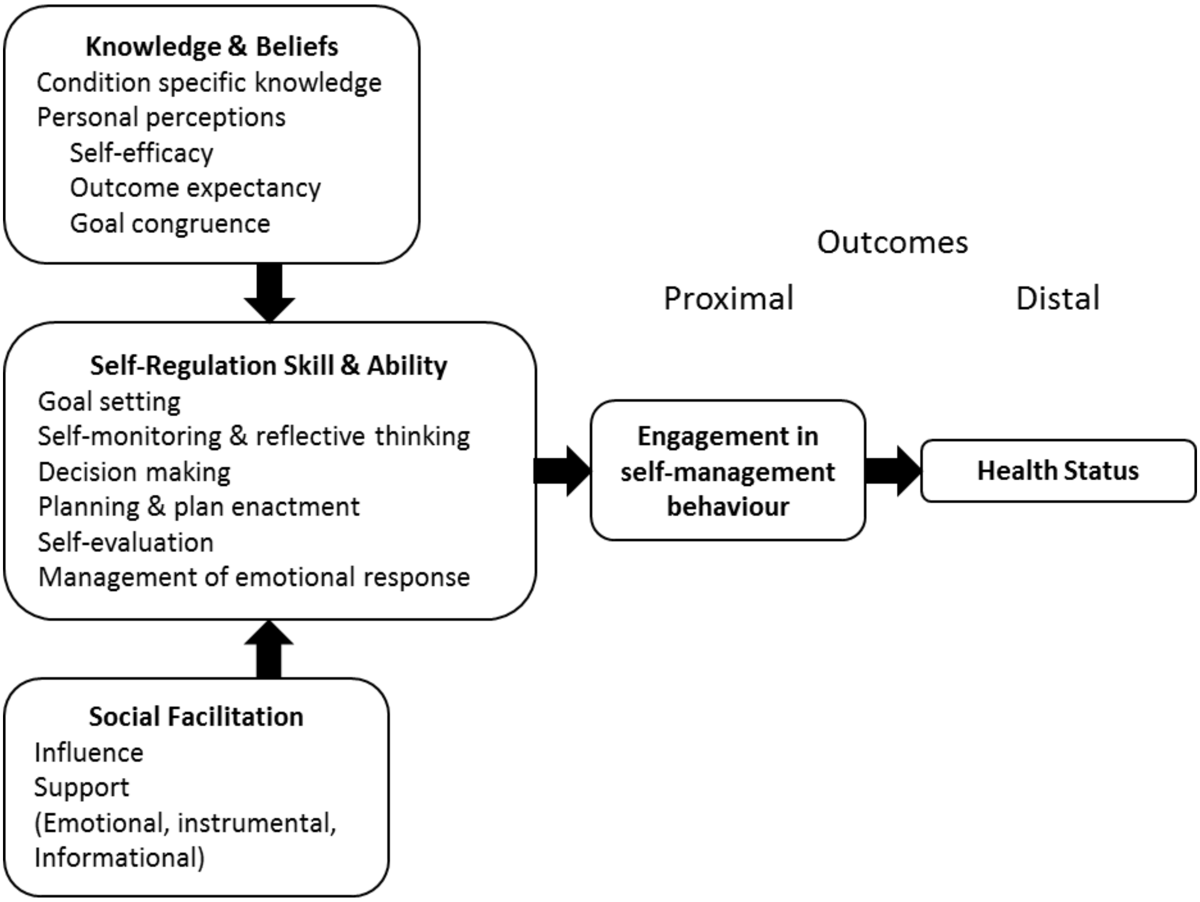


Figure 10: Integrated theory of health behaviour change

Applying this theory to the workshop, the provision of information about how cancer can cause weight loss and what to eat was predicted to lead to improved knowledge and beliefs, thereby enhancing self-regulation skills and ability. Goal setting seemed to be an important element to include to augment self-regulation ability. The social facilitation element was already addressed, by asking patients and carers to attend a workshop together. Whilst ITHBC provides a useful theoretical approach, some caution is required. Whilst condition-specific knowledge may be a pre-requisite for the development of self-regulation skill and ability, knowledge may not always be applied [191]. Even more fundamentally, the link between engagement in self-management behaviour and health status makes the implicit assumption that self-management behaviour is of the 'good' kind, leading to appropriate decisions to act on health status whereas patients may prioritise considerations other than health status [192].

The model of the patient experience of cancer cachexia adds to the ITHBC foundations because it is specific to cancer cachexia. The approach of using both a mid-range theory (ITHBC) and a 'small theory' (the model of the patient experience of cancer cachexia) is recognised as a useful strategy in healthcare improvement interventions [193]. Whilst interventions could be designed for any point in the model, two points were selected as the focus for the workshop. The first was concerned with reducing the risk that problems with food and eating will result in physical decline. This means maximising nutritional intake using appropriate interventions such as appetite stimulants, nutritional supplements and psychosocial interventions to increase consumption. In the context of the workshop, this suggests that for the information component, it is important to include strategies to deal with changes to eating along with information about the concept of 'nutrient dense' food.

The second selected point in the model was concerned with reducing the impact of problems with food and eating on emotional well-being by improving knowledge, coping strategies and family relationships. Knowledge can be enhanced by including information on how cancer can lead to weight loss and what to eat. The workshop as a whole promotes the development of self-efficacy which may enhance coping. More specifically, it was important to include a section on coping with changes to eating habits. The effect of cancer cachexia on family relationships, why conflict may arise and possible solutions was another important component of the workshop.

6.3 Reviewing the evidence base

Step 3 in the CIDP is to identify strategies to address the intervention targets by reviewing existing interventions. First, interventions specifically aimed at patients with cancer cachexia and their families were reviewed. As stated in Chapter 1, there are just two published psychoeducational interventions aimed at both cancer patients with cachexia and their carers. The FAWE is a nurse-delivered intervention [103] whilst the other intervention is a DVD which was developed for patients with refractory cachexia and their carers [107].

There was extensive overlap between the intervention targets for the workshop and those of FAWE. The development of FAWE was driven by the question 'what can improve the experience of weight loss and anorexia in people with incurable cancer and support their family members?' Conflict over food in families, lack of knowledge, suboptimal dietary intake and carer perception of health professional neglect were all identified as modifiable factors which could lead to ERD and WRD. It was theorised that information about cancer cachexia and support to enable coping and adaptation would alleviate ERD and WRD [194] and FAWE was therefore structured to aid perspective taking, to support talk about feelings around food and to encourage the naming of ways family members help each other.

The theory underlying the development of the DVD intervention was Lazarus and Folkman's Coping and Adaptation Theory [156]. Cancer-related weight loss was conceived as the stressor and so by facilitating effective coping, the QOL of both patients and carers was expected to improve. The DVD covers the following topic areas: the nature of cachexia; managing distress; conflict and arguments relating to food; the psychological impact of appetite and weight loss; body image; diet and exercise; fatigue management; managing social situations; and a mindfulness exercise. Apart from the mindfulness exercise, the DVD consists of experts delivering information about the listed topics by speaking directly into the camera. The reason for the inclusion of the mindfulness exercise, which is based around eating raisins in a mindful way, is not set out by the developers [107]. Although mindfulness has been shown to be beneficial in a variety of settings with different patient groups, there does not appear to be a comprehensive theoretical framework to explain its mechanism [195]. It was not clear how a mindfulness exercise could contribute to the intervention targets for the workshop. Even if it could, it was thought unlikely that most of the people who would eventually deliver the workshop would have training in teaching mindfulness.

When consulting FAWE and the DVD for intervention strategies, the key consideration was what would be expected to work best in the context of a workshop. Interactive activities which could be used with small groups were the most desirable.

6.3.1 Target 1: Provide information about eating well with cancer

In FAWE, lack of knowledge and suboptimal dietary intake are both recognised as modifiable factors whilst diet is also a topic in the DVD. In both interventions, advice about eating well is delivered by a professional. A more interactive approach was planned for the workshop.

6.3.2 Target 2: Address patient-carer conflict

The DVD includes discussion about conflicts and arguments related to food. In FAWE, the practitioner selects one of two exercises to enable patients and carers to talk about their perspective. The sharing perspective tool is a scaling exercise in which both patient and carer independently rate how much concern the patient's eating has caused. Both parties are then encouraged to explain their concerns and their scores are compared. The alternative task involves mapping changing eating habits. The patient and carer write down what they ate yesterday and compare it with what they ate before the patient became unwell in terms of amount, type of food, timing and context. Both are encouraged to talk about any changes which they find troubling. For the workshop, the scaling exercise was selected as more practical to carry out in a group situation. It was anticipated that discussing past and present food consumption would take longer as it is more complicated than simply rating current concerns.

6.3.3 Target 3: Cope with negative emotions associated with eating and weight loss difficulties

In the DVD, managing distress is a topic covered by one of the professionals. In FAWE, participants view a short film which shows an argument when the husband is trying to encourage the wife to eat more. In addition, or alternatively, they may read a story, about a woman who has cancer and her husband. The story has a therapeutic structure. The perspectives of both husband and wife are described, and then how they adapt to their new situation in order to make their time together more enjoyable.

For both the film and the story, participants are asked to think about what the protagonists' behaviour and what they are thinking and feeling. Participants are also invited to describe and evaluate the help the protagonists give each other and to consider what advice they would give to the protagonists. Finally the participants are asked to reflect on any similar situation they have experience, whether the strategies they used at the time were effective and whether they might do differently in the future.

The story was selected as a useful task to include in the workshop because it modelled solutions to the problems faced by the protagonists rather than just showing the problem, which was the focus of the short film.

6.3.4 Intervention strategies in published interventions for cancer patients and their families

Overall, although the topics covered by the DVD overlap considerably with the workshop content, the methods used to deliver this content were not applicable because the workshop was planned as a more interactive experience than watching a DVD. The FAWE on the other hand, did include a number of exercises which were selected as useful in a workshop.

Given that there were just two interventions specifically aimed at patients with cancer cachexia and their carers, other interventions for families affected by cancer in general were reviewed for strategies and activities which could prove useful in the workshop. In order to find relevant studies, that is studies about supportive interventions for patients and family members or informal carers delivered to both together at the same time, a scoping review of family interventions for people with cancer was carried out. In September-October 2015, Medline, Embase and CINAHL/Psycharticles were searched for relevant reviews using search terms related to interventions, cancer and family. This same process was also used to search for studies which were published after the most recent review. Combining the papers identified in the reviews and the study search, resulted in a grand total of 53 relevant papers. Since the workshop was going to be delivered to small groups, only the papers which described interventions delivered in groups were reviewed. There were just seven [196-202]. A search of the references in these papers found one new relevant study, described in two papers [203,204]. Across the eight studies, there were two strategies which were identified as potentially useful. First, a feasibility study exploring the use of a brief couples' workshop to improve sexual experiences after prostate cancer treatment [202] included the idea of setting a specific behavioural goal, as this has been found to be an effective technique to achieve behaviour change [205].

The second technique which was considered for inclusion in the workshop was the fishbowl technique [206,207], which was used in an intervention for breast cancer survivors and their spouses [199]. In this exercise, patients sit in a circle and describe their experience whilst their spouses sit outside the circle and listen. Patients and spouses then swap positions and the spouses tell their stories whilst the patients listen. This technique allows the discussion of topics which may have previously been taboo and can make experience seem less aversive because patients and spouses hear others are in the same situation. It was decided that employing the fishbowl technique in the workshop would be too time consuming. However it was expected that during the exercises which were included in the workshop, there would be many opportunities for participants to share experiences and to recognise that there were others in a similar situation.

6.3.5 Eating well with cancer

One of the targets of the workshop was to provide information about eating well with cancer. A review published in 2011 had examined what cancer patients living with involuntary weight loss should eat [208]. The review found that there was little robust evidence to support the two approaches commonly advocated. One approach is to advise patients to maximise intake by eating nutrient dense food, using supplements and eating frequently. The other approach is simply to advise patients to eat what they fancy. The search in this review had been carried out in 2008. As it was important to ensure that the advice included in the workshop was current, the review was updated by running the same searches on 13/8/15, screening any papers from 2008 onwards. After reviewing the title and abstract of the 377 references identified in the search, four full articles [209-212] were obtained and scrutinised along with an additional, already known article which was not identified by the review [213]. These new papers did not alter the conclusions of the original review. There remains a lack of evidence as to whether dietary counselling and nutritional supplements are beneficial, as is also the conclusion in other published reviews [214-216].

The 2011 review described how many authors assume that patients with potentially curative disease should try to maximise intake whilst patients with incurable disease should eat what they wish. The authors argue that the two approaches are not mutually exclusive and both could be used simultaneously throughout the cancer journey. The optimising of intake is therefore the underlying principle of nutritional care, with the proviso that if a patient reaches a time when they no longer wish to eat, this wish is respected. This principle was adopted for the workshop.

6.4 Discussion

This chapter has described how the CIDP was followed to develop the workshop protocol, a preliminary version of which is presented in the next chapter along with a diagram to illustrate the target outcomes, theoretical underpinnings and key processes of the intervention (see Figure 15). CIDP was the method selected because it provided clear process guidelines and had previously been used to develop a self-management workshop, for testicular cancer survivors. At the start of the workshop development process, few published papers described the process for developing interventions in sufficient detail to be able to utilise that process, and descriptions of the interventions themselves were not detailed enough to allow replication [124].

One paper which did provide detailed information about the development process demonstrated considerable overlap in the methods used with those of the CIDP [217]. This paper described the development of a web-based intervention to enhance self-efficacy to live with cancer-related fatigue (CRF). A theoretical framework for the intervention was established and reviews of the literature and guidelines were used to identify evidence based interventions to manage CRF and strategies to enhance self-efficacy. Existing sources of patient information were reviewed for content. A design team contributed to the development of a prototype which was refined in two rounds of user testing resulting in a final prototype. Content for the intervention was prioritised using MoSCoW (M– Must have; S – Should have; C – Could have; W– Would like if time permits).

The approach used to develop this web-based intervention is similar to the CIDP with respect to the literature reviewing, the use of a theoretical framework, prioritising content and revising the content of the intervention. In terms of specifying intervention targets, the CIDP method provides a completely transparent method whereas it is not quite as clear how this was achieved for the CRF intervention, perhaps because the theoretical framework is the main driver for the actual content. Both approaches are viable and selecting which to use will partly be determined by the degree to which the developers want to use existing theory rather or whether the intervention is more tailored to a particular situation.

More recently, a framework for the development and delivery of psycho-educational and supportive care interventions has been published [218]. The framework is intended to guide the development of effective, feasible and sustainable interventions and provides guidance in seven key areas: i) direct intervention target to address the needs of the patient group; ii) tailor the depth or intensity of the intervention to the needs of each individual; iii) promote self-management in patients; iv) take a low intensity approach; v) ensure adequate training and adherence to the intervention protocol; vi) make the content and mechanism of delivery evidence-based; and vii) ensure intervention acceptable to stakeholders. These are all important areas to address but this framework does not provide detailed instructions about how to actually produce an intervention.

There still seems to be a black box element to the process of developing most interventions. Careful descriptions of the input (e.g. stakeholder interviews, literature reviews etc.) are provided and then information about the resulting intervention is described, but it is not often clear how the input leads to the output. Methodologists need to provide more guidance in this area and researchers needs to provide more transparent descriptions of the methods they use to produce interventions. In the same way that a careful description of the content can improve the comparability of interventions to determine which strategies are most effective [219], better descriptions of the development process will allow the most effective methods to be identified.

The two published cancer cachexia specific psychoeducational interventions aimed at both patients and carers were carefully reviewed to assess which strategies could be used in the workshop. With respect to strategies to include in the workshop, the literature search revealed that there are very few small group interventions aimed at cancer patients and their carers in general. There have been some barriers proposed to explain this small number, including poor enrolment rates, concerns about cost-effectiveness and lack of knowledge about the most efficacious delivery methods [220]. Unfortunately, this is somewhat of a chicken and egg situation. Without more research, it will not be possible to produce evidence about how to implement successful, cost-effective interventions for patients and carers.

Similarly, there remains a lack of evidence on the dietary counselling and the use of nutritional supplements for cancer patients. There is a strong need for large prospective RCTs which include end points which are of most concern to oncologists, like OS, and also patient reported outcomes, like HRQOL [221].

Chapter 7: Preliminary workshop protocol

7.1 Introduction

The previous chapter described the theories underpinning the workshop and the results of literature searches to inform the information provided by the workshop and the methods used to do this. Synthesising this work, the preliminary protocol for the workshop is presented in this chapter.

7.2 Method

A first draft of the workshop protocol was emailed to the advisory panel members, along with a summary of the development process. Most of the panel members made general comments about the comprehensiveness of the plans but the carer/patient representative was keen to meet in person to discuss further. The key changes to come out of the discussion were improvement to the appearance of the workshop slides and the addition of a follow up phone call a week after the workshop. The phone call would have two clear purposes. Firstly, it would inform HCPs what participants were getting from the workshop so encourage them to keep delivering it. Secondly, it would check whether participants felt equipped to self-manage or whether they needed further help, and if so, HCPs could then signpost them to that help.

7.3 Workshop protocol

The workshop, summarised in Table 16, has seven parts with a follow up phone call a week later. Two hours of activities are timetabled, along with a suggested break of ten minutes. Ideally, two workshop facilitators are required. One facilitator takes the lead role of delivering the workshop whilst the other facilitator assumes a more supportive role e.g. helping participants do the activities, timekeeping. The support facilitator may need to leave the room with a participant if the participant is finding the discussion too difficult and needs a break.

Although it is anticipated that the workshop will most often be delivered by clinical nurse specialists or dietitians with experience of working with cancer patients, other HCPs may also act as facilitators. Detailed facilitator's notes are provided in a handbook to support workshop delivery but facilitators need to be able to set aside some time to become familiar with the workshop. It is also important that facilitators are confident in their own ability to address questions which workshop attendees may ask.

Table 16: Workshop timetable

Part	**Time Needed (minutes)**	**Content**	**Activity**	**Outcome for participants**
1a Welcome	5	Welcome participants. Facilitator/s introduce themselves. Housekeeping information.	Facilitator presentation	Feel welcome. Introduced to facilitators. Know relevant housekeeping information.
1b Introduction & ground rules	10	Workshop timetable. Ground rules.	Facilitator presentation. Opportunity for participants to ask questions	Know what to expect from the workshop. Feel comfortable.
1c Meeting participants	10	Introductions among participants (icebreaker)	Participants introduce themselves to group. In pairs, participants discuss food and eating and then share one thing from discussion with the group.	Introduced themselves to each other. Practised talking to the group.

Part	**Time Needed (minutes)**	**Content**	**Activity**	**Outcome for participants**
2a How does cancer lead to weight loss?	15	Reasons why cancer can lead to unintentional weight loss.	Small group (3 or 4 individuals) discussion (5 mins). Sharing ideas with whole group (5 mins). Facilitator sums up (5 mins).	Can explain why cancer may cause unintentional weight loss.
2b What should people with cancer and weight loss eat?	20	Eating well and suggested foods	Small group (3 or 4 individuals) discussion about "eating well" (5 mins). Sharing ideas with whole group (5 mins). Facilitator clarifies (5 mins). Whole group brainstorming about suitable foods (5 mins)	Can describe what eating well means for people with cancer who are losing weight. Can list suitable foods.
10 minute comfort break				
3 Rating concern caused by weight loss	10	Rate concern caused by unintentional weight loss and share with loved one.	Scaling exercise. Compare patient and carer scores in pairs. Facilitator discusses results and implication of different scores.	Have evaluated their own levels of concern related to the patient's weight loss. Recognise that other people have different scores & possible consequences of this.

Part	**Time Needed (minutes)**	**Content**	**Activity**	**Outcome for participants**
4 Coping with changes to eating habits	35	Strategies and solutions for dealing with changes to eating habits.	Listen to Tom & Joan story podcast (5 mins) & discuss related questions in small groups (3 or 4 individuals) (10 mins). Discuss solutions to eating problems in small groups (10 mins). Share ideas with whole group & facilitator summarises (10 mins).	Feel more confident about self-management of eating difficulties.
5 Summary	5	Summary	Facilitator presentation.	Reminded of the topics covered by the workshop.
6 Planned behaviour changes	5	Document planned changes to behaviour	Changes form	Have written down planned changes, if any, to behaviour
7 Sources of help	5	How to get more help	Opportunity for participants to ask questions.	Know sources of help.

7.3.1 Part 1: Welcome, introduction and ground rules

The workshop was developed as a standalone intervention. It was assumed that the participants taking part would never have met before. Therefore, the first part of the workshop is concerned with making all participants feel at ease and happy to contribute to discussions during the rest of the session. Each facilitator introduces herself or himself in turn and then any necessary housekeeping information is provided. Participants are reminded of the purpose and limitations of workshop. They are informed that the information included in the workshop is based on the best evidence currently available and that although there are no quick, easy solutions to eating and weight loss problems in cancer, there are things to do, practically and emotionally to help each other.

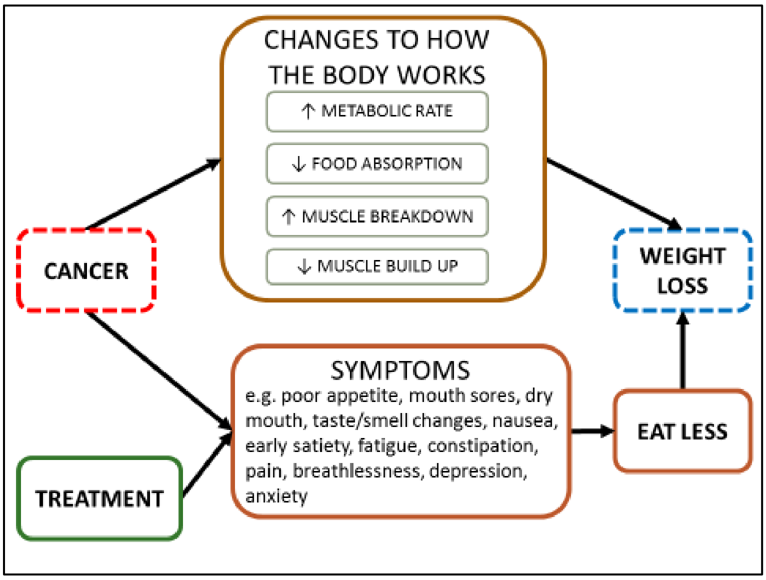
After outlining the workshop timetable, the lead facilitator reminds participants that some ground rules are required because it is an interactive session. Participants are asked to agree to the following ground rules, and all are asked whether they feel any others are needed:

1. Respect confidentiality & other people’s privacy.
2. Only share what you are comfortable sharing.
3. Let all members of the group speak. Listen and support each other.
4. If you need a break or you want to leave, that is absolutely fine.

Once the ground rules have been established, each participant is asked to introduce themselves, simply stating their name and whether they are attending the workshop because they have cancer or they are supporting someone else. Next, everyone is encouraged to have a two minute chat about food and eating with someone they don’t know and then tell the whole group about one thing discussed. The purpose of this ice breaker task is to ensure everyone has practised speaking to the whole group.

7.3.2 Part 2: How cancer can cause weight loss and what to eat if you have cancer and weight loss

Workshop participants are asked to get into small groups and discuss how cancer can cause weight loss. The two facilitators can encourage conversation if the groups need a catalyst. After five minutes, the group as a whole comes back together to share thoughts and the facilitator talks through a summary slide, Figure 11, the content of which is revealed box by box to make it easier to follow.



CHANGES TO HOW THE BODY WORKS

↑ METABOLIC RATE

↓ FOOD ABSORPTION

↑ MUSCLE BREAKDOWN

↓ MUSCLE BUILD UP

CANCER

WEIGHT LOSS

SYMPTOMS

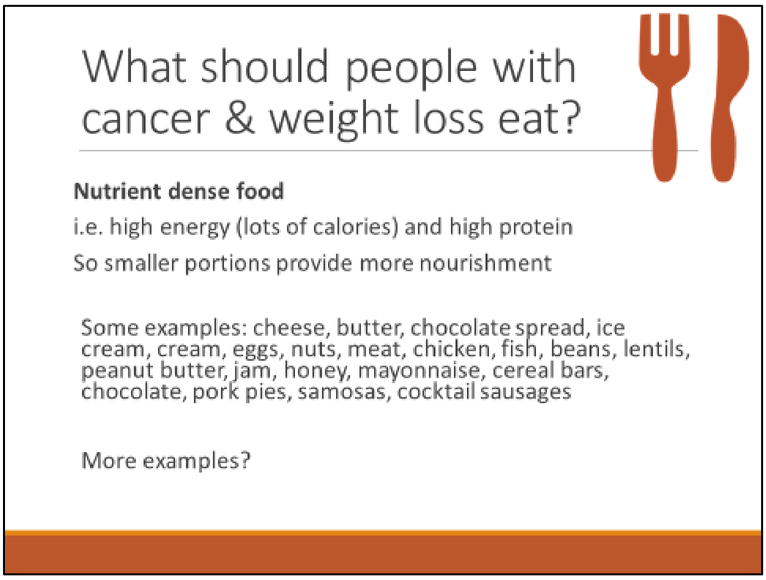
e.g. poor appetite, mouth sores, dry mouth, taste/smell changes, nausea, early satiety, fatigue, constipation, pain, breathlessness, depression, anxiety

EAT LESS

TREATMENT

Figure 11: **How cancer can lead to unintentional weight loss slide**

Next, again in small groups, participants are asked to discuss what it means to ‘eat well’ when someone has cancer and weight loss, either in general terms or giving specific examples of food to eat. After five minutes, the groups share their ideas and then the facilitator presents the slide shown in Figure 12. Participants are asked to suggest any other foods they can think of.



What should people with cancer & weight loss eat?

Nutrient dense food

i.e. high energy (lots of calories) and high protein

So smaller portions provide more nourishment

Some examples: cheese, butter, chocolate spread, ice cream, cream, eggs, nuts, meat, chicken, fish, beans, lentils, peanut butter, jam, honey, mayonnaise, cereal bars, chocolate, pork pies, samosas, cocktail sausages

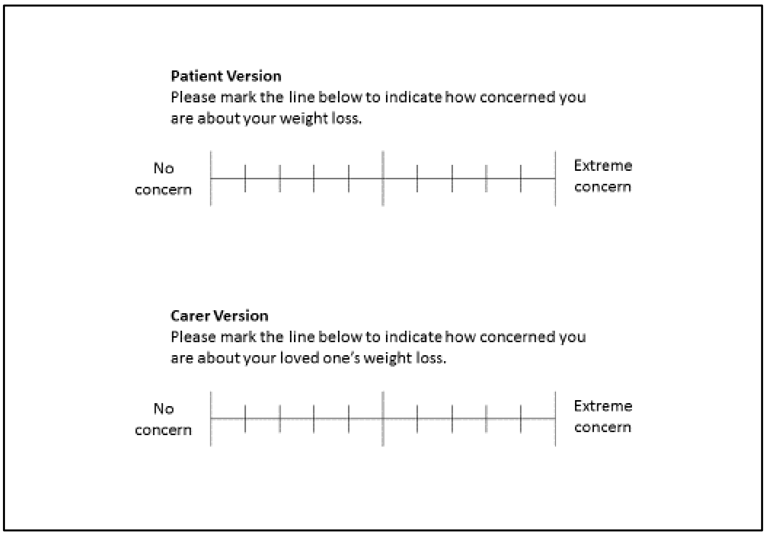
More examples?

Figure 12: **What to eat slide**

At this point in the workshop, it is suggested a ten minute break is offered.

7.3.3 Part 3: Rating concern caused by weight loss

Patients and carers are asked to score their concern about the patient’s weight loss using the appropriate version of the scale, shown in Figure 13. Participants are asked to refrain from sharing where they have placed their mark until everyone has completed the exercise. Those participants who are attending the workshop with someone else are encouraged to compare their scores. Anyone who is attending the workshop alone is invited to take a copy of the scale home if they have someone they would like to compare their score with.



Patient Version
Please mark the line below to indicate how concerned you are about your weight loss.

Carer Version
Please mark the line below to indicate how concerned you are about your loved one's weight loss.

Figure 13: Scaling exercise

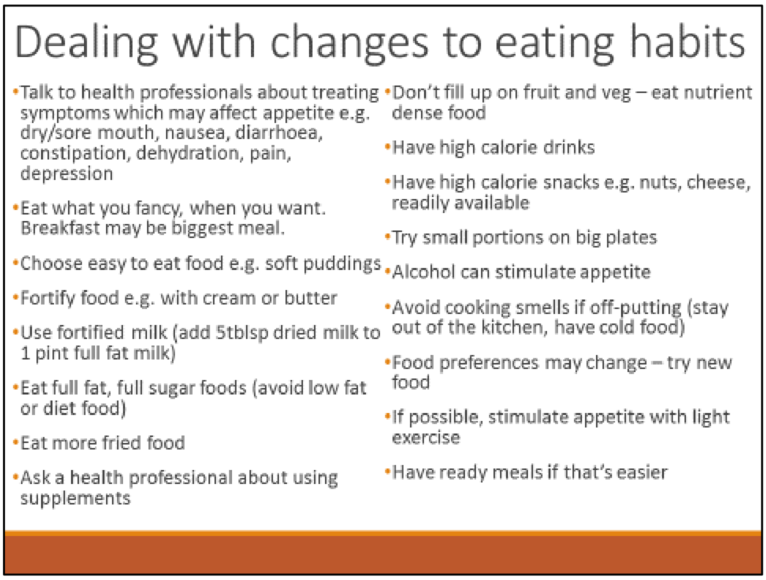
Based on previous research [72], it is anticipated that carers will typically score higher on the scale than patients. The group are encouraged to consider the consequences if there are differences in the level of concern between patients and carers.

7.3.4 Part 4: Coping with changes to eating habits

This part of the workshop begins with participants being invited to listen to a recording of one of the therapeutic stories from the FAWE. The transcript from the story is shown in Appendix K. The story describes how Tom and Joan, who has advanced cancer, are managing Joan's lack of appetite. The couple progress from using less successful strategies which result in upset and arguments to finding some solutions to the problem which mean they can enjoy their time together.

In small groups, participants are asked to discuss the following questions: What are Tom and Joan feeling? How do they help each other? What do you think of the ways they help each other? What advice might you give? By reflecting on these questions it is anticipated that participants will see parallels to their own situations and be inspired to come up with solutions to their own problems.

Thinking up strategies to deal with changes to eating habits is the next topic for participants to discuss in their groups. After ten minutes, the small groups are encouraged to share their ideas with the rest of the participants. The facilitator also provides a list of suggestions, as shown in Figure 14.



Dealing with changes to eating habits

- Talk to health professionals about treating symptoms which may affect appetite e.g. dry/sore mouth, nausea, diarrhoea, constipation, dehydration, pain, depression
- Eat what you fancy, when you want. Breakfast may be biggest meal.
- Choose easy to eat food e.g. soft puddings
- Fortify food e.g. with cream or butter
- Use fortified milk (add 5tblsp dried milk to 1 pint full fat milk)
- Eat full fat, full sugar foods (avoid low fat or diet food)
- Eat more fried food
- Ask a health professional about using supplements
- Don't fill up on fruit and veg – eat nutrient dense food
- Have high calorie drinks
- Have high calorie snacks e.g. nuts, cheese, readily available
- Try small portions on big plates
- Alcohol can stimulate appetite
- Avoid cooking smells if off-putting (stay out of the kitchen, have cold food)
- Food preferences may change – try new food
- If possible, stimulate appetite with light exercise
- Have ready meals if that's easier

Figure 14: Slide to summarise strategies for dealing with changes to eating habits

7.3.5 Parts 5-7: Workshop summary, planned behaviour changes and sources of help

The facilitator reminds participants of the topics covered in the workshop before inviting those who wish, to complete the changes form, shown in Appendix L. This form invites participants to put into writing anything that they plan to do differently following the workshop.

Finally, the facilitator provides a list of additional sources of help, including Macmillan Cancer Support and a list of the HCPs who they could discuss any problems.

Participants are provided with a pack to take home. The pack included a summary of the workshop and three Macmillan Cancer Support booklets: Eating Problems and Cancer, The Building-Up Diet and Looking after someone with Cancer.

7.3.6 Follow up phone call

About a week after the workshop, all participants, both patients and carers, should be contacted and the following questions asked:

1. Did you find the workshop useful?

2. Did you write anything on the changes form?

3. Have you made any changes as a result of attending the workshop?

4. Do you have any questions about eating and weight loss?

As the phone call is the last contact directly related to the workshop, patients and carers should be reminded of this and given information about who to contact if they require further support.

7.3.7 Risk associated with attending the workshop

Although the workshop was obviously designed to be of benefit to patients and carers, there are some potential risks associated with attendance. Some participants could have unrealistic expectations that by attending the workshop, all weight loss- and eating- related problems would be solved. They could feel angry or distressed as they learn that it is the cancer itself which is the main cause of the patient’s problems and that this is out of both patient and carer control. Participants could begin to comprehend or be reminded that they are approaching the end of life and this could be associated with a number of negative emotions.

Carers may come to realise that their previous strategies to improve intake and diet may have been part of the problem. This realisation could lead to feelings of guilt, distress or even anger.

7.4 Discussion

This chapter has described the provisional protocol for the workshop. The model of the developed intervention is shown in Figure 15. The workshop, which is underpinned by ITHBC, was developed to address the three intervention targets: providing information about eating well with cancer, addressing patient-carer conflict and addressing negative emotions associated with eating and weight loss difficulties.

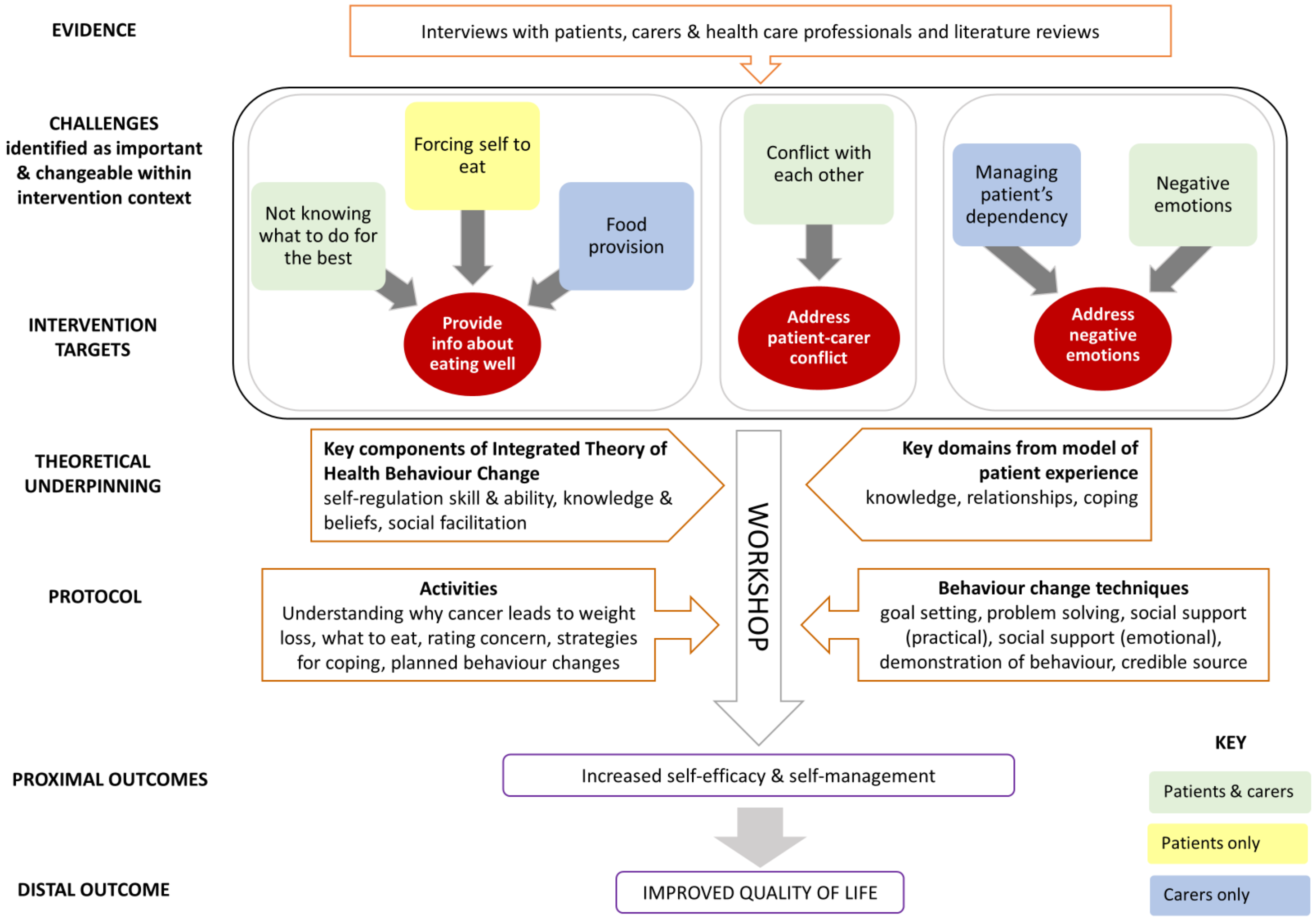


Figure 15: Model of the developed intervention

Development was guided by the model of the patient experience of cancer cachexia but the workshop also maps onto the carer experience, as identified by the carer systematic review in Chapter 3). The carer review identified five important themes: ‘impact on everyday life’, ‘taking charge’, ‘need for outside help’, ‘conflict with patient’ and ‘emotions’. Part 4 of the workshop may help to reduce ‘impact on everyday life’ by suggesting simple strategies to maximise nutritional intake whilst the podcast may help carers prioritise what is important for their everyday life. The problems associated with ‘taking charge’ are addressed in part 2a of the workshop, when carers learn that the weight loss is not something which is controllable because it is primarily the cancer which is causing the problem. This may allow carers to take the pressure off themselves. The podcast in part 4 demonstrates some alternative approaches to offering care. The ‘need for outside help’ may be reduced because the workshop should increase the self-efficacy of the carers, partly through furnishing carers with information and knowledge. If ‘conflict with the patient’ is being driven, to some extent, by different expectations of the amount and types of food which the patient should be consuming, better education for both patient and carer may help to avoid this conflict. The workshop will therefore help reduce carer-patient conflict by ensuring both parties have the same information, particularly the knowledge provided in part 2. In addition, in part 3, carers may come to realise that they have a different level of concern compared to patients and that this is a potential source of conflict. Finally, some negative ‘emotions’, such as anger, guilt and helplessness, may be reduced by improved knowledge and self-efficacy (parts 2 and 4) and by promoting empathy (parts 3 and 4).

Having developed a workshop protocol, it is useful to describe the mechanisms which the workshop employs to change behaviour [219]. This is important for implementation and replication of the workshop, but also so the workshop can be easily included in future systematic reviews. The Behaviour Change Technique Taxonomy (v1), developed through expert consensus, provides a hierarchically structured taxonomy of techniques used in behaviour change interventions [219]. Consultation of this taxonomy identified six mechanisms included in the workshop, as shown in Table 17.

Table 17: Behaviour change techniques used in the workshop

Behaviour change technique & number	**Workshop component**
1.1 Goal setting	Changes form
1.2 Problem solving	Changes form
3.2 Social support (practical)	Group discussions

3.3 Social support (emotional)	Group discussions
6.1 Demonstration of the behaviour	Podcast
9.1 Credible source	Introduction

Although the workshop was developed through a comprehensive procedure including interviews with patients, carers and HCPs, along with several reviews of the literature, it is only through actually delivering the workshop to patients and carers that any unforeseen issues could be ironed out. The next chapter describes these pilot workshops and the lessons learned from them.

Part D: Testing and revising the workshop

Chapter 8: Pilot testing the workshop

8.1 Introduction

The pilot workshops were conducted at the Countess Mountbatten Hospice (CMH), a hospice within the University Hospital Southampton NHS Foundation Trust. CMH provides a regional NHS palliative care service, with a 27 bed inpatient unit, a dedicated day care service and a community specialist palliative care team. The hospice regularly delivers what is described as a therapeutic clinic programme for patients with terminal illnesses or conditions and their carers. Sessions include legal/financial issues, physiotherapy and occupation therapy, counselling, social work, information about local services, exercise, emotional touch points along with a session called food for thought. There are also individual assessments for patients and a carer group, complementary therapies are available each afternoon and a chiropodist sometimes attends. The programme is led by a clinical nurse specialist (CNS), with support from a healthcare assistant (HCA) and hospice volunteers. The programme comprises six weekly sessions of four hours. Each clinic starts with 15 minutes of welcome and refreshments followed by a 75 minute session. Lunch is then provided, followed by another 90 minute session with more refreshments served towards the end.

The CNS was keen to revise the food for thought session because she was dissatisfied with both the content and how it was being delivered. Although the attendees of this clinic did not exactly match the participants for whom the workshop was devised, because the patients would not necessarily have cancer and would not necessarily have unintentional weight loss, this clinic offered the opportunity to pilot the workshop in terms of its acceptability to patients with life limiting conditions and their carers. It also provided an opportunity to consider how the workshop could be adapted to different situations. It was agreed that SW would deliver the first workshop whilst the team watched. The CNS would then deliver the workshop in the next food for thought session. Each of the workshops are described below.

8.1.1 Aim and objectives

The main aim of the piloting was to test whether the workshop were acceptable to patients and whether it could be delivered by a HCP. The objectives were to check

i) that the workshop could be delivered in the allocated time
ii) that participants were able to take part in the activities

iii) whether any of the activities needed to be modified

iv) whether there was any evidence of harm

v) that the written materials provided enough guidance for HCPs to deliver the workshop

8.2 Workshop one

Some adaptations were made to reduce the length of the workshop from two hours to the 90 minutes available for the session. This was achieved by taking out the first ice breaker activity, which was not required because the group had already spent time together and also by keeping the first activity (why cancer causes unintentional weight loss) as a whole group activity, rather than splitting up into groups and then coming together again. Although all the patients in this particular group had cancer, at the start of the workshop, it was unknown whether weight loss was an issue or not. The introduction was adapted to recognise this situation and to suggest that these issues may have been a problem in the past, may be a problem now or could be a problem in the future.

The workshop was attended by four patients and three carers. Also present was an occupational therapist student on placement as well as the CNS, HCA and a volunteer. One of the patients was visibly thin and quite frail. He was not concerned about the weight loss but was very aware his wife was and described being ‘nagged’. A second patient, also very slim, vomited straight after lunch but recovered quickly and participated fully in the workshop. Unintentional weight loss was clearly something which she was experiencing and knew lots about – she contributed some very good ideas and explained early satiety in terms of imagining trying to eat more just after you have had a Christmas dinner. Although currently highly concerned about the weight loss, the reason for the concern was whether she would be able to find any appropriate clothes that would fit as she was now a size six and still getting smaller.

Unintentional weight loss had been a past problem for the third patient – it was the reason she had first gone to the doctors - but it was no longer an issue. The fourth patient did not have weight loss problems. In fact, he was putting weight on, although he had experienced some taste changes. However, he still engaged fully in the workshop.

On the whole the first pilot workshop went very well. The timings were about right and it did not feel rushed. There were a few, fairly straightforward questions and at the end, participants spontaneously said it had been very good and interesting and they enjoyed doing the activities. There were some lessons learned from this first workshop. Firstly, in the small group activities, it was easier to go through what the small groups had written rather than write everything out again. Secondly, the importance of having a second facilitator for the session was underlined by the absence of one – even just for simple tasks like giving out pens and handouts. Third, the CNS wanted a list of high protein foods for her own knowledge. Fourth, the possibility of using supplements should be added to the slide summarising dealing with changes to eating habits.

A few weeks after the first workshop, the CNS and HCA were available to give their feedback on the workshop and to discuss any changes they planned to make when they were running it for themselves. Both were enthusiastic about the content of the workshop and keen to make use of it. The CNS lacked confidence about some of the content, specifically the how cancer can result in weight loss section, but was reassured that all the information required was in the handbook. They planned to do all the activities as a whole group, rather than splitting up into smaller groups. Unfortunately, a slide projector is not usually available in the day centre at CMH. The slides summarising how cancer can cause weight loss, what to eat and strategies for dealing with changes to eating habits were all considered essential slides so it was arranged to have them printed as posters. The information and instructions in the other slides could be provided verbally or written on a whiteboard. The CNS suggested adding the Changes Form to the Participant Handbook which was done.

8.3 Workshop two

The second workshop held at CMH was delivered by the CNS, with some assistance from the HCS. SW observed. This time there were five patients and three carers, but one of the patients had heart failure and one had a degenerative neurological condition. It was unclear whether weight loss was currently or had ever been an issue for the patients with cancer. The CNS had been provided with a very concise version of the handbook to help with the delivery. She had had some time the day before to prepare and this allowed her to deliver the workshop in a natural, confident manner. She stuck quite closely to the suggested content of the workshop. The one addition was that after the podcast and discussion, she passed round the cartoon shown in Figure 16, which participants found humorous.

Again, the workshop was well received. Although the workshop has been developed for people with cancer, much of the content is applicable to other conditions. For CMH, this meant ensuring that the materials given to participants acknowledged the value of some of the information for people with conditions other than cancer.

Figure 16: Cartoon used at CMH workshop

One of the participants suggested that eating kale would help fight the cancer. After the workshop, SW suggested to the CNS that this was something which should be gently challenged, as there is no scientific evidence to support claims that diet can cure or control cancer. This information was then added to the handbook. Another suggestion was to include the Advice Questionnaire, which was developed for the feasibility study (see Appendix O) at the start and the end of the workshop. This would help summarise what participants had learned during the workshop and would help reinforce important messages.

There were a few technical hitches during the workshop. For example, the CD player was too quiet and participants could not hear the podcast, and there were not enough pens available. The importance of checking equipment was added to the handbook and pens were inserted in the equipment list.

8.4 Workshop three

Six weeks after workshop two, the third workshop was delivered by the same CNS at CMH. The group was larger than previous workshops with eight patients and two carers. There were two male lung cancer patients who were visibly cachectic. One female patient had lost 1.5 stone before getting her cancer diagnosis, but had stopped losing weight now, although she was unable to regain any of the weight she had lost. Another lady had also lost 1.5 stone and had reached the point where she was keen to not to lose any further weight. Two patients were gaining weight because they were on steroids. It was unclear what the diagnosis of the remaining two patients was and whether weight loss was an issue.

Unfortunately, the CNS had not had time to review the contents of the workshop since the last session and this was reflected in a less confident delivery of the content. The CNS had also not had time to prepare the paperwork for this workshop. Therefore, whilst the CNS photocopied the forms and participant packs, SW ran through the Advice Questionnaire as a group exercise. The Advice Questionnaire (Appendix O) is a test of knowledge about self-management of eating difficulties and weight loss problems. At the end of the workshop, most participants were able to give the correct answers to the questions on Advice Questionnaire, and they spontaneously discussed the changes in their responses. However, there were still some wrong answers so it seemed that it was a useful exercise to use the Advice Questionnaire as a tool to reinforce workshop content.

8.5 Workshop four

The fourth workshop was delivered as part of a support group for patients with fatigue and breathlessness provided by occupational therapists (OTs). Five patients had been invited to attend but one had died, and two were too ill to come. Carers were not invited to attend this group. The workshop was delivered by the same CNS who had delivered workshops two and three. The group felt rather imbalanced because as well as the CNS and SW observing, there were two OTs, i.e. five professionals and just two patients. One of the patients had prostate cancer and COPD and was visibly cachectic. He did not seem to learn very much from the workshop as he gave many incorrect answers on the Advice Questionnaire at the end of the workshop. However, he did go away with some very clear planned changes, such as switching to full fat milk. The other patient, who had breast cancer, said she was eating little and had a very poor appetite but she was not losing weight even though she wanted to as she felt this would help her get around more easily. She clearly learned a lot from the workshop, as evidenced by the Advice Questionnaire, but her complicated situation may have benefitted from more specialist advice.

8.6 Workshop five

The final workshop SW observed was held about three months after workshop four. This workshop was again delivered by the same CNS as part of the CMH Therapeutic Clinic Programme. The group had 14 participants; not all patients had cancer and unintentional weight loss was not a problem for all.

The early parts of the workshop, covering how cancer can cause weight loss and what to eat, were not very interactive. However, the rating exercise and podcast prompted much more discussion. For the first time in any of the workshops, there was a family who did not seem to benefit from the workshop but who was clearly in need of some extra support. The wife of a man with cancer appeared visibly furious about the difficulties of trying to feed her husband. She was angry about the waste – both money and time - and found it very hard to accept that his tastes had changed. She did not appreciate her husband asking for something which a few days later, when she had been shopping, he no longer fancied. She said, “I can’t find a solution.” Her husband complained that “she goes on and on about food” and that by listing lots of possibilities, his wife was putting him off eating anything. She commented, “Ready meals have lots of preservatives and that’s no good for cancer.” Her anger started to subside a little and turn to sadness as she described herself as “disheartened” and admitted she often felt like she was nagging her husband. It seems that this carer was too angry and upset about the problem to listen properly and to take in the information provided by the workshop. Perhaps it was the first time she had had chance to realise what a big problem this was for her and how difficult she was finding it. A follow up phone call after a week may have been enough but this carer was clearly in need of extra support.

8.7 Discussion

Piloting the workshop in the hospice setting provided many valuable insights leading to improvements in the workshop itself and also information about how to support HCPs in the delivery of the workshop. However, taking the pragmatic approach of piloting within an established programme with an unselected group had the drawback that not all participants matched the target population: some patients did not have unintentional weight loss and some did not even have cancer.

According to the most recent national survey of patient activity data for specialist palliative care services, about 24% of patients seen in day care within this setting have a non-cancer diagnosis [222]. Cachexia is a serious consequence of almost all chronic diseases in the advanced phase [223] and anorexia has a reported prevalence of 50% or higher in conditions such as COPD, end stage renal disease and AIDS [224]. Information about unintentional weight loss and eating difficulties may be helpful for many of the patients attending day care in hospices and the CNS delivering the workshop at CMH was satisfied that the information and guidance provided was acceptable for non-cancer patients. However, the research presented in this thesis was restricted to cancer patients. The mechanisms contributing to cachexia in other conditions have not been reviewed and neither have the patient or carer experience. Additional research would be required before the use of the workshop with patients and carers affected by non-cancer related cachexia could be recommended.

Amongst the patients with cancer attending the programme, unintentional weight loss was not a current concern for all. Some patients had experienced this in the past and seemed to find it helpful to clarify why this might have occurred. Some patients had no experience of unintentional weight loss and some of the workshop participants were actually gaining weight, usually because of medication. It is estimated that up to 80% of cancer patients will develop cachexia before death [225], meaning the workshop provides information which many patients could find useful in the future, even if it is not currently applicable. The optimal timing of patient education to maximise satisfaction needs to be explored empirically [226] but self-management depends on patients having the right information available. The workshop could introduce or reinforce the idea that nutrition is vital for health and encourage patients to alert their clinicians earlier if eating and/or weight loss does become a problem at a later time. The drawback to this argument, that it is beneficial to educate people prophylactically, is that resources are expended on people without a problem who may never experience that problem. Careful health economic evaluation would be required to investigate whether this is a viable approach.

Most participants across the pilot workshops seemed to enjoy doing the activities and understood what was required. The exception was the concern rating task was sometimes confusing for those participants not currently affected by unintentional weight loss. If the patient was not currently losing weight, participants were asked to complete the chart supposing that the patient was having problems in this area, by either recalling past experiences or relying on their imagination. Although some participants were able to do this, others recorded a score of zero concern because it was not currently an issue. Discussion of the impact of patients and carers having different levels of concern was still possible in these circumstances but this issue illustrates the difficulty of including participants who do not match the characteristics of the target population.

During discussions related to the tasks, participants shared their own experiences and some participants spontaneously offered advice to others. This is a common outcome in small group interventions. However, some participants did not fully engage with the workshop, even when it could have been beneficial. For some participants, this was as a result of falling asleep in their chairs after lunch. This underlines the importance of careful consideration of the time of day when the workshop is scheduled. Some participants had hearing problems and missed some of the content. This is a disadvantage of delivering interventions in a group situation as it is not always possible to check that participants have taken in all the information as the intervention progresses. Finally, there were one or two participants who it was not entirely clear why they did not engage fully with the workshop or take in the information. It may have been that they were in discomfort resulting in distraction or it may have been related to learning levels. To address the latter, in the feasibility study (see Chapter 9), participants were asked to rate how easy it was to understand the information presented in the workshop and whether the pace was correct.

As well as reflecting on the participants' experience of the workshop, the pilot workshops provided information about how to support HCPs in the delivery of the workshop. HCPs tend to be very time pressured and may have to read through the handbook and learn how to deliver the workshop outside working hours [227]. Although a detailed handbook may be perceived by some HCPs as essential, for others, this will result in feelings of pressure and burden [227]. These observations were consistent with the pilot workshops. The CNS at CMH appreciated having a very concise version of the handbook. However, given that some HCPs may be delivering the workshop when this is not their area of expertise, it is beneficial to provide a more detailed handbook as well. Following the pilot workshops, more information about high protein foods was added to the handbook as well as a frequently asked question section. It is also important to remind workshop facilitators to check that they know who to refer participants on to if they are particularly distressed by the topics covered in the workshop.

The pilot workshops reinforced the importance of having a checklist of the resources required to deliver the workshop. This checklist should include absolutely everything and there needs to be a reminder for all equipment to be checked before running the first workshop. In anticipation that the workshop will not always be delivered in places where all the required equipment is available, the handbook should also make suggestions for alternative approaches. At CMH, for example, there is no slide projector available so posters of the vital information were produced instead.

8.8 Conclusion

The workshop was acceptable to participants and could be successfully delivered by a HCP. Some minor modifications were required to the activities and the supporting written materials. For most participants, there was no evidence of actual harm, but there was concern about one couple suggesting a possible limitation of the workshop format for families with greater ERD and/or WRD.

Chapter 9: Feasibility study

9.1 Introduction

The use of the workshop in the therapeutic programme for patients and carers at the Countess Mountbatten Hospice was encouraging both in terms of the response by participants to the information received and the activities used to present this information. However, the original aim of the workshop was to provide a first stop for any cancer patient meeting the consensus definition for cancer cachexia [5]. If workshop attendance maximises the ability of patients to self-manage their eating and weight loss difficulties, then this could mean delaying the need for more specialist intervention. This would allow dietitians to focus on patients with the most challenging, complex problems.

Before the effectiveness of the workshop can be evaluated for patients referred from the hospital oncology population, a feasibility study was required. The feasibility study explored whether it would be practical to conduct an RCT into the effectiveness of the workshop, whether the workshop was acceptable for patients and carers and whether the planned evaluation framework was appropriate. The feasibility study was informed by the 'Can it work? Is there some evidence that the intervention might work?' questions posed in Bowen et al.'s description of feasibility study design [228] and guidelines issued by NIHR [229], as well as the advice offered in the MRC guidelines for developing a complex intervention [121] (see Table 18). Along with addressing feasibility issues, this study also provided an opportunity to start exploring the appropriateness of the theoretical foundation of the workshop, particularly the model of the patient experience of cancer cachexia, described in Chapter 3, by looking at whether there are the expected changes to scores in the outcome measures.

9.2 Aims

1. To determine the acceptability and practicality of the intervention for patients and carers.

2. To assess the acceptability of the data collection process and inform the selection of measures for a future evaluation study.

9.3 Method

9.3.1 Objectives

The feasibility study was designed to inform the issues listed in Table 18. This table also summarises how the topics were addressed.

Table 18: Feasibility study topics

Area of Focus	Questions	Assessment
Practicality	To what extent can the intervention be carried out using existing resources?	Review of where workshop is held & availability of staff to deliver it
Recruitment	How willing are clinicians to refer patients to the study? How many eligible participants can be reached and recruited? How willing are participants to attend the workshop?	Recruitment record review
Acceptability	To what extent can the intervention be successfully delivered to participants? To what extent is the intervention judged as satisfying to the recipients?	Observation of workshop by SW, participant feedback form, +6 weeks participant interview
Attrition	How many participants complete all the components of all the assessments?	Participant records
Evaluation framework	Is the proposed evaluation framework appropriate? What sample size would be required in a future RCT?	Review of missing data, scores and effect sizes
Limited efficacy	Does the intervention show promise of being successful with the intended population?	Comparison of scores on measures at baseline and follow ups

9.3.2 Participants

Following the general rule of thumb for determining feasibility study sample size [230], the goal was to recruit 30 pairs of patients and carers. The inclusion criteria for patients included a confirmed diagnosis of cancer, at any site and at any stage, with unintentional weight loss, defined as a least 5% of body weight in a six month period. A carer was defined as anybody who provides unpaid support and care to a family member, partner or friend, irrespective of whether they were in receipt of the Carer's Allowance or not.

Both patients and carers had to be aged 18 years or over, be able to read and write in English and physically capable of attending Southampton General Hospital in order to take part in a workshop.

A patient would be excluded if they were unaware of their cancer diagnosis.

9.3.3 Recruitment

Clinical nurse specialists (CNS) attending a Wessex oncology away day were informed of the purpose of the workshop and the study and had the opportunity to ask questions. All the nurses were provided with written information about the workshop along with flyers to give out to any potential participants. When asked what the best strategy was to encourage them to look for participants, the CNSs suggested emailing once a week. This advice was followed, with an email being sent to nearly 60 CNSs. As well as reminding the CNSs to look for participants in the weekly email, an offer for SW to attend the clinics in person was also made. In addition, the project was introduced to the community palliative care CNS team at one of their monthly meetings and they were then visited on a weekly basis to encourage them to discuss the project with patients and carers who may be interested in participating.

All 28 of the hospital based clinical and medical oncologists were emailed individually with written information to inform them about the study and flyers for potential participants. The oncologists were asked to introduce the study to any potential participants and again, the offer to attend clinics was made. A reminder email was sent two weeks later. SW also attended a chemotherapy clinic on three occasions and introduced the study to every patient who attended both verbally and with a written flyer.

Finally, two local support groups were also approached – Wessex Cancer Trust and the Living with Dying Self-Help and Support Group.

9.3.4 Procedure

All individuals who expressed an interest in taking part in the project were provided with a participant information sheet, tailored for patients or carers as appropriate. They were given the opportunity to ask questions about the project and the workshop itself. After providing informed consent, all participants were interviewed individually, either in person or by telephone depending on personal preference, and completed the measures described in section 9.3.6. Pre-paid envelopes were provided to return the questionnaires if necessary. If both patient and carer were taking part in the study, one person filled out the questionnaires whilst the other was interviewed and then *vice versa*. The questionnaires were repeated again about one week after the workshop and then again for a third and final time about six weeks after the workshop. On this third occasion, participants were also re-interviewed.

The pre-workshop interview template is shown in Appendix M and the post-workshop interview template is shown in Appendix N. Questions relating to coping and knowledge about the patient's weight loss were the same for both patients and carers. Questions about relationships, problems relating to the patient's eating and weight loss and the impact of these were tailored to patients and carers. The purpose of the interviews was to gain a better understanding of the individual participants rather than carry out a detailed qualitative analysis across the sample. The post-workshop interview checked whether there were any changes in the topics which were covered by the workshop, whether the information provided by the workshop was sufficient and whether participants would recommend the workshop to people in a similar position. It was anticipated that the post-workshop interviews could provide evidence of benefit and may suggest alternative domains which quantitative measures in a future RCT should assess, if the measures selected for the feasibility study did not capture any changes.

All interviews were audio-recorded, either using a digital recorder or ACR, a mobile phone app. Each interview recording was listened to several times, précised and particularly salient passages were transcribed in full.

9.3.5 Workshop delivery

The workshops were held in a room in the Macmillan Centre, which is within Southampton General Hospital. The room was quite small but had large windows overlooking a courtyard garden. A projector and screen were available along with speakers. The Macmillan Centre aims to "…offer a peaceful, welcoming and confidential space for people affected by cancer." Workshop participants who arrived early were able to gather in the main drop-in lounge. Refreshments were available.

During the planning phase of the study, a senior dietitian had agreed to deliver the workshop. Unfortunately she left her post before the study started. An experienced consultant nurse was then approached and was keen to be involved in the study because she recognised the importance of the topic and the limited information provided to patients and their families. A few weeks ahead of the workshop, the consultant nurse was provided with the handbook and had the opportunity to ask questions, but she did not observe a workshop being delivered in practice. During the workshops, SW was in the room but she explained to participants that her role was as an observer and the consultant nurse would be leading the session.

At the end of the workshop, participants were invited to complete an evaluation form about the experience of taking part in the workshop, and their views on the content and the delivery. Participants were also provided with the participant pack to take home, which included a summary of the workshop and Macmillan Cancer Support booklets. Along with the pack, the participants were given a second set of questionnaires to complete after a week, with a pre-paid envelope. Participants were contacted by phone a week after the workshop to remind them to fill out the second set of questionnaires.

9.3.6 Measures

It was hypothesised that workshop attendance would have an effect on the following: QOL, knowledge about issues related to weight loss and eating difficulties in cancer; mood; relationships; distress levels; and coping strategies. Measures for each of these constructs were therefore included in each of the three assessment points (pre-workshop, one week- and six weeks-post workshop).

9.3.6.1 Quality of life

HRQOL in patients was assessed using the EORTC QLQ-C30 [169] and QLQ-CAX24 [231]. The QLQ-C30 comprises 30 items made up of five functional scales (physical, role, cognitive, emotional and social), seven symptom scales and items (fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation and diarrhea), one item assessing perceived financial impact of disease and treatment, and scales to rate overall health and quality of life. Patients rate items using a four point Likert response scale, or seven point for the overall health and quality of life scales. A time period is not specified for the physical functioning scale items. The time frame for all remaining items is the past week. For the functional scales and overall QOL, high scores mean better functioning whereas for the symptom scales and financial impact, high scores are a worse outcome. There have been several publications exploring what constitutes a clinically significant score change on the QLQ-C30 [232-237]. A rough rule of thumb for QOL instruments is that a clinically significant difference is indicated by a 10% change in score [232]. Improvements or deterioration on the QLQ-C3O between baseline and each follow up were therefore recorded if there was a ten point difference between scores as all scores are scaled to 0-100. This approach was also used for the QLQ-CAX24, which also scales score to 0-100.

The QLQ-CAX24, the development of which was described in Chapter 4, supplements the QLQ-C30 in assessing HRQOL in cancer patients with cachexia. Like the QLQ-C30, it uses a four point Likert response scale. The time frame for all 24 questions is the past week. The QLQ-CAX24 is hypothesised to comprise five multi-item scales (food aversion, eating and weight-loss worry, eating difficulties, loss of control and physical decline) and four single items (dry mouth, indigestion/heartburn, forcing self to eat and inadequate information). For all scales and single items, a higher score is indicative of greater problems.

The QOL in carers was measured using the Caregiver Quality of Life Index-Cancer (CQOLC) Scale [97]. This single scale questionnaire contains 35 items and asks carers about the past week. Carers use a five point Likert scale to respond. Eight items are reverse-scored and a total score is then calculated, with a maximum possible score of 140. Higher scores indicate worse QOL. Using the 10% rule of thumb, a 14 point difference between scores at baseline and the follow ups was noted as a change.

9.3.6.2 Knowledge

A study-specific measure of knowledge was devised for the project (Appendix O). The measure was framed as an advice questionnaire, with correct answers based on knowledge from the literature around best practice as described in Chapter 6. Participants were given a list of ten pieces of advice for people with cancer and unintentional weight loss and a list of ten pieces of advice for carers. For each piece of advice they were asked to indicate if it was good advice i.e. advice which should be followed, with the response options of yes, no and don’t know available. The total number of correct answers, and the number of ‘don’t know’ responses were calculated. Arbitrarily, a difference of two or more for both total score and number of ‘don’t knows’ between baseline and each follow up, was recorded as a change.

9.3.6.3 Mood

The Positive and Negative Affect Schedule (PANAS) was used to assess mood [238]. The PANAS comprises twenty words which describe different feeling and emotions. For each word, participants rate to what extent they had felt this way over the past week using a five-point Likert response scale. Half the items contribute to a positive affect score and the other half contribute to a negative affect score. Scores for positive affect and negative affect are relatively independent [239]. As indicated in the scoring instructions, scores for positive affect were marked as high if above the population norm means: 33.3 for positive affect and 14.8 for negative affect. Changes in affect were recorded if participants changed category (high vs. not high) between baseline and each follow up.

9.3.6.4 Relationships

Relationship functioning was assessed using the Family Relationships Index (FRI) [240]. Participants are asked to rate each of twelve statements as true or false for their family. There are three subscales in the FRI, each with four items: cohesiveness, expressiveness and conflict. As well as scores for each of the subscales, a total score is calculated with higher scores indicating better functioning. The FRI has been shown to have excellent sensitivity but poor specificity for screening families at risk of dysfunction [240]. Families are deemed at risk if one or more members scores less than four on cohesiveness or has a total FRI score equal to, or less than nine. These cut-offs were used to classify participant scores as improved, no change or reduced between baseline and the two follow ups.

9.3.6.5 Distress

A modified version of the distress thermometer was used to assess distress in both patients and carers [241,242]. As is usual practice, participants were asked to circle the number (0-10) on a pictorial thermometer that best describes how much distress they had been experiencing in the past week. To reduce participant burden, the checklist which usually follows the thermometer task was not included. This checklist asks about practical, family, emotional and physical problems along with spiritual/religious concerns. Instead participants were asked to circle the number (0-10) on a second thermometer to indicate the amount of distress they had experienced in the past week which was directly related to the patient's eating difficulties and/or weight loss. For both general distress and eating- and weight loss-related distress, scores were classified as low (0-3), medium (4-6) or high (7-10), with a reduction or increase noted if the participant changed category [243].

9.3.6.6 Coping strategies

The brief COPE [244] was used to check how frequently patients and carers were using particular strategies in the last week to cope with any stress caused by the weight loss and/or eating difficulties experienced by the patient. The COPE comprises 14 scales, each with two items. The scales are self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion and self-blame. Responses are given using a four point Likert scale. The COPE has been demonstrated to have a two-factor structure for patients and carers as follows [245] : 1) **active coping** comprising use of emotional support, positive reframing, active coping, planning, and acceptance; 2) **avoidant coping** comprising denial, substance use, behavioural disengagement and venting. Self-distraction, humour and religion do not load on either factor. Participants' active and avoidant coping scores were standardised from 0 to 100 and a ten point change between baseline and the follow ups was arbitrarily chosen to represent a meaningful change.

9.3.7 Statistical analysis

Nonparametric statistical tests were planned to look for evidence of change in the outcome measure scores.

9.4 Results

All names of participants have been changed.

9.4.1 Participants and recruitment

Despite the multiple methods used, recruitment rates were low, falling well short of the planned 30 pairs of patients and carers. A total of five patients and three carers agreed to take part. Three workshops were originally scheduled. The third workshop was postponed on one occasion because no participants had been found. The third workshop was then cancelled when nobody could be recruited for the second date.

One medical oncologist and one clinical oncologist contacted patients to invite them to take part. Two patients were recruited in this way (Carol and Eric). In addition, one patient was keen to participate but was away with work for all the possible dates and one patient declined because her appetite was now improving and she did not want to “be a nuisance” to the people she was reliant on taking her to the hospital. There was no response from any of the other 26 oncologists.

One patient (Alan) was recruited via the community palliative care CNS team whilst his wife (Beth) independently asked to take part after receiving a participant flyer from one of the CNSs in the hospital. Two patients were recruited from the chemotherapy clinics (Helen and Guy). There was no response to enquiries made to the support groups.

Attending the first workshop were two families; Alan (patient) and his wife Beth (carer) and Carol (patient), her daughter Dawn (carer) and Carol’s 12 year old granddaughter. At the second workshop, there was a female carer, Fay, whose husband Eric was too ill to attend and Guy (patient) who had not wished anyone else to take part with him. Helen, a patient, had been due to attend this workshop after completing the interview and baseline measures, but did not attend because she decided to go on a last minute holiday instead.

Unfortunately, one person did arrive for the cancelled third workshop. This gentleman had kept the project flyer which he had received in the chemotherapy clinic but only made contact with SW when he had returned home again.

Further details of all the individuals taking part in the project are given below. Direct participant quotes, taken from the pre-workshop interviews, are shown in quotation marks. These details are provided to demonstrate the different experiences of the families who attended the workshop to give an indication of who the workshop is applicable to and how it may help people in different circumstances. In this respect, the results can be considered as a series of case studies.

9.4.1.1 Alan (family 1, patient)

Alan, aged 55 years, had been diagnosed with oesophageal cancer in September 2013. He had recovered well from an oesophagectomy, returning to eating normal portion sizes and able to enjoy his usual hobbies and activities. Unfortunately the cancer was detected in several lymph nodes requiring further chemotherapy in early 2016. At the three month post chemo check-up in May 2016, Alan described how spots of cancer had been found in the peritoneum which were interfering with the peristaltic action of the gut. Since then the weight had been falling off – an estimated 20% in the last six months - and he had to force himself to eat and take dietary supplements.

Alan described his wife Beth as very supportive. For example, she protected him from unhelpful suggestions from family, friends and acquaintances and was patient when he struggled to eat. Alan was dissatisfied with a perceived lack of support from some HCPs about his eating difficulties and weight loss.

A week after the workshop, Alan was admitted to hospital for an emergency operation to relieve a blockage in his bowel. He was therefore nil by mouth when he completed the second set of questionnaire measures. He completed the questionnaires at week six but did not respond to two requests for an interview.

9.4.1.2 Beth (family 1, carer)

Beth, aged 52 years, was concerned that Alan’s problem was not being properly addressed by HCPs and thought the focus needed to change from treating the cancer to addressing Alan’s nutritional needs. She wanted more information about what “proper food” to try rather than the supplements suggested by the dietitian.

Although Beth was under considerable pressure from caring for elderly relatives as well as Alan, and working, she did not feel her relationship with Alan had changed. They still enjoyed spending time together, including sometimes eating together. Beth’s own eating had changed somewhat because she could not bothered to cook just for herself.

From what Alan and Beth said, it was clear that they were just beginning to really accept that Alan’s life was coming to an end but the changes that accompanied that stage of his life, particularly the eating difficulties, were very difficult to deal with.

9.4.1.3 Carol (family 2, patient)

Carol was 68 years old and had been diagnosed with breast cancer in 2013, following on from Hodgkin's lymphoma in 1976 and a lung cancer diagnosis in 2010. She was not currently having any treatment for the cancer. Carol was bothered about her weight loss and was forcing herself to eat as she never wanted to eat anything. She was concerned that the food she was eating was “bad food” as she was eating sweets and chocolate: "I do worry that the food I eat is rubbish food. I prefer to be eating more healthy food. But I don't seem to be able to do a lot about that because if I don't eat the rubbish, I not eating anything." Carol’s oncologist had prescribed protein drinks when she was having chemotherapy but she could not face them now. The oncologist had now asked the GP to discuss diet with Carol.

Carol lived with her daughter Dawn, who had multiple sclerosis (MS), and also Dawn’s daughter for some of the time. Carol and Dawn thought of themselves as carers for each other. They had an easy-going relationship, with no arguments about food and eating.

9.4.1.4 Dawn (family 2, carer)

Dawn, aged 44 years, had been living with MS for five years. She recognised that her mother was struggling to eat but was confident that Carol was doing everything she could and was self-managing her eating difficulties. Nevertheless Dawn described feeling helpless.

9.4.1.5 Eric (family 3, patient)

Eric, aged 69 years, had been diagnosed with mesothelioma a few months earlier and although asymptomatic at diagnosis, was keen to start chemotherapy straightaway. He had just completed his third cycle. Eric’s oncologist had emphasised the importance of maintaining weight and this was important to Eric too: "I would like to be heavier. I associate loss of weight with being ill. I think if I put some weight on I would feel better about that. You know, it's quite important for me because I don't want it to negatively affect my ability to have the chemo...I want to be fit enough and strong enough for the chemo." He estimated that he had lost about 5% of his body weight since diagnosis but as a slim man already, he felt this was very noticeable. Eric wanted to live for as long as possible and was willing to try any diet or dietary supplement to achieve this. Eric had been on the ketosis diet (high fat, low carbohydrate) at the suggestion of his wife, Fay. He had given up on the ketosis diet because he had found it difficult to gain weight and had grown tired of consuming so much fat. Eric was now taking paw paw tablets and curcumin.

9.4.1.6 Fay (family 4, carer)

Fay, aged 65 years, was disappointed that Eric had given up on the ketosis diet because she was convinced that carbohydrates produce sugar which fuels the cancer: “If it was me, I would have ditched the chemo and carried on with the diet. But he made the choice to do the other thing which is up to him - it's his body. But to me the diet was so logical. If you know something is going to feed your cancer, you don't do it. But that's for him to decide really." Fay was concerned that, “He [Eric] can only eat what he fancies, not what's good for him," and she wanted him to eat bigger meals to help put weight on. Despite disagreeing with some of Eric’s decisions, Fay felt their relationship had improved following the cancer diagnosis: "Before we were both fairly independent people but less so now. I try to look after him.”

9.4.1.7 Guy (family 5, patient)

Guy, aged 70 years, lived with his wife and his younger daughter (who was 32) but did not wish either to attend the workshop. Guy had been diagnosed with prostate cancer four years previously and had received radiotherapy. The cancer had just reoccurred and Guy was about to have his second cycle of chemotherapy. Guy was eating fairly normally but had lost a little weight (about 3% since the cancer had reoccurred) and he was keen not to lose any more. He expressed an interest in attending the workshop after receiving a flyer at a chemotherapy clinic and despite not meeting the 5% weight loss criterion, SW agreed he could attend.

9.4.1.8 Helen (family 6, patient)

Helen, aged 54 years, had been diagnosed with colorectal cancer about a year previously. Since then she had lost about 16% of her body weight. Helen described having a poor appetite and was unhappy about the noticeable weight loss, describing how, “My skin doesn't fit on my body very well.” She had been referred to the dietitian by her oncologist. Helen had seen the dietitian once and was prescribed supplements but found them “foul - they are disgusting”. She lived with her husband but described her grown up daughter who lived elsewhere as her main carer and hoped that her daughter would attend the workshop with her. As described above, Helen did not attend a workshop.

9.4.2 Measures

As there were only four patients and three carers who took part in the workshops, it was not possible to carry out any statistical analyses on the measures. The scores for each participant at the three time points (baseline, +1 week and +6 weeks) are shown in Appendix Q, and summarised in terms of whether there was any difference between the baseline scores and the two follow up time points in Appendix R. For both the QLQ-C30 and the QLQ-CAX24, two patients did not realise that there were items on both sides of the paper so did not complete nearly half the items (the last 14 items on the QLQ-C30 and the last 11 items on the QLQ-CAX24), at both the one week and six week follow ups. With such a large amount of missing data it would be imprudent to look for any patterns in the data. For the CQOLC, there was no change on the total score for any of the carers between baseline and the two follow up times.

All but one participant had an improved score on the advice questionnaire, both one week and six weeks after the workshop. On the distress thermometer, four out of the six participants had more general distress one week after the workshop. There was no clear pattern on any of the measures for mood, relationship functioning, or coping strategies.

9.4.3 Field notes

Brief field notes were made following both workshops. Points of interest are shown below.

9.4.3.1 Workshop one

It was a really hot day and Alan visibly wilted as the session went on (and indeed he scored the workshop as too long on the feedback form). The presence of Carol’s 12 year old granddaughter made the session more challenging as she was reluctant to contribute to the workshop but had not brought anything to occupy herself with. The consultant nurse gave her the task of scribe for some of the activities but she struggled with this task and continuously asked her mum, Dawn, how to spell the words.

The two families did not really bond and at no point had a conversation which did not go through consultant nurse. The breaking the ice tasks did not happen and the interactive elements of the workshop were not very interactive. The consultant nurse did not closely follow the workshop script. Everything she said was useful but it did not always relate to eating and weight loss. She interpreted “supplements” on the strategies slide as referring to vitamins and trace elements (e.g. magnesium and mood). For the “what does it mean to eat well task”, she asked what the patients were actually eating. There was no discrepancy in the amount of worry that the weight loss was causing patients and carer so this was not discussed further.

The consultant nurse and SW discussed some of these issues after the workshop. The consultant nurse confessed that she was not always very good at “sticking to the script”. Some of the other issues were clarified in the notes. The importance of trying to promote more interactivity, starting with the breaking the ice tasks were noted.

9.4.3.2 Workshop two

Fay and Guy had met in the waiting area of the Macmillan Centre and already chatted before coming into the workshop room. The consultant nurse therefore did not feel the need to do the warm up tasks as planned. Before the workshop, she had even thought about leaving the room at some point e.g. to fetch water, so that the participants would have been forced to talk to each other. However Fay and Guy had already established a good rapport.

Fay had described in her interview about wanting Eric to avoid carbohydrates because these are broken down into sugar and sugar feeds the cancer. The consultant nurse had been forewarned about this belief. She carefully explained that the cancer would take what it needed and if the sugar didn’t come from food, it would come from breaking down fat in the body and then muscle. This message was repeated several times and by the end of the workshop it had started to be taken in. The consultant nurse did this very well, with great respect and empathy.

Guy asked at the start of the workshop what the content was based on. By briefly explaining the evidence for the content (systematic reviews, expert opinion, research etc.) Guy was able to accept the integrity of the workshop and therefore bought into it. He found it very useful only questioning why the advice provided wasn’t given out as standard at the start of chemotherapy.

9.4.4 Six week follow up interviews

9.4.4.1 Carol (family 2, patient)

Before attending the workshop Carol had been trying to eat fruit and vegetables as she perceived this to be healthy. She had been finding this very difficult. Following the workshop, Carol only had this type of food if she fancied it, and was reassured that eating “bad” food was fine: "Before I would have thought it's not good for me eating all this rubbish but now I think it's calories so it's good for me…I'm quite happy to eat the cream cakes. They slide down easy. And chocolate and things. I do eat a strange diet but it's what I can eat." Carol was only just holding her weight and would like to put a bit on.

In terms of following tips from the workshop Carol had tried having alcohol before meals. Although it did not seem to improve her appetite, she enjoyed it. Carol could not remember any other specific tips but she would recommend the workshop to others, saying: "The workshop covered things that I hadn't even thought of really… I thought it was really good."

9.4.4.2 Dawn (family 2, carer)

Dawn could not remember any specific strategies given in the workshop but was sure everything was covered. "I know we both came away thinking, you know, that was good, that was interesting, you know just sort of highlighting, you know, don't worry and if you can't eat just do what you can, even if it is liquidy. So yes there were lots of sort of little tips in there." Dawn felt reassured and knew her mum did as well.

9.4.4.3 Eric (family 3, patient)

Eric, who had been too ill to attend the workshop, could not remember his wife telling him anything about it but acknowledged that communication may have been difficult. He had not looked at any of the written material.

9.4.4.4 Fay (family 4, carer)

Fay described how the workshop had: "totally change my opinion about what I had to do because I was under the impression that he shouldn't be eating any carbs. And that came as a shock to me that he actually should be eating all the things that I thought were going to be encouraging his cancer to grow. And of course it was explained why. And that changed, I wasn't happy about it, but I had to accept it I think." Fay found the workshop trustworthy, "even though it went against the grain for me." She thought that the workshop "…was definitely useful. Useful on different levels. Useful for people doing the wrong thing. Useful for people with not much dietary knowledge to point them in the right direction."

Fay was disappointed that her own diet was not very good because they were eating whatever her husband fancied. She had been trying to lose weight but had regained a stone of the 21 pounds she had previously lost.

In terms of using the ideas presented in the workshop, some had been more successful than others. When Fay told Eric that ready meals were an option, he had responded “yuk!”, perhaps because they were used to cooking from scratch with produce from the garden. Nevertheless, Fay had bought some frozen sausage rolls which could be easily cooked when Eric fancied them. Fay had been surprised about the advice that drinking small amounts of alcohol could be used to stimulate the appetite. Eric was pleased when she bought him a bottle of whisky and had enjoyed a drink but Fay thought the tiny amount he had consumed was not enough to trigger appetite.

9.4.4.5 Guy (family 5, patient)

Guy was pleased that he was maintaining his weight during chemotherapy and thought that he would have lost weight if he had not been using some of the preventative measures he learned from the workshop. Guy maintained that there was "…nothing coming from the medics about diet and it seems to be a big gap." He would certainly recommend the workshop to other people in his position.

9.4.5 Feedback

The feedback from all workshop attendees was positive. Everybody thought it was both about the right pace and the right length, apart from Alan who felt it was too long. The workshop was easy or very easy to understand for everyone. It was held at a convenient day and time, and the location was reported to be convenient for everyone except Fay, who would have preferred it not to be held at the hospital. All but Fay agreed that it was beneficial for patients and carers to attend the workshop together. Nobody thought there were any topics which had not been covered and nothing about the content or the delivery of the workshop was felt to be a problem.

9.5 Discussion

This study explored the feasibility of conducting an RCT to determine the effectiveness of the workshop for cancer patients with unintentional weight loss and their carers in a secondary setting. The biggest problem encountered was disappointing recruitment. Although the participants who attended considered the workshop useful, there were too few to provide any evidence of potential benefit and it is difficult to assess the appropriateness of the planned evaluation framework for a future RCT. Further feasibility work, focussing on recruitment, will be required before an RCT can be carried out.

The low recruitment rates occurred despite attempts to encourage oncologists, cancer and palliative care CNSs to invite patients to take part in the project. Demand was therefore low and it seems unlikely that clinicians would be willing to refer patients to an RCT in sufficient numbers. It is not clear why this is the case for the workshop specifically but recruitment is a common challenge for studies which are relevant to palliative care populations [246-252] and recruitment has been an issue for the cancer cachexia DVD RCT [108]. Gatekeeping, 'the process whereby healthcare providers prevent access to eligible patients for research recruitment' [253] has long been identified as a significant issue in palliative care research. A recent systematic review identified five groups of potential gatekeepers – HCPs, research ethics committees, management, relatives and researchers – and a host of reasons leading to gatekeeping [254]. Examples are presented in Table

19, in the categories identified by the authors of the review. Which, if any, of these reasons for gatekeeping were applicable in the current study is not known but should be explored in future feasibility work.

Table 19: Reasons for gatekeeping

Category	**Examples**
Fear of burdening patients	Fear of burdening mentally or physically frail patients; feeling responsible for protecting patients approaching end of life (EOL); not wanting patients to develop false hope.
Difficulty with disclosure of health status	Reluctance to talk about research EOL projects; objections to including any terminology which is considered too confronting; avoiding discussion about EOL.
Fear of burdening patient's relatives	Fear of increasing burden on the family; fear of distressing the family
Doubts about importance or quality of study	Concern that the study topic is not worth the patient's effort; disapproval of the study intervention; doubts regarding the suitability of the intervention for the individual patient; prioritising treatment studies above supportive studies
Attitude towards research	Lack of research experience; assumption that patient prefers not to participate; difficulty identifying eligible patients; difficulty seeking consent from patients who are unlikely to benefit from the study; excluding patients when relatives do not want them to participate; paternalistic research ethics committees
Logistics	Lack of time; research study interrupts usual processes of care; avoiding discussing study because patients also raise other time-consuming treatments and care-related questions;

Although it was assumed that clinicians were not inviting eligible patients to join this research project, an alternative explanation is there simply were not enough eligible patients. This seems unlikely given the high prevalence of cachexia in cancer patients, as discussed in section 1.4. A recent study in France also confirmed the high levels of malnutrition in cancer patients [255]. The study was a one day prevalence study of malnutrition in 1903 patients across 154 wards, including day care units. Malnutrition was defined on the basis of low BMI and/or >10% loss in body weight since disease onset. Using this definition 39% of the patients were malnourished, rising to 51% if a definition of >5% loss in body weight was used instead. Although there is no evidence to support the possibility there were not enough patients who met the eligibility requirement, the issue of 'hidden cachexia' (see section 1.3) may have reduced the visibility of eligible patients.

The willingness of patients to take part in the feasibility study specifically was not explored during the course of the project. However, in general, palliative care patients and their relatives are interested and willing to take part in research, whether or not it promises any benefit to themselves [256,257]. Of course not all potential participants want to take part in research and there are a myriad of reasons for this including feeling too unwell, wanting to defer the decision, the distance from home to the place where the research takes place, a lack of interest, transfer to another unit, inability to give consent and family objection [250,258,259].

As well as assessing recruitment, the feasibility study was concerned with whether the workshop was practical, whether it was acceptable to participants and what the attrition rates were like. From the feasibility study, it appears that it is practical to deliver such a workshop in the hospital setting. All but one of the participants considered the hospital to be a good setting for the workshop. The pilot work described in Chapter 8 illustrated how adaptations to the delivery of the workshop are possible if equipment such as a slide projector is not available. The issue of whether HCPs would be willing to deliver the workshop was not explored specifically in this study.

The workshop seemed acceptable to participants, based on the feedback they provided. This is encouraging given the diversity of the patients and carers who attended in terms of their cancer experience and current symptoms, and the beliefs and involvement of the carers. Patients and carers who were recruited to the project, on the whole, remained enthusiastic and keen to complete all the assessments. However, one patient who completed the baseline interview and questionnaire measures was not able to attend a workshop because of a last minute holiday and one couple completed all the questionnaire measures but did not respond to requests for the second interview. The low numbers make it difficult to extrapolate and it is not reasonable to estimate attrition rates based on the collected data.

In terms of how the intervention was delivered, it is interesting to note the difference between the CNS in the pilot work, who generally adhered to the suggested content and delivery very closely, and the more experienced consultant nurse in the feasibility study, who used the workshop protocol more as a general guide. Sometimes positive outcomes can be achieved even when an intervention is not delivered as planned [122]. For the future RCT, it will therefore be very important to standardise the training of workshop facilitators to ensure that it is the workshop itself which is evaluated.

Although the low numbers also make it difficult to assess the evaluation framework, and it is not possible to extrapolate the sample size required for a future RCT, the measures used seemed to be acceptable to participants, evidenced by their willingness to complete them on three occasions. However, there was some missing data, particularly for the patient HRQOL measures. This may have been because unlike the other measures, the HRQOL questionnaires were printed on both sides of the paper. Improved presentation of these questionnaires could reduce the amount of missing data. In addition, it may be beneficial to conduct the six week follow up interview at an earlier time as participants found it difficult to remember exact details about the workshop.

A measure for self-efficacy was not included in the feasibility study and this was an oversight, given that self-efficacy is an important concept in ITHBC, the theory underpinning the workshop, and also that one of the main aims of the workshop was to promote self-efficacy for both patients and carers. As well as evidence for significant correlations between self-efficacy scores and outcomes including emotional adjustment [260] and depression [261], some studies have demonstrated that greater self-efficacy can modify the impact of other negative effects in cancer patients. For example, the degree to which symptoms interfere with daily life [262], the effects of age on physical HRQOL [263] and the impact of physical symptoms to functional and emotional well-being [264].

Self-efficacy has also been explored in relation to both advanced cancer patients, with a >6 months life expectancy, and their primary carer [265]. Although self-efficacy was related to mental and physical health for both patients and carers, and patients and carers influenced each other's mental and physical health, there was no relationship between partner's self-efficacy scores. This suggests that it is important to evaluate both patients and carers with respect to self-efficacy because if either is not confident about managing cancer, both may experience negative outcomes.

Two studies have explored whether caregiving training can enhance carer self-efficacy and psychological outcomes. One study found that although a training programme for carers on home care and symptom management improved self-efficacy, there was no effect on the carer's psychological well-being, nor on the patient's physical symptoms [266]. The other study demonstrated that training for carers in cancer symptom and stress management improved self-efficacy in the short term, but not at the two week and four week follow ups and there was no effect on psychological outcomes for the carers at any time point [267]. Further work is required to explore how the early benefits of training programmes can be maintained and what other factors need to be addressed to ensure that carers' increased confidence to manage patients' symptoms translates into better outcomes for the carer. These will also be important considerations for the RCT planned for the workshop.

9.6 Revised workshop protocol

Following the pilot testing and feasibility study, a slightly revised version of the workshop was produced with a revised handbook for facilitators (Appendix S) and a revised participant handout (Appendix T). The main change to the workshop was the addition of the Advice Questionnaire at the start and the end to help reinforce some of the key messages of the workshop. Most of the other changes were relatively minor. The recommendation to discuss the use of supplements was inserted on the slide about changes to eating habits. Suggestions for how the workshop could be used in different circumstances were added to the handbook. These suggestions included ideas on how to reduce the length of the workshop if time was an issue and how to adapt the workshop if it was being used as part of programme for patients and carers, rather than a standalone workshop. Extra information about high protein food was added to the handbook, along with a note about there being no scientific evidence to support claims that any food or diet can cure or control cancer. An additional Macmillan booklet, on coping with fatigue, was included in the pack that participants take home at the end of the workshop.

Finally, the name of the workshop was changed from “Workshop for people with cancer and weight loss and their carers,” to “Understanding and managing poor appetite and weight loss in cancer: A workshop for patients and carers” to indicate more clearly the purpose of the workshop.

Part E: Discussion and conclusions

Chapter 10: General discussion

This thesis has described the development of the first small group intervention for cancer patients with unintentional weight loss and their carers, along with preliminary testing to inform a future RCT. The main objective of the devised workshop was to improve the QOL of patients and carers so systematic reviews of the literature were carried out to identify how cancer cachexia affects patients and carers, and a model of the patient experience of cancer cachexia was constructed. These reviews were also used to supplement the interviews with patients, carers and HCPs which informed the intervention targets for the workshop. Further literature reviews and consultation of extant interventions were used to address the intervention targets and a preliminary protocol was produced. Pilot and feasibility testing provided information about how to modify the workshop and demonstrated that a different recruitment approach will be required for a future RCT. Along with the workshop, another tangible output from this work is a questionnaire to assess HRQOL in cancer patients with cachexia.

The main obstacle identified in the feasibility study was recruitment. This final chapter starts with a discussion of how to overcome this issue. The next two sections consider why self-management is important and how the workshop, designed to promote self-management, could fit within the UK health care system. Next, some limitations to the work presented in this thesis are discussed, along with the next steps required to evaluate the workshop. Finally, an overall conclusion is offered.

10.1 Overcoming recruitment challenges

Further feasibility work is required before a RCT can be carried out, with improvements to recruitment strategy a necessity. The well-documented challenges of recruitment in palliative care studies in general has resulted in a number of suggestions about how to overcome these problems [259,268,269]. In the feasibility study, HCPs were asked to help recruit patients but the recruitment rates were disappointing. A Cochrane review found that there was no strong evidence for any single strategy to help HCPs to recruit. Nevertheless, the review concluded that it was important to facilitate the process of identifying potential participants to ensure that they receive information about studies and can make their own decision about whether to participate [270]. Three recruitment strategies were identified by the review: i) Alert system – doctors are alerted to a potential participant by a computerised alert or by a nurse or clinical trial screening co-ordinator; ii) Additional input to sites in the form of informative and educational information; and iii) Additional personnel – this seemed to be the most promising strategy. For example, recruitment improved in a study of a palliative radiation therapy when a member of research staff was engaged specifically to recruit patients [271].

The appointment of a dedicated specialised recruitment nurse also improved recruitment in a RCT of different service delivery models to improve pain control in the palliative setting [259]. This study followed social marketing techniques, which emphasised the importance of building relationships with clinical staff, and developed study resources to support recruitment. The resources included recruitment scripts, separate information booklets for patients and carers and a triage algorithm which provided the referring doctor with very broad eligibility criteria. Eligible patients could then consent to trial staff to contact them for more detailed screening.

Some of these techniques were employed in the feasibility study but there was no funding available for a dedicated recruitment nurse. Identification of eligible patients was not straightforward as information about weight loss is not always recorded reliably in hospital records. In an RCT investigating the use of statins in adults with a life expectancy of one to six months, the prognostic criteria required to check for eligibility were not routinely recorded in medical records making it difficult to identify potential participants [268]. Some sites in the study were able to add in a screening question for patients on admission to address this issue. The community palliative care team in Southampton added a question about weight loss and eating difficulties to the information they gathered on the first meeting with new patients. However, this did not seem to improve recruitment to the feasibility study. In the statin RCT, the engagement of clinical champions also improved recruitment. These clinical champions, who typically had a scientific interest in the study, provided access to patient populations and help build enthusiasm about the trial. This seems a promising strategy for future evaluation of the workshop.

In general, reports on how to improve recruitment in palliative care trials, all stress the importance of using diverse, flexible strategies and the need for the research budget to include adequate personnel time for recruitment activities [259,268,269]. In addition to these strategies, the use of patient and public involvement (PPI) has been shown to assist with recruitment to studies and improve response rates [272]. For further evaluation of the workshop, PPI involvement will be crucial.

10.2 Self-management

The workshop was produced as a tool to aid the self-management of cancer cachexia. Self-management is one of a number of terms which has arisen as a result of the shift from the view of a patient as a passive recipient of medical care to the idea that patients are active partners in their own health and well-being. These terms include patient -empowerment, -centredness, -

activation, -participation, health literacy and self-efficacy. There is much debate in the literature about definitions and theoretical frameworks for these terms. For example, one recent systematic review identified 20 definitions of patient empowerment, 13 definitions of patient participation and 20 definitions of patient-centredness before concluding that these three concepts are inter-related and presenting their own framework [273]. These debates, while important, may serve as a smokescreen to the issue of implementation of self-management interventions within healthcare.

Although there are few self-management interventions for patients with cancer cachexia specifically, a systematic review identified over 40 published RCTs which have investigated self-management education (SME) interventions for patients with cancer [274]. Based on these RCTs, the authors of the review outlined eight core element of SME interventions, although they were not able to assess the relationship between the core elements and effect sizes in the interventions. The core elements suggested that SME interventions should be tailored to patients, facilitate self-efficacy to manage illness and care (two items), support patients to communicate with HCPS, be delivered by a specially trained instructor but with the support of the health care team (two items), include goal setting or action planning and finally to facilitate problem-solving skills. The workshop included most of these elements but the results from the feasibility study cannot help discern which of the eight core elements are most important.

Self-management has become important within health services because of the shift from the treatment of acute conditions to the management of long term health conditions. NHS England defines self-management as [275]

> …a term used to include all the actions taken by people to recognise, treat and manage their own health.

Linked with this is person-centred care, defined as follows: [275]

> Person-centred care supports people to develop the knowledge, skills and confidence they need to more effectively manage and make informed decisions about their own health and care. It is coordinated and tailored to the needs of the individual, and healthcare professionals work collaboratively with people who use the services.

On the basis of this definition, people need three things to self-manage: information, training and good self-efficacy. The workshop provides information and training, with the assumption that this will improve self-efficacy. As noted in the previous chapter, a self-efficacy measure was not included in the feasibility study, an oversight which will be addressed in future work. The hypothesis is that the workshop will improve participants' confidence that they can manage eating and weight loss difficulties and so the distress associated with these problems will be reduced.

10.3 Palliative care, rehabilitation or prehabilitation?

The workshop was conceived as a reactive intervention to provide support for carers and patients who were already affected by cancer cachexia and as such, it was expected to be used as a palliative care intervention. A simplified diagram of the patient experience of cancer is shown in Figure 17. One simplification is the portrayal of palliative care as a separate step in the patient experience. Ideally, palliative care should be offered early and alongside cancer treatments because there is compelling evidence that it improves patient symptom control, patient QOL, and both patient and carer satisfaction, as well as facilitating advance carer planning and lowering health care utilisation [276] [277]. It may even provide a survival benefit [278]. Nevertheless, in reality, there remains a gap between the recommended timing of palliative care and what actually occurs in clinical practice [279].

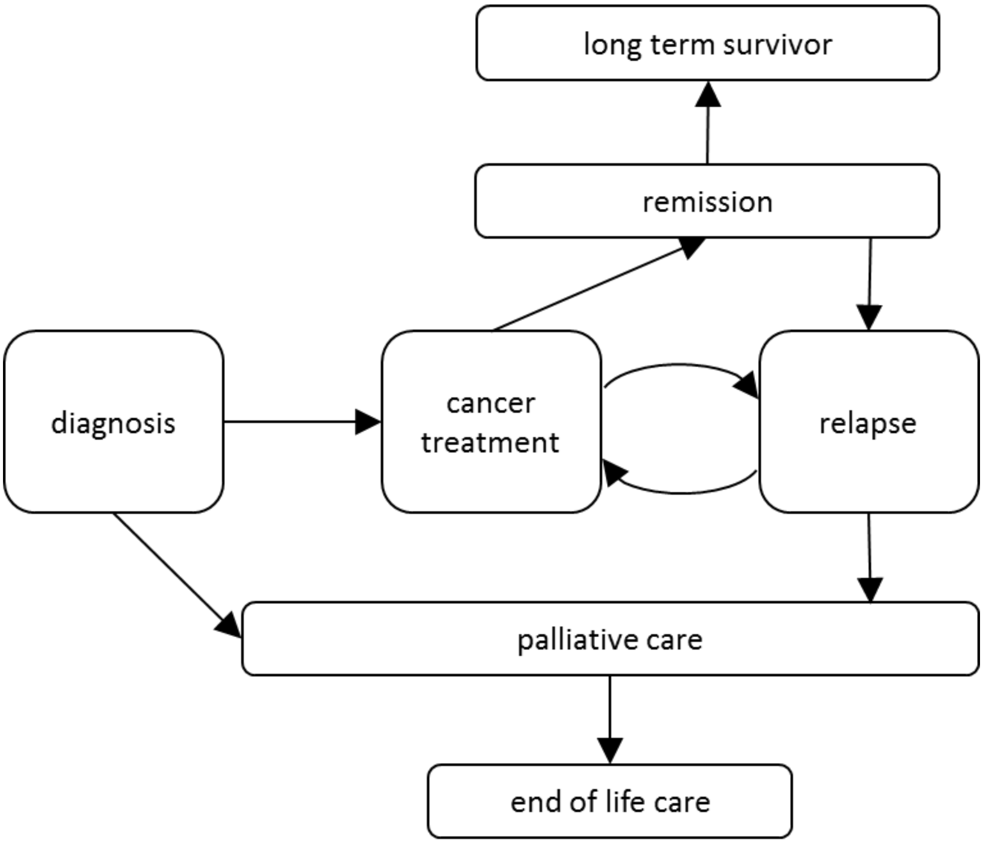


Figure 17: Simplified diagram of a cancer patient's journey

A number of barriers has been identified as contributing to this gap. Although oncologists welcome the idea of early referral to palliative care teams, they report limited availability and access to the teams and issues with communication, perhaps fuelled by their perception of palliative care teams as outsiders whose focus of concern is too narrow [280]. For oncologists, the involvement of another team in the core planning requires more co-ordination and interaction, using up resources, and there can be concerns about the balance of power and who makes the final decision if there are disagreements about the care plan [281]. In addition, some oncologists may lack awareness or knowledge of the role of palliative care and some report concerns about early referral because society at large, including patients and carers, are concerned that palliative care means no more cancer treatment [282]. Although oncologists in one study believed that changing the name of the service from palliative care to supportive care made no difference to their referral behaviour, in reality, they referred more patients and earlier in the disease trajectory [281]. Indeed there is a negative stigma associated with the term ‘palliative care’: for patients and carers the term refers to very end of life care and death, with these views often originating from interactions with HCPs [283]. This stigma may result in some ambivalence about the need for early palliative care in some patients [284]. Nevertheless, patients and carers report that early palliative care provides holistic support, guiding families through the illness experience and the healthcare system, aiding decision making and providing an opportunity to discuss the future, as well as ensuring prompt, personalised symptom management [284].

The perception that palliative care refers solely to end of life care is not surprising given its origins in terminal cancer care [285] and the ongoing inconsistencies and confusions amongst palliative care HCPs and researchers in the terms used [286]. ‘Supportive care’ may be a more palatable term but whatever the term used, the education of oncologists, patients, carers and other stakeholders about the importance and benefits of the early use of this care is vital for patients and their families. Providing further evidence of the benefits of early palliative care would encourage oncologists to embrace the use of early palliative care. The need for research in this area was one of the recommendations in the report published by the Independent Cancer Taskforce in July 2015 [287]:

> Recommendation 49: NHS England should pilot, through new or existing vanguard sites, assessment of holistic needs for cancer patients at the point of diagnosis, evaluating the benefit of earlier palliative care and/or intervention from AHPs [allied health professionals].

The report, which included nearly 100 recommendations to improve outcomes for cancer patients treated in the NHS, also highlighted the importance of cancer rehabilitation:

> Recommendation 70: NHS England and Health Education England should support a national review of the cancer rehabilitation workforce and promote the role of AHPs in multi-disciplinary teams.

Both palliative care and cancer rehabilitation are concerned with improving cancer-related symptoms or treatment-related side effects. Whereas palliative care is concerned with improving the QOL of patients and their families through the early identification, assessment and treatment of symptoms and other physical, psychosocial and spiritual problems [288], rehabilitation uses the approach of creating treatment plans with individualised goals to improve function and reduce disability [289]. In the UK, cancer rehabilitation has traditionally been delivered by specialist allied health professionals (AHPs), such as dietitians and physiotherapists [60]. The need to develop a new definition of cancer rehabilitation has been recognised in order to reflect the role it can have supporting people to live with cancer at all stages of the disease [290,291].

Within cancer rehabilitation is the emerging field of cancer prehabilitation. Cancer prehabilitation occurs between diagnosis and the beginning of acute treatment. Baseline functional levels are assessed and existing impairments addressed. Interventions to promote physical and psychological health and to prevent or reduce the severity of existing or expected treatment-related impairments that may cause disability are provided [289,292]. Hypothetically, the workshop could be used in this context to promote the maintenance of adequate nutrition but currently, the evidence base for the use of physical fitness as a tool for risk assessment and as an intervention is more substantial than that for nutrition [293]. For example, a systematic review found that there were functional and clinical benefits to patients with lung, prostate and colorectal cancer who took part in pre-surgical exercise interventions involving either aerobic or resistance training [294]. Introducing exercises in prehabilitation could facilitate adherence to post treatment programmes because patients may be physically more able to comply and psychologically more motivated [295]. Cancer prehabilitation has the potential to improve health outcomes and reduce healthcare costs by, for example, reducing the length of stay in hospital [292]. However, future research will need to explore whether this potential can be realised.

This discussion of palliative care, rehabilitation and prehabilitation services begs the question as to which discipline the workshop is most suited to. In fact it has the potential to be used in any of these settings, and in other situations as well. For example, a myeloma support group requested the workshop at one of their meetings, and this was well received by the patients and carers who attended. The workshop should be viewed as a tool for discussing how cancer can affect the body and how to deal with these changes if this does occur. These messages may be appropriate for patients at any point in their journey. Whether the workshop could be used proactively to help prevent the unintentional weight loss many patients will experience during the course of their disease is an intriguing question for future investigation. Currently, there is a lack of research to support this approach.

As described in section 1.5, there is one open clinical trial, MENAC, which is investigating a multimodal intervention initiated immediately after diagnosis to prevent or attenuate cachexia in advanced cancer patients undergoing chemotherapy [45]. This intervention does not contain a psychosocial component and nor does it explicitly recognise the role of carers. The workshop could fulfill this role because it provides information for patients and carers which supplies a rationale for the nutrition, exercise and anti-inflammatory interventions used in MENAC, which are also the treatments proposed as the best available management plan [14]. Previous research suggests that the understanding of conditions and treatments which patients in general have is positively related to adherence [296]. Carers could play a significant role in supporting patients to follow the nutrition and exercise components of the management, in the same way that family support facilitates cardiac rehabilitation [297] and compliance to treatment regimens, including diet and physical activity in diabetes [298]. As the workshop encourages greater empathy and communication between patients and carers, this could help ensure attention is focused on complying with intervention goals, rather than being distracted by disputes.

The discussion in this section has highlighted the role of palliative and rehabilitation specialities. An alternative approach is to improve the training of all HCPs so that they are able to deliver appropriate supportive care. The integration of palliative care into existing health systems is referred to as the public health approach to palliative care [299]. This approach is likely to become a necessity in order to meet demand in an aging population. There are some skills which all clinicians need, such as symptom management and aligning treatment with patients goals, which could be considered primary palliative care whilst specialist palliative care input will still be required for more complex and difficult cases [300].

Primary palliative care could be supported through the use of a holistic needs assessment, as advocated at the point of diagnosis in Recommendation 49 of the Independent Cancer Taskforce (quoted above). In 2007, the Cancer Action Team published guidance for the holistic assessment of the supportive and palliative care needs of adults with cancer [301]. The guidance outlined five domains of assessment – background information, physical needs, social and occupational needs, psychological well-being, and spiritual well-being – and advocated a patient concern-led approach. Despite the comprehensive assessment, the ambitious suggestion was that all the domains could be covered in 30 minutes. Proposed assessment points included at diagnosis, start and completion of primary treatment, disease recurrence, when incurability was recognised, when the dying process began and at any other time the patient or HCP thought was appropriate. Whether holistic needs assessment is achievable in practice remains an area of investigation [302], with time pressures, limited resources and the challenge of integrating the practice into existing care pathways to overcome [303]. If the assessment does become routine for all cancer patients, then it will be important for HCPs to be able to refer patients to specialist supportive services when more complex concerns arise.

10.4 Limitations and further work

Most of the work described in this thesis, with the exception of the development of the EORTC QLQ-CAX24, has been carried out at one site in the UK. Participants in the development, piloting and feasibility studies lacked diversity in terms of age range, socioeconomic status and ethnicity. The same lack of diversity is also evident in the literature which contributed to the workshop development. This draws into question whether the workshop will be applicable to patients and carers from other sociodemographic groups. Further work will be required to explore this. However, the central role of food in everyday life and its importance beyond nourishment are universal [157]. Families with a member who has poor appetite and unintentional weight loss are likely to require support, irrespective of other circumstances. The workshop may be the tool which can be used to do this.

As well as the lack of diversity in sociodemographic terms, the vast majority of carers who took part in the research were women. To some extent this reflects the figures in the UK for carers of cancer patients in general, were 68% of carers are women [61]. Although there is currently no evidence that the experience of being a carer for someone with cancer cachexia is any different for males and females, this is a possibility. Further research will be required to explore whether there are any differences, and if so whether they impact the acceptability and/or the effectiveness of the workshop.

Health literacy, defined by WHO as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"[304] of the research participants was not explored directly. There is no reason to believe that this was a problem for any of the participants but it would be useful to explore the acceptability and efficacy of the workshop with a group of participants with low health literacy, given that adequate health literacy is generally viewed as a pre-requisite for successful self-management [305].

The papers which were included in the systematic reviews exploring the impact of cancer cachexia on patients and carers (Chapter 3) were published between 1991 and 2011, so it is important to consider whether the experience of cancer cachexia has changed for patients and carers in that time. There is no evidence from the interviews conducted during the course of this PhD that this is the case. The concerns and issues raised mirrored those identified in the earlier body of work. Some families still feel that unintentional weight loss is not addressed by HCPs, even though this is very worrying for families. Beth, a participant in the feasibility study described the rapid weight loss her husband was experiencing and the perceived lack of support from professionals, "Sometimes he's losing a pound a day but I don't think I can get anyone to take it seriously enough." If the HCPs that patients and their carers come into contact with do not address eating difficulties and weight loss, then some families will turn to other sources of information. For example, Fay, another feasibility study participant, found the ketosis diet on the internet and encouraged her husband, Eric, to follow it.

The establishment of cancer cachexia clinics can improve knowledge and understanding of cachexia across hospitals, not just for the referred patients [306]. This may provide HCPs with the confidence to discuss cachexia-related issues with families, even if the patient is not referred to the cancer cachexia clinic. Although not common, there are a small number of published reports on cancer cachexia clinics in Australia, Canada, USA and the UK [19,211,306-311]. A multi-disciplinary approach is taken, often including palliative care doctors and nurses, physiotherapists dietitians and social workers. Typically, the clinics have been established and championed by a senior clinician with an interest in cancer cachexia. However, even in the countries where these clinics have been established, there does not seem to be a strategy for widespread adoption. It may be that by promoting a proactive, rather than reactive, approach to cancer cachexia, the effectiveness of interventions can be demonstrated more convincingly, which will then lead to more extensive implementation.

Throughout the research, patients were defined as cachectic on the basis of unintentional weight loss, often self-reported. This approach was taken for pragmatic reasons but the result is that the participants may comprise a non-homogeneous sample with respect to the cause of their weight loss. It may be that this is not important from the perspective of workshop attendees. For people attending the workshop because they have eating difficulties and unintentional weight loss, what is important is how to cope with these problems. From a research point of view, it may be important to be able to categorise participants in case the workshop is less effective with different groups. However, in clinical practice, the problems remains that diagnosing cachexia is not straightforward and clinicians may share the same perspective as participants in terms of who may find the workshop beneficial.

One difficulty with trying to evaluate the potential benefit of the workshop in clinical practice is that it was being delivered in the context of a research project, separate from the usual care offered by the hospital. Participants had to fill out forms, questionnaires and have interviews, and clinicians could not simply refer patients and carers to the workshop. There is a risk of selection bias because of the added burden of workshop attendance in the context of a research study.

Unfortunately, there was no mechanism to monitor recruitment. It is not known how many people were invited to participate and why eligible people declined so whether it was the workshop itself that people did not want to attend, or whether it was the fact that it was in the context of a research project cannot be ascertained. For the future workshop RCT, it will be a real challenge to try and collect enough data to demonstrate efficacy, whilst minimising the burden of taking part in a research project. Linked in with this is that in the feasibility study, in general, arbitrary changes in scores were selected to indicate change, but there was no evidence that these changes were clinically meaningful. Streamlining the research measures used, whilst ensuring there is evidence of clinical benefit, will be another hurdle in the development of the workshop RCT protocol.

The feedback on the workshop in both the piloting and feasibility studies was very positive. However, participants were all aware that SW had developed the workshop and SW collected the pre and post-workshop data, including the feedback forms. Even though participants were strongly encouraged to provide feedback about how the workshop could be improved, they may have felt inhibited about giving anything but positive comments. It would be beneficial if a different researcher, who could be identified by participants as separate from the research team, could collect feedback about improvements to the workshop.

The final limitation was that there was no health economic evaluation component included in the research. Development of the appropriate HE approach will form part of the protocol development process for the RCT.

10.5 Conclusion

Cancer cachexia is a challenge to identify clinically, particularly in the age of obesity, but early intervention is essential to maximise treatment potential. The workshop developed in this thesis is a tool which, along with other supportive interventions, could help cancer patients maintain or even improve HRQOL. By including carers at this early stage, their role in supporting the patient and the importance of their own QOL is established and some of the psychosocial issues which can arise may be avoided. Establishing the effectiveness of the workshop for patients and carers requires further research, and this will demand the active engagement of oncologists and other clinicians to ensure adequate recruitment. With limited resources, clinicians and commissioners need compelling evidence that early palliative care can improve outcomes. Researchers in this field need to work with clinicians to provide that evidence.

Appendix A European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines on nutrition in cancer patients

The 21 guidelines which start with the letter B are applicable to all cancer patients; the 22 starting with the letter C are interventions which are relevant to specific patient categories, e.g. post-surgery, survivors.

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
B1 - 1	To detect nutritional disturbances at an early stage, we recommend to regularly evaluate nutritional intake, weight change and BMI, beginning with cancer diagnosis and repeated depending on the stability of the clinical situation.	very low	strong	strong
B1 - 2	In patients with abnormal screening, we recommend objective and quantitative assessment of nutritional intake, nutrition impact symptoms, muscle mass, physical performance and the degree of systemic inflammation.	very low	strong	consensus
B2 - 1	We recommend, that total energy expenditure of cancer patients, if not measured individually, be assumed to be similar to healthy subjects and generally ranging between 25 and 30 kcal/kg/day.	low	strong	consensus
B2 - 2	We recommend that protein intake should be above 1 g/kg/day and, if possible up to 1.5 g/kg/day	moderate	strong	strong

Appendix A

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
B2 – 3	In weight-losing cancer patients with insulin resistance we recommend to increase the ratio of energy from fat to energy from carbohydrates. This is intended to increase the energy density of the diet and to reduce the glycemic load	low	strong	consensus
B2 - 4	We recommend that vitamins and minerals be supplied in amounts approximately equal to the RDA and discourage the use of high-dose micronutrients in the absence of specific deficiencies.	low	strong	strong
B3 - 1	We recommend nutritional intervention to increase oral intake in cancer patients who are able to eat but are malnourished or at risk of malnutrition. This includes dietary advice, the treatment of symptoms and derangements impairing food intake (nutrition impact symptoms), and offering oral nutritional supplements.	moderate	strong	consensus
B3 - 2	We recommend to not use dietary provisions that restrict energy intake in patients with or at risk of malnutrition.	low	strong	strong
B3 - 3	If a decision has been made to feed a patient, we recommend enteral nutrition if oral nutrition remains inadequate despite nutritional interventions (counselling, ONS), and parenteral nutrition if enteral nutrition is not sufficient or feasible.	moderate	strong	strong

	Recommendation	Level of evidence	Strength of recommendation	Consensus
B3 - 4	If oral food intake has been decreased severely for a prolonged period of time, we recommend to increase (oral, enteral or parenteral) nutrition only slowly over several days and to take additional precautions to prevent a refeeding syndrome.	low	strong	consensus
B3 - 5	In patients with chronic insufficient dietary intake and/or uncontrollable malabsorption, we recommend home artificial nutrition (either enteral or parenteral) in suitable patients	low	strong	strong
B4 - 1	We recommend maintenance or an increased level of physical activity in cancer patients to support muscle mass, physical function and metabolic pattern.	high	strong	consensus
B4 - 2	We suggest individualized resistance exercise in addition to aerobic exercise to maintain muscle strength and muscle mass.	low	weak	strong
B5 - 1	We suggest considering corticosteroids to increase the appetite of anorectic cancer patients with advanced disease for a restricted period of time (1-3 weeks) but to be aware of side effects (e.g. muscle wasting, insulin resistance, infections).	high	weak	consensus
B5 - 2	We suggest considering progestins to increase the appetite of anorectic cancer patients with advanced disease but to be aware of potential serious side effects (e.g. thromboembolism).	high	weak	consensus

	Recommendation	Level of evidence	Strength of recommendation	Consensus
B5 - 3	There are insufficient consistent clinical data to recommend cannabinoids to improve taste disorders or anorexia in cancer patients	low	no recommendation	consensus
B5 - 4	There are insufficient consistent clinical data to recommend currently approved androgenic steroids to increase muscle mass	low	no recommendation	consensus
B5 - 5	There are insufficient consistent clinical data to recommend the supplementation with branched-chain or other amino acids or metabolites to improve fat free mass.	low	no recommendation	strong
B5 - 6	There are insufficient consistent clinical data to recommend non-steroidal anti-inflammatory drugs to improve body weight in weight losing cancer patients.	low	no recommendation	strong
B5 - 7	In patients with advanced cancer undergoing chemotherapy and at risk of weight loss or malnourished, we suggest to use supplementation with long-chain N-3 fatty acids or fish oil to stabilize or improve appetite, food intake, lean body mass and body weight.	low	weak	strong
B5 - 8	In patients complaining about early satiety, after diagnosing and treating constipation, we suggest to consider prokinetic agents, but to be aware of potential adverse effects of metoclopramide on the central nervous system and of domperidone on cardiac rhythm	moderate	weak	consensus

	Recommendation	Level of evidence	Strength of recommendation	Consensus
C1 - 1	For all cancer patients undergoing either curative or palliative surgery we recommend management within an enhanced recovery after surgery (ERAS) program; within this program every patient should be screened for malnutrition and if deemed at risk, given additional nutritional support.	high	strong	consensus
C1 - 2	For a patient undergoing repeated surgery as part of a multimodal oncological pathway, we recommend management of each surgical episode within an ERAS program.	low	strong	consensus
C1 - 3	In surgical cancer patients at risk of malnutrition or who are already malnourished we recommend appropriate nutritional support both during hospital care and following discharge from hospital.	moderate	strong	consensus
C1 - 4	In upper GI cancer patients undergoing surgical resection in the context of traditional perioperative care we recommend oral/enteral immunonutrition.	high	strong	strong
C2 - 1	We recommend that during radiotherapy (RT) with special attention to RT of the head and neck, thorax and gastrointestinal tract e an adequate nutritional intake should be ensured primarily by individualized nutritional counseling and/or with use of oral nutritional supplements (ONS), in order to avoid nutritional deterioration, maintain intake and avoid RT interruptions	moderate	strong	strong

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
C2 - 2	We recommend enteral feeding using naso-gastric or percutaneous tubes (e.g. PEG) in radiation-induced severe mucositis or in obstructive tumors of the head-neck or thorax.	low	strong	strong
C2 - 3	We recommend to screen for and manage dysphagia and to encourage and educate patients on how to maintain their swallowing function during enteral nutrition.	low	strong	strong
C2 - 4	There are insufficient consistent clinical data to recommend glutamine to prevent radiation-induced enteritis/diarrhea, stomatitis, esophagitis or skin toxicity.	low	no recommendation	strong
C2 - 5	There are insufficient consistent clinical data to recommend probiotics to reduce radiation-induced diarrhea.	low	no recommendation	strong
C2 - 6	We do not recommend parenteral nutrition (PN) as a general treatment in radiotherapy but only if adequate oral/enteral nutrition is not possible, e.g. in severe radiation enteritis or severe malabsorption	moderate	strong	consensus
C3 - 1	During anticancer drug treatment we recommend to ensure an adequate nutritional intake and to maintain physical activity.	very low	strong	strong

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
C3 - 2	In a patient undergoing curative anticancer drug treatment, if oral food intake is inadequate despite counselling and ONS, we recommend supplemental enteral or, if this is not sufficient or possible, parenteral nutrition.	very low	strong	consensus
C3 - 3	There are insufficient consistent clinical data to recommend glutamine supplementation during conventional cytotoxic or targeted therapy.	low	no recommendation	strong
C4 - 1	During intensive chemotherapy and after stem cell transplantation we recommend to maintain physical activity and to ensure an adequate nutritional intake. This may require enteral and/or parenteral nutrition	very low	strong	strong
C4 - 2	If oral nutrition is inadequate we suggest preferring enteral tube feeding to parenteral nutrition, unless there is severe mucositis, intractable vomiting, ileus, severe malabsorption, protracted diarrhoea or symptomatic gastrointestinal graft versus host disease (GvHD).	low	weak	strong
C4 - 3	There are insufficient consistent clinical data to recommend a low bacterial diet for patients more than 30 days after allogeneic transplantation	low	no recommendation	strong

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
C4 - 4	There are insufficient consistent clinical data to recommend glutamine to improve clinical outcome in patients undergoing high-dose chemotherapy and hematopoetic stem cell transplantation.	low	no recommendation	strong
C5 - 1	We recommend that cancer survivors engage in regular physical activity.	low	strong	consensus
C5 - 2	In cancer survivors we recommend to maintain a healthy weight (BMI 18.5-25 kg/m^2) and to maintain a healthy lifestyle, which includes being physically active and a diet based on vegetables, fruits and whole grains and low in saturated fat, red meat and alcohol.	low	strong	strong
C6 - 1	We recommend to routinely screen all patients with advanced cancer for inadequate nutritional intake, weight loss and low body mass index, and if found at risk, to assess these patients further for both treatable nutrition impact symptoms and metabolic derangements.	low	strong	consensus
C6 - 2	We recommend offering and implementing nutritional interventions in patients with advanced cancer only after considering together with the patient the prognosis of the malignant disease and both the expected benefit on quality of life and potentially survival as well as the burden associated with nutritional care.	low	strong	consensus

	Recommendation	**Level of evidence**	**Strength of recommendation**	**Consensus**
C6 - 3	In dying patients, we recommend that treatment be based on comfort. Artificial hydration and nutrition are unlikely to provide any benefit for most patients. However, in acute confusional states, we suggest to use a short and limited hydration to rule out dehydration as precipitating cause.	low	strong	strong

Appendix B Summary of European Palliative Care Research Collaborative Recommendations

Treatment	**Recommendation**
Enteral nutrition therapy	May be partially effective for selected patient groups. Provision of appetising food & enteral nutritional support in a context that does not add to eating-related distress recommended for refractory cachexia.
Parenteral nutrition therapy	Rarely beneficial. Burden will likely out-weight benefits.
Supplements, vitamins and minerals	Not enough evidence for general recommendation.
Nutritional counselling or education	Some evidence that counselling has positive effects on nutritional status and quality of life in cancer patients undergoing anti-neoplastic therapy but evidence for advanced cancer/refractory cachexia is lacking.
Psychotherapeutic interventions	Some evidence that relaxation therapy has positive effects on quality of life. No evidence of effect on nutritional status. For refractory cachexia, reduced performance status & short prognosis may preclude this intervention.
Physical training and other physical interventions	Beneficial as a preventive procedure to maintain functional status. No evidence that is appropriate in patients with advanced cancer/refractory cachexia.
Thalidomide and cytokine antagonists	Not enough evidence

Treatment	**Recommendation**
Cannabinoids	Not enough evidence
Omega-3-fatty acids, including EPA	Not enough evidence.
Megestrol and progestins	Seem to stimulate appetite and increase body weight, though not muscle mass. Progestins should be considered for patients with refractory cachexia if anorexia is a major distressing symptom.
Steroids	Recommended for short periods (maximal 2 weeks) for appetite stimulation and to improve quality of life.
Non-steroidal anti-inflammatory drugs	No evidence of benefit when offered alone.
Prokinetics	Recommended for patients with early satiety, chronic nausea, dyspeptic symptoms & gastroparesis.
Anticancer treatment	Use of palliative anti-cancer treatment should be considered very carefully for cachectic patients who have progressed through anticancer treatment. Not recommended for patients with refractory cachexia.
Multimodal therapy	Should be offered as combination of nutrition, medication and non-drug-treatment may be more effective than monotherapy. More research needed to evaluation the concept and also for cachexia.
Prophylaxis	Not relevant for patients with refractory cachexia but patients at risk should be offered prophylactic interventions e.g. nutritional counselling, physical training

Appendix C Advisory panel recruitment poster

UNIVERSITY OF Southampton

University Hospital Southampton NHS
NHS Foundation Trust

Developing a workshop for cancer patients with weight loss & their carers

Help design a research project

- Are you a cancer patient with unintentional weight loss?
- Or are you caring for a loved one with cancer and unintentional weight loss?
- A research team based at Southampton General Hospital is developing a workshop & would like your help to do this

How? Give your views by email, phone or in person on
1. How the research is done
2. Workshop content & how this is presented
3. The best way of recruiting research project volunteers

Interested? Or want to know more?

Contact Sally Wheelwright

s.j.wheelwright@soton.ac.uk ☎ 023 8120 4308

Appendix D Full Medline search strategy for carer systematic review

1. Neoplasms/

2. cancer.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3. palliative.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

4. tumour.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

5. tumor.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

6. malignancy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

7. cachexia.mp. or Cachexia/

8. Anorexia/ or anorexia.mp.

9. weight loss.mp. or exp Weight Loss/

10. Systemic Inflammatory Response Syndrome/

11. systemic inflammation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

12. food.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

13. wasting syndrome.mp. or Wasting Syndrome/

14. appetite.mp. or Appetite/

15. malnutrition.mp. or Malnutrition/

16. sarcopenia.mp. or Sarcopenia/

17. muscle wasting.mp.

18. Eating/ or eating.mp.

19. nutritional assessment.mp. or Nutrition Assessment/

20. emaciation.mp. or Emaciation/

21. nutrition.mp.

22. anorexia-cachexia.mp.

23. quality of life.mp. or "Quality of Life"/

24. QOL.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

25. QL.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

26. HRQOL.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

27. HRQL.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

28. subjective health status.mp.

29. reported outcome.mp.

30. psychosocial.mp.

31. qualitative research.mp. or Qualitative Research/

32. Interview/ or interview.mp.

33. questionnaire.mp. or "Surveys and Questionnaires"/

34. emotion.mp. or Emotions/

35. emotional impact.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

36. distress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

37. anxiety.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

38. fear.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

39. manage.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

40. experience*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

41. impact*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

42. perception*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

43. belief*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

44. fight*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

45. response*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

46. concern*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

47. challenge*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

48. caregiver.mp. or Caregivers/

49. carer.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

50. family.mp. or Family/

51. partner.mp.

52. spouse.mp. or Spouses/

53. husband.mp.

54. wife.mp.

55. brother.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

56. sister.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

57. sibling.mp. or Siblings/

58. daughter.mp.

59. son.mp.

60. parent.mp. or Parents/

61. mother.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

62. father.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

63. friend.mp. or Friends/

64. relative.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

65. 1 or 2 or 3 or 4 or 5 or 6

66. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22

67. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47

68. 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64

69. 65 and 66 and 67 and 68

Appendix E Phase 1a patient interview schedule for development of EORTC module

Opening remarks: *We are asking for your help to develop a questionnaire for patients with cancer who have been losing weight or have difficulty in eating. As you probably know, this is a common problem for people with cancer. Can you tell me about your experience of weight loss?*

Further prompts: only use if patient is unable to volunteer any information. There is no need to use the headings.

Eating difficulties

- Please describe any problems you have had with eating and drinking.
- Can you tell me about changes to your appetite?
- How have mealtimes changed?

Weight loss

- Are there things you can no longer physically do (because of your weight loss)?
- What do you think about your weight loss?
- What do you think about the way you look?
- How else has weight loss changed your life?

Relationships

- Tell me about how your family and friends have reacted to your weight loss.
- How has your social life been affected?
- Tell me about the advice and support you have had from doctors and nurses.

Closing remarks: *Is there anything else you haven’t mentioned that you think is relevant?*

Appendix F Symptom checklist

I have had the following problems that have kept me from eating enough during the past two weeks:

	Not at All	A Little	Quite a Bit	Very Much
1. No appetite, just did not feel like eating	1	2	3	4
2. Nausea	1	2	3	4
3. Constipation	1	2	3	4
4. Mouth sores (stomatitis)	1	2	3	4
5. Things taste funny or have no taste	1	2	3	4
6. Problems swallowing	1	2	3	4
7. Abdominal/stomach pain	1	2	3	4
8. Other pain:	1	2	3	4
where?____________________________				
9. Vomiting	1	2	3	4
10. Diarrhoea	1	2	3	4
11. Dry mouth	1	2	3	4
12. Smells bother me	1	2	3	4
13. Feels full quickly	1	2	3	4
14. Defecation after meals	1	2	3	4
15. Shortness of breath	1	2	3	4
16. Fatigue	1	2	3	4
17. Other reason:	1	2	3	4
what?_____________________________				

Appendix G Combined HRQOL issue list from literature review and patient interviews

Issue	Description
Importance of maintaining independence	Wanting to remain independent
Keeping going	Keeping working or doing other activities despite feeling ill
Maintaining normality	Acting like things are as normal as possible
Personal responsibility	Taking control by managing own eating habits
Slowing down	Things take longer to do
Appearance	Upset by change in appearance and other people's reaction
Clothes too big	Patients know they are losing weight because their clothes are too big
Feeling less attractive	Feeling less attractive
Feeling old	Feels old or thinks look old
Loss of self-identity	Change in appearance means does not recognise self in mirror
Positive body image	Satisfied with being thin
Acknowledging importance of dietary intake	Recognising importance of eating to keep strength up
Altered appetite	Altered appetite
Aversions	Put off food by smell, portion size, thought of it or particular types (e.g. meat)
Binge eating	Binge eating until vomits or experiences pain
Change in eating habits	Change in pattern of eating
Early satiety	Feels full up after little food
Eating as a chore	Eating is hard work, forcing self to eat

Feels full all the time	Feels full all the time
Fluctuating appetite	Appetite unpredictable and changes throughout day and week
Hungry	Is hungry but can not eat
No hunger	Does not feel the need for food
No pleasure from eating	Food as a fuel rather than something which is enjoyed.
Reduced intake	Food intake has declined
Restricted diet	Bored with diet since enjoys limited foods
Skipping meals	Missing meals
Smaller portions	Patient can only manage small portions of food
Thinks alot about what to eat	Thinks alot about what to eat
Unable to eat	Does not feel able to eat anymore
Dental problems	Dental problems make mouth sore making it difficult to eat
Difficulty drinking	Problems with process of drinking
Dribbling	Dribbling
Dry mouth	Dry mouth
Food preference changes	A change in what the patient prefers to eat. Often related to changes in taste.
Gastrointestinal dysfunction	Unable to eat because of gastrointestinal dysfunction
Heartburn	Heartburn
Mechanical difficulties	Physical difficulties with eating, chewing or swallowing
Metallic taste	Has metallic taste when eating
Smell and taste changes	Change to the way food smells and/or tastes
Stomach sensations	More aware of stomach and strange perceptions
Texture	Texture of food unpleasant
Acceptance of change	That things have changed and that they can not eat as much as they used to be able to

Acceptance of terminal decline	Patient knows that they are going to die and they believe that weight loss is to do with this
Death coming too soon	Too young to die
Egocentric	Completely focussed on self
Embarrassed by eating	Embarrassed by method of eating or size of portions
Erosion of mental faculties	Can't think straight anymore
Feeling depersonalised	Being referred to in a depersonalising way
Given up	Lost the will to fight
Hope	Keeping hope alive that things will improve or a miracle cure will be found
Hopelessness	No sense of hope
Hoping	Hoping things will get better
Loss of self esteem	Loss of self esteem
Missing past experiences	Feelings of loss about past experiences that can no longer enjoy
Scared	Scared and frightened by what is happening
Wants normal life	Wants a normal life
Waste of food distressing	Patients find waste of food distressing
Worry about food costs	The "right" foods are too expensive and lots of food wasted.
Concern for family	Worried about causing stress for family and increasing their work load
Discussing with friends	Discussing problems with friends
Dreading mealtimes	Dreading mealtimes because of family tensions or because worried about feeling bad afterwards
Eating to please others	Not hungry but eating to please others (usually family)
Feeling pressured	Feeling angry because others (family, friends, HCPs) suggesting should eat more

Hiding appetite loss	Hiding full extent of appetite loss from others
Meal times not pleasurable	Meals no longer pleasurable social events
Not burdening others	Does not want to impose on carers
Others as catalyst for eating	Finds eating with others helps appetite
Prefers eating with others	Prefers eating with others
Problems eating with others	Does not want to eat with other people
Protecting family	Trying to protect family from the visible changes of their weight loss
Social isolation at home	Eating alone
Supportive family	Appreciates family trying to do their best
Taboo subject	People avoid talking about weight loss
Unwanted attention	Embarrassment caused by attention from people
Unwelcome concern from friends	Friends and acquaintances expressing concern which is not well received
Lack of HCP acknowledgement	HCPs do not talk about weight loss or eating problems
Lack of information from HCP	Information from HCPs is perceived as lacking or unsatisfactory
Lack of knowledge	Angry that nobody knows anything about the weight loss
Amount of weight loss unpredictable	The unpredictable relationship between food intake and weight loss is difficult to understand
Denial of weight loss	Choosing not to think about weight loss
Embarrassed by weight loss	Feeling uncomfortable about weight loss
Futility of monitoring weight	Patient feels can not modify behaviour if losing weight so there's no point in monitoring it.
Monitoring weight	Regular self-monitoring of weight
No control over weight	Disease controls weight rather than the patient
Shock over weight loss	Surprise at weight loss and its effects

Sign of impending death	Weight loss symbolizes approaching death
Weight as health barometer	Weight loss viewed as prognostic
Weight as power indicator	Thinks if gained a bit of weight would have more strength
Weight loss difficult to understand	Does not understand why weight loss is happening
Worried about weight loss	Concern and distress regarding weight loss

Appendix H Provisional EORTC module

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
31. Have you felt hungry?	1	2	3	4
32. Have you been unable to eat despite wanting to?	1	2	3	4
33. Have food and drink tasted different from usual?	1	2	3	4
34. Have you found the texture of food unpleasant?	1	2	3	4
35. Have you been put off eating by the thought of food?	1	2	3	4
36. Have you been put off eating by the smell of food?	1	2	3	4
37. Have you been put off eating by having too much food on your plate?	1	2	3	4
38. Have changes in what you like to eat been a problem for you?	1	2	3	4
39. Has a changeable appetite been a problem for you?	1	2	3	4
40. Have you been missing past experiences related to food or eating?	1	2	3	4
41. Have you had difficulty doing your usual activities because of your weight loss?	1	2	3	4
42. Have you been too tired to eat?	1	2	3	4
43. Have you been in too much pain to eat?	1	2	3	4
44. Have you felt full too quickly after beginning to eat?	1	2	3	4
45. Have you had problems drinking liquids?	1	2	3	4
46. Have you had a dry mouth?	1	2	3	4
47. Have you had problems chewing?	1	2	3	4

Please continue on the next page

	Not at all	**A little**	**Quite a bit**	**Very much**
48. Have you had problems swallowing?	1	2	3	4
49. Have you had indigestion or heartburn?	1	2	3	4
50. Have you worried that you do not eat enough?	1	2	3	4
51. Have you worried about your weight loss?	1	2	3	4
52. Have you been preoccupied with food and eating?	1	2	3	4
53. Has your outlook on the future worsened?	1	2	3	4
54. Have you worried about what will happen if you continue to lose weight?	1	2	3	4
55. Have you enjoyed mealtimes as social events?	1	2	3	4
56. Have you felt supported by those close to you (e.g. family, friends)?	1	2	3	4
57. Have you felt pressured by other people to eat more?	1	2	3	4
58. Have you worried that you are a burden to other people?	1	2	3	4
59. Have you had problems with eating in front of other people?	1	2	3	4
60. Have you felt embarrassed by your eating?	1	2	3	4
61. Have you felt embarrassed by your weight loss?	1	2	3	4
62. Have you been upset by how you see yourself?	1	2	3	4
63. Have you worried about your appearance?	1	2	3	4
64. Have you been upset by changes to your role in life?	1	2	3	4
65. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
66. Have you felt uncomfortable about being sexually intimate?	1	2	3	4
67. Have you felt your weight loss was out of control?	1	2	3	4
68. Have you worried about changes in your daily life?	1	2	3	4

Please continue on the next page

	Not at all	A little	Quite a bit	Very much
69. Have you worried that you might lose your independence?	1	2	3	4
70. Have you forced yourself to eat?	1	2	3	4
71. Have you tried to avoid thinking about your weight loss?	1	2	3	4
Since you have been ill:				
72. Have you accepted the changes in your eating?	1	2	3	4
In the last four weeks:				
73. Has the information you have been given about your weight loss been adequate?	1	2	3	4
74. Have you received adequate support for problems related to your weight loss from health care professionals?	1	2	3	4

THANK YOU FOR YOUR HELP

Appendix I Consultation email to advisory panel members

Dear NAME,

Thank you for agreeing to be a member of the advisory panel to help develop a workshop for cancer patients with unintentional weight loss and their carers. The first task for the advisory panel is to agree on the ‘problem statement’, which will form the basis of the interviews to inform workshop content. The suggested problem statement is:

People with cancer often have unintentional weight loss. The person with cancer and their carer may find this difficult.

I will show this statement to patients, carers and health care professionals and ask them to suggest reasons for the problem and what they think the root causes are. I will then summarise all the ideas and ask the advisory panel to agree which problems the workshop should focus on addressing.

Are you happy with this statement or can you suggest something else? Please get in touch (by email or phone) with your thoughts by Monday 23 March. If you want to discuss the task or have any questions, please email or phone. If I don’t hear from you, I will assume that you are happy with the problem statement.

Many thanks,

Sally

Appendix J Interview template for workshop content interviews

Welcome

Thank you for agreeing to take part in this project.

Introductory remarks to explain nature and purpose of study.

We are asking for your help in thinking about what are the root causes of

“People with cancer often have unintentional weight loss. This can be difficult for the person with cancer and their carer.”

i.e. Why is it difficult? We are asking patients, carers and health care professionals this same question. We will use the ideas to help develop a workshop for cancer patients with weight loss and their carers.

Issue of confidentiality

We will make every effort to ensure the information provided by you will be kept confidential. We will not identify any individual by name in our findings. You will remain anonymous.

Mapping the problem

The problem statement will be placed on the right hand side of a PowerPoint slide. Through a series of ‘why’ questions (‘why does this problem occur; why does this condition occur?’), *the facilitator will map out the interviewee’s understanding of the problem, placing the root causes (antecedents) identified to the left of the problem statement. As antecedent conditions are mentioned by the interviewee, causal linkages are mapped out. The interviewee can modify these causal linkages at any time. When the interviewee is satisfied with the map they have created, the facilitator and interviewee reviews the antecedent conditions with the interviewee by using ‘if-then’ statements, working from left to right. All interviewees will be asked to create one map for patients and one map for carers.*

Additional prompts (if required)

You could think about practical issues relating to meals & food preparation, emotional issues (patient and carer feelings), issues relating to getting support and information from outside the home. You could also think about the impact on the relationship between the patient and carer.

Closing remarks

Can you think of anything else you would like to say about the topics we have covered today? Thank you for your contribution.

Appendix K Workshop therapeutic story

Tom and Joan's Story

When I first met Tom he was feeling helpless & frustrated. His wife Joan, who had advanced cancer, was very frail and needed help with most things. He was tired with helping her wash and dress, helping her to the toilet, helping her into bed at night. He missed her company because she was too weak to talk much. But mostly he felt angry and helpless because she would not eat. If only he could get her to eat then she would have the energy to overcome all her other problems.

Tom went to great trouble trying to find out what Joan might like to eat. He prepared proper homemade meals and presented them with great attention to detail. He would help Joan to the table, where she might just eat a single mouthful and declare herself to be full. He felt that it was not just the food that was being rejected, but that he was being rejected. He felt he was trying so hard to improve their lives yet she was trying so little and no longer loved him.

Tom was someone who cared about his wife very much, but did not understand what was happening to her.

Talking to Joan it was clear that she did still care about her husband. It was her cancer that was preventing her from eating. It caused her to have a feeling of fullness all the time that became a feeling of nausea when she ate anything. Yet she had been unable to find a way of explaining this to her husband. She had come to dread mealtimes, but not because of the nausea. She dreaded mealtimes because of the anger and frustration her husband would express. He would shout and cry because she would not eat.

Once Tom realised it was the cancer that was stopping his wife eating, he began to wonder what it may be like to have no appetite. He began to think about how he could do things differently.

He bought himself ready prepared meals from the supermarket so that he didn't need to spend a lot of time cooking and washing up. He would offer his wife a little of his own meal and found that if it took her fancy, she preferred to take one or two spoonfuls from his own plate until she felt full. He also bought yoghurts and cold puddings as Joan would enjoy a little of these, and made her Build-Up drinks that she found easier to take than meals. They enjoyed more time together. They were able to go for short walks with the aid of a wheelchair and spend time looking at photographs of times they had enjoyed in the past. But most importantly, they had freed themselves from the dinner table argument routine, as Tom had come to realise his wife was eating well given her situation.

Appendix L Workshop changes form

Changes Form

As a result of this workshop, will you do anything different?

Yes ○ No○

If yes, please write down what you will now do differently in the most appropriate box.

You can write down as many changes as you like.

Diet
Eating habits
Interactions with loved ones
Other

Appendix M Template for pre-workshop interviews

Welcome

Thank you for agreeing to take part in this interview.

Introductory remarks to explain nature and purpose of study.

We are asking for your help in the development of a workshop for people with cancer and weight loss and their carers. We are interested in eating and weight loss, and how these affect your life. We will talk to you about this again a few weeks after you have done the workshop.

Issue of confidentiality

We will make every effort to ensure the information provided by you will be kept confidential. We will not identify any individual by name in our findings. You will remain anonymous. We wish to tape record the conversations in order to capture everything that is discussed.

Eating difficulties & weight loss (patient question)

Please describe any problems you have had with eating and drinking. Can you tell me about changes to your appetite? How have mealtimes changed? Are there things you can no longer physically do (because of your weight loss)? What do you think about your weight loss? What do you think about the way you look? How else has weight loss changed your life?

Patient eating difficulties & weight loss and carer emotions (carer question)

Please describe any problems [patient's name] has had with eating and drinking. How does this make you feel? Can you tell me about changes to [patient's name] appetite. How does this make you feel? How have mealtimes changed? Are there things [patient's name] can no longer physically do (because of the weight loss)? How does this affect you? How do you feel about [patient's name] weight loss?

Impact on everyday life (carer question)

Have there been any changes to your own diet or eating patterns as a result of changes in [patient's name]? Have there been any changes to the amount of time and effort you put into fool related activities, such as shopping, meal planning, cooking (what)?

Relationships (patient question)

Tell me about how your family and friends have reacted to your weight loss. How has your social life been affected? What things does your carer do in relation to food which you find helpful and what is not so helpful? Can you tell me about any disagreements you and your carer have had about food or eating.

Relationships (carer question)

Has your relationship with [patient's name] been affected? In what way? Can you tell me about any disagreements you and [patient's name] have had about food or eating?

Coping

How are you adapting to changes in your (or [patient's name]) eating and/or weight? What strategies are you using to cope with the changes?

Knowledge

Why do you think you (or [patient's name]) have lost weight? Do you feel that you have adequate information about eating and weight loss? Tell me about the advice and support you have had from doctors and nurses. How do you feel about asking doctors and nurses about these issues?

Closing remarks

Can you think of anything else you would like to say about the topics we have covered today? Thank you for your contribution.

Appendix N Template for post-workshop interviews

Introductory remarks to explain nature and purpose of study.

Thank you for agreeing to take part in this interview. We are asking for your help in the development of a workshop for people with cancer and weight loss and their carers. Today we are interested in checking whether you found the workshop helpful.

Issue of confidentiality

We will make every effort to ensure the information provided by you will be kept confidential. We will not identify any individual by name in our findings. You will remain anonymous. We wish to tape record the conversations in order to capture everything that is discussed.

Eating difficulties & weight loss (patient question)

Can you tell me about any changes to your eating and drinking since you attended the workshop? Have mealtimes changed at all (how)? How do you feel about your weight loss now? How do you feel about your appearance now?

Patient eating difficulties & weight loss and carer emotions (carer question)

Have there been any changes to [patient's name] eating and drinking since the workshop? How do you feel about this? Have there been any changes to mealtimes? Have there been any changes to what [patient's name] can physically do (because of the weight loss)? How does this affect you? How do you feel about [patient's name] weight loss now?

Impact on everyday life (carer question)

Have there been any changes to your own diet or eating since the workshop? Have there been any changes to the amount of time and effort you put into fool related activities, such as shopping, meal planning, cooking (what)?

Relationships

Have there been any changes in your relationship with your carer (or [patient's name]) since you attended the workshop? Have there been any changes in what you/your carer does in relation to food? Can you tell me about any disagreements you and your carer (or [patient's name]) are having now about food or eating?

Coping

What strategies are you using to cope with (or [patient's name]) weight loss and eating difficulties now? Did you get any new ideas for coping from the workshop?

Knowledge

Do you feel that the workshop answered all your questions about eating and weight loss? Was there any information missing?

Workshop

Have you looked at the leaflets we gave you? Were they useful? Would you recommend the workshop to other people in your position?

Closing remarks

Can you think of anything else you would like to say about the topics we have covered today?
Thank you for your contribution.

Appendix O Workshop evaluation form

1. How did you find the length of the workshop?

much too short ☐ too short ☐ about right ☐ too long ☐ much too long ☐

2. How easy was it for you to understand the information you heard today?

very easy ☐ easy ☐ neutral ☐ not easy ☐ difficult ☐

3. How did you find the pace of the workshop?

much too slow ☐ too slow ☐ about right ☐ too fast ☐ much too fast ☐

4. Was the workshop held at a convenient time and day?

Yes ☐

No ☐ If no, when would be better?____________________________________

5. Was the location of the workshop convenient?

Yes ☐

No ☐ If no, why not and where would be better?______________________________

____

6. The workshop today included people with cancer and carers together. Do you think people with cancer and carers should have separate workshops?

Separate ☐

Together ☐

7. Was there anything you found particularly helpful about the workshop?

Yes ☐ If yes, please comment____

No ☐

8. Was there any topic <u>not</u> covered which you think should have be included in the workshop?

Yes ☐ If yes, please comment____

No ☐

9. Was there anything about the content of the workshop that you did not like?

Yes ☐ If yes, please comment____

No ☐

10. Was there anything else about the workshop that you did not like?

Yes ☐ If yes, please comment____

No ☐

If you have any other comments or ideas for how the workshop could be improved, please write them here.

Appendix P Advice questionnaire

People with cancer are often given advice about food, eating and their weight. We want to know whether people with cancer and their carers are receiving the right information.

Below are ten pieces of advice for people with cancer and unintentional weight loss. For each piece of advice, please indicate whether you think it is good advice i.e. advice which should be followed. Tick YES, NO or DON'T KNOW

	YES	**NO**	**DON'T KNOW**
1. Eat lots of fruit and vegetables	○	○	○
2. Eat a high energy, high protein diet	○	○	○
3. Eat at least some solid food each day	○	○	○
4. Only eat organic food	○	○	○
5. Avoid ready meals	○	○	○
6. Eat at set meal times	○	○	○
7. Have at least one hot meal a day	○	○	○
8. Force yourself to eat	○	○	○
9. Try to exercise every day	○	○	○
10. Talk to doctors and nurses about problems with eating and weight loss, not just dietitians	○	○	○

Below are ten pieces of advice for the carers of people with cancer and unintentional weight loss. For each piece of advice, please indicate whether you think it is good advice i.e. advice which should be followed. Tick YES, NO or DON'T KNOW.

	YES	**NO**	**DON'T KNOW**
11. Weigh the patient regularly	○	○	○
12. Carefully plan meals each day	○	○	○
13. Always eat meals with the patient	○	○	○
14. Give smaller portions to the patient	○	○	○
15. Check how much the patient eats at each meal	○	○	○
16. Be firm to ensure the patient finishes meals	○	○	○
17. Expect the patient to mainly eat old favourites	○	○	○
18. Keep plenty of snack foods available	○	○	○
19. Add high fat foods like cream and butter to other food	○	○	○
20. Offer meal replacement/nutritional supplement drinks	○	○	○

Appendix Q Questionnaire scores for participants in feasibility study

Q.1 Alan (family 1, patient)

	Pre-workshop	**+1 week**	**+6 weeks**
QLQ-C30			
Global Health/QoL	16.7	16.7	16.7
Physical functioning	46.7	0.0	33.3
Role functioning	0.0	0.0	16.7
Emotional functioning	91.7	75.0	100.0
Cognitive functioning	66.7	50.0	50.0
Social functioning	0.0	0.0	33.3
Fatigue	100.0	100.0	88.9
Nausea & vomiting	66.7	100.0	100.0
Pain	100.0	100.0	100.0
Dyspnoea	0.0	100.0	33.3
Insomnia	0.0	100.0	33.3
Appetite loss	100.0	100.0	100.0
Constipation	66.7	100.0	33.3
Diarrhoea	66.7	0.0	0.0
Financial difficulties	0.0	0.0	0.0
QLQ-CAX24			
Food aversion	60.0	missing	33.3
Eating & weight loss worry	100.0	100.0	44.4
Eating difficulties	83.3	100.0	44.4

Appendix Q

	Pre-workshop	**+1 week**	**+6 weeks**
Loss of control	50.0	22.2	44.4
Physical decline	88.9	missing	44.4
Dry mouth	33.3	100.0	33.3
Indigestion	33.3	0.0	66.7
Forcing self to eat	33.3	missing	33.3
Inadequate information	100.0	0.0	66.7
Knowledge			
Number correct	14	16	9/10
Number of don’t knows	4	1	0
PANAS			
Positive affect	not high	not high	not high
Negative affect	high	high	not high
FRI			
Cohesiveness	2.5	3	3
Conflict	1	1	0
Expressiveness	4	2	2.5
FRI total	9.5	8	9.5
Distress thermometer			
General distress	medium	high	low
Eating/weight loss distress	medium	high	low
COPE			
Self-distraction	4	2	missing
Active	5	5	missing
Denial	4	2	missing
Substance	8	2	missing

	Pre-workshop	+1 week	+6 weeks
Emotional support	6	6	missing
Instrumental support	7	7	missing
Behavioural disengagement	3	5	missing
Venting	3	4	missing
Positive reframing	2	5	missing
Planning	3	3	missing
Humour	3	8	missing
Acceptance	8	8	missing
Religion	2	2	missing
Self-blame	3	2	missing
Active coping	46.7	56.7	missing
Avoidant coping	41.7	20.8	missing

Q.2 Beth (family 1, carer)

	Pre-workshop	+1 week	+6 weeks
CQOLC	85	93	85
Knowledge			
Number correct	17	13	17
Number of don’t knows	0	2	3
PANAS			
Positive affect	high	not high	not high
Negative affect	high	high	high
FRI			
Cohesiveness	3	3	2

Appendix Q

	Pre-workshop	**+1 week**	**+6 weeks**
CQOLC	85	93	85
Conflict	0	0	1
Expressiveness	3	2	3
FRI total	10	9	8
Distress thermometer			
General distress	high	high	low
Eating/weight loss distress	medium	high	high
COPE			
Self-distraction	5	5	5
Active	7	7	8
Denial	2	2	2
Substance	4	4	4
Emotional support	3	5	2
Instrumental support	6	3	8
Behavioural disengagement	5	5	2
Venting	6	2	4
Positive reframing	2	2	2
Planning	6	5	8
Humour	3	3	4
Acceptance	6	7	7
Religion	2	2	2
Self-blame	3	4	2
Active coping	46.7	53.3	56.7
Avoidant coping	37.5	20.8	16.7

Q.3 Carol (family 2, patient)

	Pre-workshop	**+1 week**	**+6 weeks**
QLQ-C30			
Global Health/QoL	16.7	missing	missing
Physical functioning	40.0	60.0	46.7
Role functioning	16.7	33.3	0.0
Emotional functioning	41.7	missing	missing
Cognitive functioning	50.0	missing	missing
Social functioning	16.7	missing	missing
Fatigue	77.8	66.7	100.0
Nausea & vomiting	50.0	16.7	33.3
Pain	0.0	0.0	0.0
Dyspnoea	100.0	66.7	100.0
Insomnia	66.7	33.3	100.0
Appetite loss	100.0	100.0	100.0
Constipation	33.3	0.0	0.0
Diarrhoea	0.0	missing	missing
Financial difficulties	0.0	missing	missing
QLQ-CAX24			
Food aversion	100.0	40.0	53.3
Eating & weight loss worry	88.9	66.7	66.7
Eating difficulties	66.7	11.1	33.3
Loss of control	66.7	16.7	16.7
Physical decline	44.4	missing	missing
Dry mouth	33.3	missing	missing
Indigestion	100.0	missing	missing

Appendix Q

	Pre-workshop	**+1 week**	**+6 weeks**
Forcing self to eat	66.7	missing	missing
Inadequate information	33.3	missing	missing
Knowledge			
Number correct	8	16	17
Number of don't knows	6	0	0
PANAS			
Positive affect	not high	not high	not high
Negative affect	high	high	high
FRI			
Cohesiveness	3	3	3
Conflict	0	0	0
Expressiveness	2	4	3
FRI total	9	11	10
COPE			
Self-distraction	4	5	5
Active	6	5	6
Denial	2	2	2
Substance	2	2	4
Emotional support	8	7	7
Instrumental support	5	5	5
Behavioural disengagement	2	2	3
Venting	4	4	5
Positive reframing	4	4	3
Planning	5	5	5
Humour	2	2	2

	Pre-workshop	+1 week	+6 weeks
Acceptance	8	8	5
Religion	4	4	4
Self-blame	2	2	2
Active coping	70.0	63.3	53.3
Avoidant coping	8.3	8.3	25.0
Distress thermometer			
General distress	low	low	high
Eating & weight loss distress	medium	low	medium

Q.4 Dawn (family 2, carer)

	Pre-workshop	+1 week	+6 weeks
CQOLC	56	50	56
Knowledge			
Number correct	12	11	10
Number of don’t knows	3	3	2
PANAS			
Positive affect	not high	not high	not high
Negative affect	high	high	high
FRI			
Cohesiveness	3	3	3
Conflict	0	0	0
Expressiveness	4	3.5	4
FRI total	11	10.5	11
Distress thermometer			

	Pre-workshop	**+1 week**	**+6 weeks**
General distress	low	medium	high
Eating/weight loss distress	medium	medium	high
COPE			
Self-distraction	3	3	3
Active	4	3	3
Denial	2	5	2
Substance	2	2	2
Emotional support	4	3	3
Instrumental support	2	2	2
Behavioural disengagement	2	2	2
Venting	3	2	3
Positive reframing	3	3	2
Planning	3	3	2
Humour	2	2	2
Acceptance	4	4	4
Religion	2	2	2
Self-blame	2	3	3
Active coping	26.7	20.0	13.3
Avoidant coping	4.2	12.5	4.2

Q.5 Eric (family 3, patient)

	Pre-workshop	**+1 week**	**+6 weeks**
QLQ-C30			
Global Health/QoL	58.3	missing	missing

	Pre-workshop	+1 week	+6 weeks
Physical functioning	46.7	46.7	53.3
Role functioning	66.7	33.3	66.7
Emotional functioning	77.8	missing	missing
Cognitive functioning	100.0	missing	missing
Social functioning	83.3	missing	missing
Fatigue	33.3	66.7	33.3
Nausea & vomiting	16.7	33.3	16.7
Pain	33.3	33.3	33.3
Dyspnoea	33.3	33.3	33.3
Insomnia	33.3	33.3	0.0
Appetite loss	0.0	33.3	33.3
Constipation	0.0	0.0	0.0
Diarrhoea	33.3	missing	missing
Financial difficulties	0.0	missing	missing
QLQ-CAX24			
Food aversion	20.0	53.3	26.7
Eating & weight loss worry	22.2	33.3	33.3
Eating difficulties	0.0	11.1	11.1
Loss of control	16.7	16.7	16.7
Physical decline	0.0	missing	missing
Dry mouth	33.3	missing	missing
Indigestion	33.3	missing	missing
Forcing self to eat	0.0	missing	missing
Inadequate information	33.3	missing	missing
Knowledge			

Appendix Q

	Pre-workshop	**+1 week**	**+6 weeks**
Number correct	10	12	14
Number of don't knows	0	1	0
PANAS			
Positive affect	not high	not high	not high
Negative affect	not high	high	not high
FRI			
Cohesiveness	4	3	4
Conflict	0	1	0
Expressiveness	3	3	2
FRI total	11	9	10
Distress thermometer			
General distress	low	medium	low
Eating/weight loss distress	low	low	low
COPE			
Self-distraction	5	6	6
Active	6	2	6
Denial	2	2	2
Substance	2	2	2
Emotional support	6	4	6
Instrumental support	6	3	5
Behavioural disengagement	2	2	2
Venting	4	4	5
Positive reframing	4	2	2
Planning	6	2	5
Humour	4	2	4

	Pre-workshop	**+1 week**	**+6 weeks**
Acceptance	8	7	8
Religion	2	2	2
Self-blame	2	4	2
Active coping	66.7	23.3	56.7
Avoidant coping	8.3	8.3	12.5

Q.6 Fay (family 3, carer)

	Pre-workshop	**+1 week**	**+6 weeks**
CQOLC	50	56	41
Knowledge			
Number correct	7	11	10
Number of don’t knows	1	0	0
PANAS			
Positive affect	high	not high	high
Negative affect	high	high	high
FRI			
Cohesiveness	4	2	3
Conflict	1	0	0
Expressiveness	2.5	2	1
FRI total	9.5	8	8
Distress thermometer			
General distress	low	medium	low
Eating/weight loss distress	high	high	low
COPE			

	Pre-workshop	+1 week	+6 weeks
Self-distraction	2	7	7
Active	6	6	5
Denial	2	2	2
Substance	5	8	8
Emotional support	8	5	4
Instrumental support	8	3	4
Behavioural disengagement	2	2	2
Venting	3	2	2
Positive reframing	2	2	2
Planning	5	4	4
Humour	2	2	2
Acceptance	6	8	6
Religion	2	2	2
Self-blame	2	2	2
Active coping	56.7	50.0	36.7
Avoidant coping	16.7	25.0	25.0

Q.7 Guy (family 4, patient)

	Pre-workshop	+1 week	+6 weeks
QLQ-C30			
Global Health/QoL	66.7	66.7	58.3
Physical functioning	93.3	93.3	93.3
Role functioning	66.7	66.7	66.7
Emotional functioning	100.0	100.0	100.0

	Pre-workshop	+1 week	+6 weeks
Cognitive functioning	100.0	83.3	83.3
Social functioning	66.7	83.3	83.3
Fatigue	44.4	44.4	22.2
Nausea & vomiting	0.0	0.0	0.0
Pain	16.7	0.0	0.0
Dyspnoea	0.0	0.0	0.0
Insomnia	66.7	66.7	66.7
Appetite loss	33.3	0.0	0.0
Constipation	0.0	0.0	0.0
Diarrhoea	33.3	33.3	0.0
Financial difficulties	0.0	0.0	0.0
QLQ-CAX24			
Food aversion	0.0	0.0	0.0
Eating & weight loss worry	0.0	0.0	0.0
Eating difficulties	0.0	0.0	0.0
Loss of control	0.0	5.6	0.0
Physical decline	0.0	0.0	0.0
Dry mouth	0.0	0.0	0.0
Indigestion	0.0	0.0	0.0
Forcing self to eat	0.0	0.0	0.0
Inadequate information	66.7	33.3	33.3
Knowledge			
Number correct	4	7	7
Number of don’t knows	9	4	3
PANAS			

Appendix Q

	Pre-workshop	**+1 week**	**+6 weeks**
Positive affect	high	high	high
Negative affect	not high	not high	not high
FRI			
Cohesiveness	4	4	4
Conflict	0	0	0
Expressiveness	1	1	1
FRI total	9	9	9
Distress thermometer			
General distress	low	low	low
Eating/weight loss distress	low	low	low
COPE			
Self-distraction	2	4	3
Active	3	4	5
Denial	2	2	2
Substance	2	2	2
Emotional support	2	3	4
Instrumental support	2	2	2
Behavioural disengagement	2	2	2
Venting	2	2	2
Positive reframing	4	3	3
Planning	2	4	4
Humour	2	2	4
Acceptance	6	5	5
Religion	2	2	2
Self-blame	2	2	2

	Pre-workshop	**+1 week**	**+6 weeks**
Active coping	23.3	30.0	36.7
Avoidant coping	0.0	0.0	0.0

Q.8 Helen (family 5, patient)

Only completed pre-workshop measures

	Pre-workshop
QLQ-C30	
Global Health/QoL	66.7
Physical functioning	86.7
Role functioning	100.0
Emotional functioning	66.7
Cognitive functioning	50.0
Social functioning	100.0
Fatigue	33.3
Nausea & vomiting	33.3
Pain	16.7
Dyspnoea	33.3
Insomnia	0.0
Appetite loss	33.3
Constipation	0.0
Diarrhoea	0.0
Financial difficulties	0.0
QLQ-CAX24	
Food aversion	6.7

Appendix Q

	Pre-workshop
Eating & weight loss worry	33.3
Eating difficulties	11.1
Loss of control	27.8
Physical decline	0.0
Dry mouth	33.3
Indigestion	0.0
Forcing self to eat	33.3
Inadequate information	100.0
Knowledge	
Number correct	11
Number of don’t knows	2
PANAS	
Positive affect	high
Negative affect	high
FRI	
Cohesiveness	3
Conflict	1
Expressiveness	1
FRI total	7
Distress thermometer	
General distress	low
Eating/weight loss distress	low
COPE	
Self-distraction	4
Active	4

	Pre-workshop
Denial	4
Substance	2
Emotional support	3
Instrumental support	5
Behavioural disengagement	4
Venting	2
Positive reframing	2
Planning	2
Humour	4
Acceptance	3
Religion	2
Self-blame	2
Active coping	13.3
Avoidant coping	16.7

Appendix R Changes in scores on feasibility study measures

R.1 Change in patient QLQ-C30 scores

	+1 week			+6 weeks		
Scale	**Improved**	**Deteriorated**	**Missing**	**Improved**	**Deteriorated**	**Missing**
Global Health/QoL	0	0	2	0	0	2
Physical functioning	1	1	0	0	1	0
Role functioning	1	1	0	1	1	0
Emotional functioning	0	1	2	0	0	2
Cognitive functioning	0	2	2	0	2	2
Social functioning	1	0	2	2	0	2
Fatigue	1	1	0	2	1	0
Nausea & vomiting	1	2	0	1	1	0
Pain	1	0	0	1	0	0
Dyspnoea	1	1	0	1	0	0
Insomnia	1	1	0	1	2	0
Appetite loss	1	1	0	1	1	0
Constipation	1	1	0	2	0	0
Diarrhoea	1	0	2	2	0	2
Financial difficulties	0	0	2	0	0	2

R.2 Changes in patient QLQ-CAX24 scores

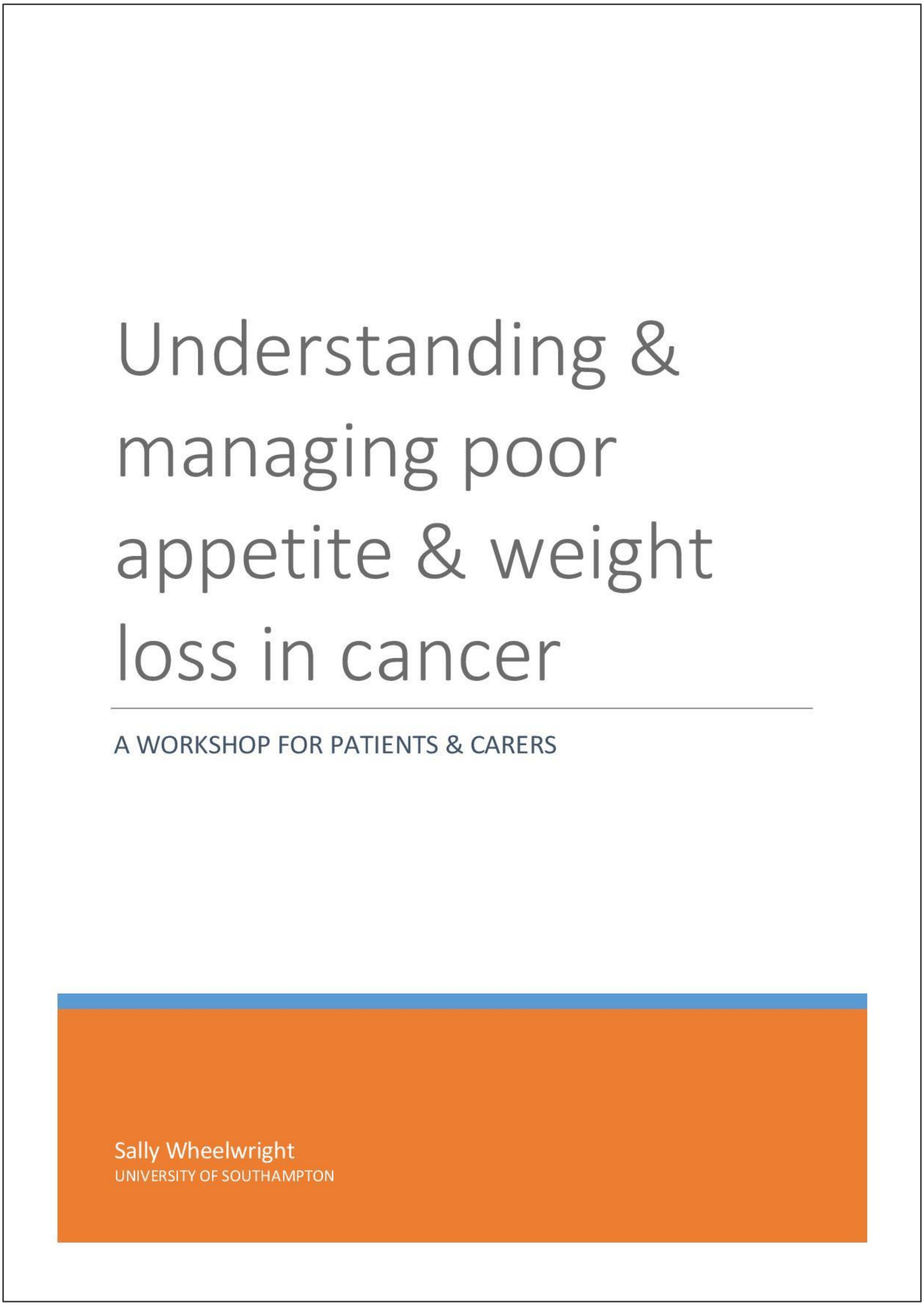
	+1 week			+6 weeks		
Scale	**Improved**	**Deteriorated**	**Missing**	**Improved**	**Deteriorated**	**Missing**
Food aversion	1	1	1	2	0	0
Eating & weight loss worry	1	1	0	2	1	0
Eating difficulties	1	2	0	2	1	0
Loss of control	2	0	0	1	0	0
Physical decline	0	0	3	1	0	2
Dry mouth	0	1	2	0	0	2
Indigestion	1	0	2	0	1	2
Forcing self to eat	0	0	3	0	0	2
Inadequate information	2	0	2	2	0	2

R.3 Changes in scores assessing knowledge, mood, relationship functioning, distress and coping strategies between baseline and the two follow ups

	Patients (n=4)		**Carers (n=3)**	
	+1 week	**+6 weeks**	**+1 week**	**+6 weeks**
Knowledge				
Improved total score	4	4	2	3
Reduced total score	0	0	1	0
Reduced number of don't knows	3	3	0	0
Increase number of don't knows	0	0	0	0
PANAS				
Increased positive affect	0	0	1	0
Reduced positive affect	0	0	2	1
Reduced negative affect	0	1	0	0
Increased negative affect	1	0	0	0
FRI				
Improved cohesiveness	0	0	0	0
Reduced cohesiveness	1	0	1	1
Improved FRI total	1	1	0	0
Reduced FRI total	1	0	1	1
Distress thermometer				
Reduced general distress	0	1	0	1
Increased general distress	2	1	2	1
Reduced eating & weight loss distress	1	1	0	1

	Patients (n=4)		**Carers (n=3)**	
	+1 week	**+6 weeks**	**+1 week**	**+6 weeks**
Increased eating & weight loss distress	1	0	1	2
COPE				
More active coping	1	1	0	1
Less active coping	0	2	0	2
More avoidant coping	0	1	0	0
Less avoidant coping	1	0	1	1

Appendix S Workshop handbook



Understanding & managing poor appetite & weight loss in cancer

A WORKSHOP FOR PATIENTS & CARERS

Sally Wheelwright
UNIVERSITY OF SOUTHAMPTON

Appendix S

Introduction

This handbook is for people who are planning to deliver the "Understanding & managing poor appetite & weight loss in cancer workshop". All the information you need to run the workshop is contained in this handbook. The workshop is designed as a one off session with a single telephone follow up. Two hours of activities are timetabled, along with a suggested break of ten minutes.

The aims of the workshop are to 1) educate patients and carers about cancer and weight loss, 2) aid coping and 3) provide relationship support. The workshop may be of benefit to any patient with cancer who is losing weight unintentionally, or is at risk for this, and who is able to attend and participate in the activities, along with their carers. A carer is anybody who provides unpaid support and care to a family member, partner or friend, whether or not they receive Carer's Allowance. The workshop is unlikely to be useful for patients who are unable to eat at all.

The suggested number of attendees at each workshop is ten, five patients and five carers. Exact numbers are not crucial: what is important is to have enough participants to contribute to the activities whilst ensuring everyone has the opportunity to voice their ideas and questions. Patients and carers may attend the workshop alone but their loved ones should also be encouraged to come. Including a roughly equal number of patients and carers will result in a well-balanced workshop, ensuring both patient and carer perspective is represented and both groups feel equally supported.

Two workshop facilitators are required. One facilitator should take the lead role of delivering the workshop whilst the other facilitator assumes a more supportive role e.g. helping participants do the activities, timekeeping. The two facilitators should discuss and agree on their roles ahead of time. Although it is anticipated that the workshop will most often be delivered by clinical nurse specialists or dietitians with experience of working with cancer patients, other healthcare professionals may also act as facilitators. Detailed facilitator's notes are provided in this handbook to support workshop delivery. Facilitators will need to set aside some time to become familiar with the workshop. It is also important that facilitators are confident in their own ability to address questions which workshop attendees may ask.

We hope you will find the workshop simple to deliver and useful for patients and carers. If you are interested, you can read more about the theoretical background and development of the workshop online at http://eprints.soton.ac.uk.

Comments, feedback and suggestions can be emailed to Sally Wheelwright at s.j.wheelwright@soton.ac.uk

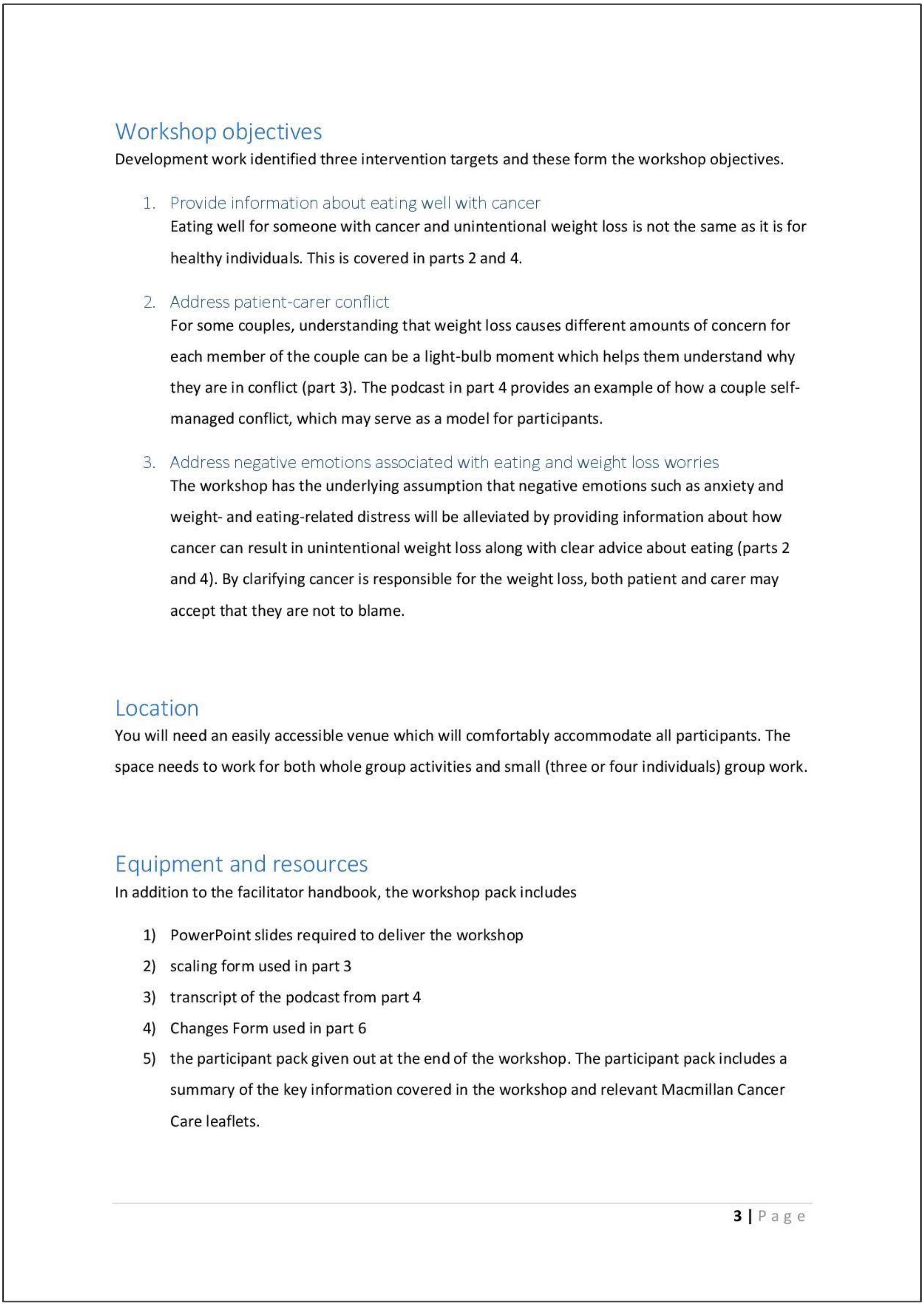
Workshop content summary

1. Welcome, introduction & ground rules (20 minutes)
2. How cancer causes weight loss and what to eat if you have weight loss and cancer (35 minutes)
3. Rating concern caused by weight loss (10 minutes)
4. Coping with changes to eating habits (35 minutes)
5. Workshop summary (10 minutes)
6. Participants' planned behaviour changes (5 minutes)
7. Sources of help (5 minutes)

+1 wk Post workshop follow up phone call (20 minutes)

Timekeeping

It is important to keep to the approximate times allocated for each part of the workshop, and not to run over time. This will ensure the full content of the workshop is delivered in the allocated time. However, some flexibility may be required to take into account different attention spans and fatigue levels. The supporting facilitator will usually take responsibility for timekeeping.



Workshop objectives

Development work identified three intervention targets and these form the workshop objectives.

1. Provide information about eating well with cancer

   Eating well for someone with cancer and unintentional weight loss is not the same as it is for healthy individuals. This is covered in parts 2 and 4.

2. Address patient-carer conflict

   For some couples, understanding that weight loss causes different amounts of concern for each member of the couple can be a light-bulb moment which helps them understand why they are in conflict (part 3). The podcast in part 4 provides an example of how a couple self-managed conflict, which may serve as a model for participants.

3. Address negative emotions associated with eating and weight loss worries

   The workshop has the underlying assumption that negative emotions such as anxiety and weight- and eating-related distress will be alleviated by providing information about how cancer can result in unintentional weight loss along with clear advice about eating (parts 2 and 4). By clarifying cancer is responsible for the weight loss, both patient and carer may accept that they are not to blame.

Location

You will need an easily accessible venue which will comfortably accommodate all participants. The space needs to work for both whole group activities and small (three or four individuals) group work.

Equipment and resources

In addition to the facilitator handbook, the workshop pack includes

1) PowerPoint slides required to deliver the workshop
2) scaling form used in part 3
3) transcript of the podcast from part 4
4) Changes Form used in part 6
5) the participant pack given out at the end of the workshop. The participant pack includes a summary of the key information covered in the workshop and relevant Macmillan Cancer Care leaflets.

In addition, you will require

- ☐ Names badges, ideally colour coded to indicate whether someone is a patient or a carer.
- ☐ Plenty of paper and pens for participants
- ☐ Flip chart and marker pens or something similar for whole group work
- ☐ Equipment to project PowerPoint slides
- ☐ Equipment to play the podcast
- ☐ Tissues, in case participants get upset

Make sure you check that all the equipment works in the venue before the workshop.

What risks are associated with workshop attendance?

Some participants may have the unrealistic expectation that by attending the workshop, all weight loss- and eating- related problems will be solved. They may feel angry or distressed as they learn that it is the cancer itself which is the main cause of the patient's problems and that this is out of both patient and carer control. Participants could begin to comprehend or be reminded that they are approaching the end of life and this could be associated with a number of negative emotions.

Carers may come to realise that their previous strategies to improve intake and diet may have been part of the problem. This realisation could lead to feelings of guilt, distress or even anger.

It is crucial that there are at least two facilitators in attendance at the workshop so that one can leave the room to help participants if required. This may be the case if a patient or carer finds the discussion too difficult and needs a break. This will also ensure that the workshop can continue for the other participants.

Adapting the workshop

The workshop may be used in isolation or as one session in a programme for patients and carers. If the latter, the introduction and breaking the ice tasks could be reduced or adapted to meet the needs of the group.

Ideally, facilitators should be aware whether the group comprises patients who are already experiencing appetite loss and unintentional weight loss, patients who are at risk for this or a mixture, and take this into consideration in their delivery of the workshop.

The length of the workshop could be reduced by doing some activities with the whole group rather than in break out groups. Note that people who are less confident may be uncomfortable speaking to the whole group so may need some extra support and encouragement to contribute fully.

Appendix S

Timetable

Part	Time Needed (minutes)	Content	Activity	Resources Required	Outcome for participants
1a Welcome	7	Advice questionnaire. Welcome participants. Facilitator/s introduce themselves. Housekeeping.	Participants complete questionnaire. Facilitator presentation	PowerPoint slide 1. Advice questionnaires, pens	Completed pre-workshop measure. Feel welcome. Introduced to facilitators. Know relevant housekeeping information.
1b Introduction & ground rules	3	Workshop timetable. Ground rules.	Facilitator presentation. Opportunity for participants to ask questions	PowerPoint slides 2 & 3.	Know what to expect from the workshop. Feel comfortable.
1c Meeting participants	10	Introductions among participants (icebreaker)	Participants introduce themselves to group. In pairs, participants discuss food and eating and then share one thing from discussion with the group.	PowerPoint slide 4.	Introduced themselves to each other. Practised talking to the group.
2a How does cancer lead to weight loss?	15	Reasons why cancer can lead to unintentional weight loss.	Small group (3 or 4 individuals) discussion (5 mins). Sharing ideas with whole group (5 mins). Facilitator sums up (5 mins).	Paper & pens. Flip chart, marker pens. PowerPoint slide 5 and then 6 at end of activity.	Can explain why cancer may cause unintentional weight loss.
2b What should people with cancer and weight loss eat?	20	Eating well and suggested foods	Small group (3 or 4 individuals) discussion about "eating well" (5 mins). Sharing ideas with whole group (5 mins). Facilitator clarifies (5 mins). Whole group brainstorming about suitable foods (5 mins)	Paper & pens. Flip chart, marker pens. PowerPoint slide 7 and then 8 during whole group discussion.	Can describe what eating well means for people with cancer who are losing weight. Can list suitable foods.

Part	Time Needed (minutes)	Content	Activity	Resources Required	Outcome for participants
10 minute comfort break (PowerPoint slide 9)					
3 Rating concern caused by weight loss	10	Rate concern caused by unintentional weight loss and share with loved one.	Scaling exercise. Compare patient and carer scores in pairs. Facilitator discusses results and implication of different scores.	Scaling forms, pens, calculator. PowerPoint slide 10.	Have evaluated their own levels of concern related to the patient's weight loss. Recognise that other people have different scores & possible consequences of this.
4 Coping with changes to eating habits	35	Strategies and solutions for dealing with changes to eating habits.	Listen to Tom & Joan story podcast (5 mins) & discuss related questions in small groups (3 or 4 individuals) (10 mins). Discuss solutions to eating problems in small groups (10 mins). Share ideas with whole group & facilitator summarises (10 mins).	Podcast & speakers, podcast transcript, paper & pens, flip chart, marker pens. PowerPoint slides 11-14.	Feel more confident about self-management of eating difficulties.
5 Summary	10	Summary & consolidation	Facilitator presentation, repeat Advice Questionnaire	PowerPoint slide 15. Advice questionnaire, pens	Reminded of workshop content.
6 Planned behaviour changes	5	Document planned changes to behaviour	Changes form	Changes forms, pens. PowerPoint slide 16.	Have written down planned changes, if any, to behaviour
7 Sources of help	5	How to get more help	Opportunity for participants to ask questions.	PowerPoint slides 17 & 18. Participant pack.	Know sources of help.

Detailed contents

In this section, each part of the workshop is described in more detail. The script is provided as a starting point for delivering the workshop. It includes the main points to make and the key information to get across. Facilitators should read through this script but should not make any attempt to learn it word for word. Rather, facilitators should find their own words so that they can deliver the workshop in a natural way which will be more engaging for the attendees.

Part 1a: Welcome

Activity: complete Advice Questionnaire, facilitator presentation

Time: 7 minutes

Materials: Advice Questionnaires and pens, PowerPoint slide 1

Facilitator actions

Welcomes participants.

Invites participants to complete Advice Questionnaire.

Each facilitator introduces herself or himself in turn.

Explain any necessary housekeeping information, e.g. fire exits/tests; location of toilets

Remind participants of purpose and limitations of workshop.

Script

Welcome to the workshop

Slide 1

Hello everyone. Welcome. Please fill out an Advice Questionnaire whilst everyone is getting settled and keep it somewhere safe. Thank you for coming. You are all here today because you have cancer with weight loss, or someone you care about is experiencing this, or eating and weight loss problems are something which you may need to deal with in the future. First of all, let me introduce myself.

State name and role. Other facilitator introduces himself or herself in same way. Explain any necessary housekeeping information e.g. fire exits/tests, location of toilets.

All the information we give you today is based on the best evidence currently available. Unfortunately, we cannot offer you an easy solution to eating and weight loss problems in cancer because there isn't one. However, there are things you can do to help yourself and your loved ones both practically and emotionally and that's what we are going to cover today. So let's have a look at the timetable.

Outcomes

Feel welcome and know housekeeping information.

Part 1b: Introduction and ground rules

Activity: facilitator presentation and questions

Time: 3 minutes

Materials: PowerPoint slides 2 & 3

Facilitator action

Talk through workshop timetable.

Talk through ground rules.

Invite questions.

Script

Slide 2

Timetable

First of all, we will spend a few minutes getting to know each other so everyone feels relaxed in each other's company. Then we will look at how cancer can sometimes lead to weight loss. We will follow that up by considering what sort of food to eat. After a short break, we will look at concerns related to weight loss. The largest chunk of time will be spent exploring how to cope with changes to eating habits. Towards the end of the session, there will be a quick summary of what we have covered and you can fill out the Advice Questionnaire again to see if you have changed your mind about anything. I will then ask you to write down any changes you plan to make, as a result of the workshop. I will finish up by giving you some pointers on how to get more information and then there will be an opportunity to ask any final questions. At the end of the workshop, everyone will get a pack which will include the information covered and some Macmillan booklets.

Slide 3

Ground rules

This is an interactive session. The idea is that this will be more interesting for everyone rather than me talking at you for two hours. Because it is interactive, we have a few ground rules that I hope seem reasonable to everyone.

Run through ground rules

Is everyone OK with those rules? Does anyone have any questions so far?

Outcomes

Know what to expect from workshop and feel comfortable.

Part 1c: Meeting participants

Activity: facilitator presentation and questions

Time: 10 minutes

Materials: PowerPoint slide 4

Facilitator actions

Invite everyone to introduce him or herself.

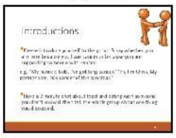
Help participants get into a pair with someone they do not know.

Allow pairs 2 minutes to chat to each other about anything to do with food and eating.

Invite pairs to share with whole group something the talked about.

Script

Slide 4



Introductions

So far, I've done a lot of talking so it would be really nice to hear from you. Please could you introduce yourself and say whether you are here because you have cancer or because you are supporting someone else. There's a couple of examples on the slide here of the kind of thing you could say.
Everyone introduces himself or herself.
Thank you. Now please have a quick chat with someone you don't know, so not the person you came with, about food and/or eating. Anything at all to do with food or eating.
Help people get into pairs & encourage talk if pairs are struggling.
Make sure both members of the pair talk.
After a couple of minutes,
So what sort of thing did you talk about?
Make encouraging responses to replies but avoid detailed discussion at this stage.

Outcomes

Introduced to group.

Practised talking to a stranger one-to-one.

Practised talking to the group.

Part 1c: Meeting participants

Activity: facilitator presentation and questions

Time: 10 minutes

Materials: PowerPoint slide 4

Facilitator actions

Invite everyone to introduce him or herself.

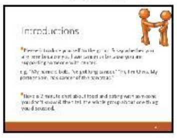
Help participants get into a pair with someone they do not know.

Allow pairs 2 minutes to chat to each other about anything to do with food and eating.

Invite pairs to share with whole group something the talked about.

Script

Slide 4



Introductions

So far, I've done a lot of talking so it would be really nice to hear from you. Please could you introduce yourself and say whether you are here because you have cancer or because you are supporting someone else. There's a couple of examples on the slide here of the kind of thing you could say.

Everyone introduces himself or herself.

Thank you. Now please have a quick chat with someone you don't know, so not the person you came with, about food and/or eating. Anything at all to do with food or eating.

Help people get into pairs & encourage talk if pairs are struggling.

Make sure both members of the pair talk.

After a couple of minutes,

So what sort of thing did you talk about?

Make encouraging responses to replies but avoid detailed discussion at this stage.

Outcomes

Introduced to group.

Practised talking to a stranger one-to-one.

Practised talking to the group.

Part 2a: How does cancer lead to weight loss?

Activity: small group discussion, whole group discussion, facilitator presentation

Time: 15 minutes

Materials: PowerPoint slides 5 & 6; paper and pens; flip chart and marker pens

Facilitator actions

Help participants get into groups of 3 or 4, with a mix of patients and carers in each group. Separate partners.

Give groups 5 minutes to write down reasons that people with cancer lose weight.

Ask groups to share their ideas. Write reasons on flip chart. Gently correct if completely wrong.

Talk through summary slide (PowerPoint slide 6).

Invite questions.

Script

Slide 5

How can cancer lead to unintentional weight loss?

Now could you please get into small groups *(suggest 3 or 4 per group depending on total number)*. Each group can have some paper and pens so that you can write down why you think people with cancer sometimes lose weight. I'll give you about 5 minutes to do that and then we can talk about what you come up with.

Prompt discussion if necessary

After 5 minutes, ask groups to call out their ideas and write on a flip chart for all to see or run through what each group has written down. Gently correct any ideas that are completely wrong.

Part 2a continues on the next page.

Note that slide 6 is animated so that the information is presented step-by-step.

Script

Slide 6

You have come up with some really good reasons. Here is a slide which explains current understanding. First of all, cancer can change how the body works. The changes may include speeding up the metabolic rate, that is the rate that the body uses energy. In other words, the body burns calories faster. At the same time, food absorption may not be as good as it used to be. So the body is getting less energy from food, whilst using up energy quicker. Cancer can also affect muscle – it can make muscle breakdown more and it can make it harder for the body to build muscle up again.

All these changes to how the body works can result in weight loss. As well changes to the body, cancer can also cause weight loss in another way. Cancer and cancer treatments can cause lots of symptoms, and some of these symptoms can make people eat less. You can see here examples of a wide variety of symptoms, including poor appetite, feeling full too quickly, having a sore mouth, nausea, constipation, being in pain or too tired to eat, breathlessness, being depressed and being anxious. Eating less contributes to weight loss. Here's the whole diagram. Does anyone have any questions about this?

Outcomes

Can explain why cancer may cause unintentional weight loss.

Part 2b: What should people with cancer and weight loss eat?

Activity: small group discussion, whole group discussion, facilitator presentation

Time: 20 minutes

Materials: PowerPoint slides 7 & 8; paper and pens; flip chart and marker pens

Facilitator actions

Help participants get into groups of 3 or 4, with a mix of patients and carers in each group. Separate partners. Groups can remain the same as previous task if worked well or encourage new groups.

Give groups 5 minutes to write down what "eating well" means for someone with cancer who is losing weight either in general terms or give examples of foods.

Ask groups to share their ideas. Write reasons on flip chart. Gently correct if completely wrong.

Talk through summary slide (PowerPoint slide 8).

Ask for suggestions of other suitable foods and add to flip chart.

Invite questions.

Script

Slide 7

What should people with cancer & weight loss eat?

The next task is to spend 5 minutes talking about what it means to "eat well" when you have cancer and weight loss. You can talk about this in general terms or come up with some specific examples of food to eat. Again, you have paper and pens so you can write your ideas down.
Help participants get into small groups. These can stay the same as the last task if those groups worked well or encourage new groups.
Prompt discussion if necessary.
After 5 minutes, ask groups to call out their ideas and write on a flip chart for all to see. Gently correct any ideas that are completely wrong.

Slide 8

What should people with cancer & weight loss eat?

It is important to emphasise that there is no evidence that any diet or food can cure or control cancer. The suggestion here is that if you are not able to eat very much quantity wise, you could try to maximise the energy and protein content of the food you can eat. Here are some examples of some nutrient dense food.
Go through list on slide.
Can you think of anything else?
Write any valid suggestions on flip chart.
Does anyone have any questions about this topic?

Part 2b continues on the next page.

Reference Information for facilitators

The infographic shows high protein foods, with how much you would need to eat to get the same amount of protein. This information is provided for comparison purposes only. Seitan, tempeh and tofu are vegetarian foods.

And here's a word list of good sources of protein:

Meat and meat products: Beef, pork, lamb, sausages, deli meats such as ham.

Beans and pulses: Chickpeas, kidney beans, lentils, peas, butter beans, baked beans, haricot beans, flageolet beans, soya beans.

Fish: White fish: e.g. cod, coley, haddock, pollock, hake. Oily fish: e.g. salmon, sardines, mackerel, fresh tuna, trout.

Shellfish: Prawns, scallops, mussels, oysters, squid and crab.

Poultry: Chicken, turkey, duck, goose.

Eggs

Nuts

Tofu

Mycoprotein e.g. Quorn

Dairy: milk, cheese, cottage cheese, Greek yoghurt, yoghurt

Part 2b continues on the next page.

Outcomes

Can describe what eating well means for people with cancer who are losing weight. Can give examples of suitable foods.

Break time

PowerPoint slide 9

Suggested time: 10 minutes

Facilitator reminds participants location of toilets and, if available, refreshments.

Slide 9

Break time

Thank you everyone for your contribution so far. We are going to have 10 minutes break now, starting again at (*time*).
Remind participants location of toilets and, if available, refreshments.

Part 3: Rating concern caused by weight loss

Activity: complete scaling forms, discuss score with partner, whole group discussion

Time: 10 minutes

Materials: PowerPoint slide 10; scaling forms and pens; calculator

Facilitator actions

Ask everyone to mark their concern about unintentional weight loss in the patient on scaling form.

Invite partners to share their scores with each other. If there are some participants attending without a loved one, encourage them to take a scale form home for their partner and carry out the activity at home.

Discuss consequences if patients and carers score differently.

Script

Slide 10

Rating concern

Welcome back everyone. In a moment, I'm going to give everyone a scale and I'd like you to mark on that scale how concerned you are about weight loss in the person who has got cancer. I am talking about unintentional, unplanned weight loss. This is something that might be happening now, or if this were to happen in the future, how concerned would you be? Don't discuss it with anyone else just yet, or show anyone where you are putting your mark. *Distribute scale forms.*

You can mark the line with a cross or anything else you fancy. Mark the line somewhere on the left if you are not too concerned and mark it more to the right if this is something which is very concerning for you. Has everyone done this?

Now if you are here with a loved one, compare your rating with that person's rating. If your loved one isn't here today, please feel free to take a scale form with you so you can do this activity together at home. For people in pairs now, are your scores similar or is one of you more concerned than the other about the weight loss?

What do you think the consequences are if there are differences in the level of concern?

Outcomes

Have evaluated concern caused by patient's weight loss. Recognise that other people have different scores.

Part 4: Coping with changes to eating habits

Activity: podcast, small group discussion, whole group discussion, facilitator presentation

Time: 35 minutes

Materials: PowerPoint slides 11-14; podcast and speakers; paper and pens; flip chart and marker pens

Facilitator actions

Play podcast.

Help participants get into groups of 3 or 4, with a mix of patients and carers in each group. Separate partners. Groups can remain the same as previous task if worked well or encourage new groups.

Distribute podcast transcriptions. Give groups 10 minutes to discuss the questions on PowerPoint slide 12.

Give groups 10 minutes to write down ways to help someone to eat if they have a small appetite and/or little interest in eating.

Ask groups to share their ideas. Write suggestions on flip chart.

Talk through summary slide (PowerPoint slide 14).

Invite questions.

Script

Slide 11

Coping with changes to eating habits

Now I have a podcast for you to listen to which tells the story of Tom and Joan. On the next slide there are some questions to think about as you listen to the story. Once the podcast has finished, please get into small groups to discuss the questions. We will have about 10 minutes on this.

Slide 12

Questions to think about

Sit back, relax and enjoy the podcast.
After podcast, help participants get into small groups. These can stay the same as the last task if those groups worked well or encourage new groups. Distribute podcast transcripts. Prompt discussion if necessary. After 10 minutes,

Part 4 continues on the next page.

Slide 13

Strategies for dealing with changes to eating habits

Now could you move on to talking about ways you could help someone to eat if they have a small appetite and/or little interest in eating. Each group has paper and pens so that you can write down your ideas. I'll give you about 10 minutes to do that and then we can talk about what you come up with.
Prompt discussion if necessary. After 10 minutes, ask groups to call out their ideas and write on a flip chart for all to see.

Slide 14

Dealing with changes to eating habits

Thank you for all your suggestions. Here is a summary of current expert opinion. As a group, you came up with some/most of these ideas.
Run through all items on the slide
Does anyone have any questions about this topic?

Outcomes

Feel more confident about self-management of eating difficulties.

Part 5: Summary

Activity: facilitator presentation, repeat Advice Questionnaire

Time: 10 minutes

Materials: PowerPoint slide 15, Advice Questionnaires, pens

Facilitator actions

Summarise the topics covered by the workshop.

Invites participants to complete Advice Questionnaire.

Script

Slide 15

Today we have discussed…

1. How cancer can result in weight loss.
2. What to eat when you have cancer and are losing weight.
3. Why weight loss can be concerning and sometimes lead to tension.
4. Strategies to help with changes to eating habits.

Please fill out the Advice Questionnaire again. Have any of your answers changed?

We are getting towards the end of the session now so I want to sum up what we have talked about today. We started off covering how cancer can cause weight loss. Cancer changes how the body works and this can result in weight loss. Along with treatment, cancer can also cause symptoms which causes people to eat less, again leading to weight loss.

Next we talked about what it means to eat well when you have cancer and are losing weight. We talked about the idea of eating nutrient dense food – food which is high in calories and high in protein.

Then everyone rated how concerned they were about the weight loss, and we found that (*paraphrase results*).

The podcast told the story of Tom and Joan. We heard about how Joan's weight loss was causing friction between them but Tom and Joan found a way to improve things so that they could enjoy their time together.

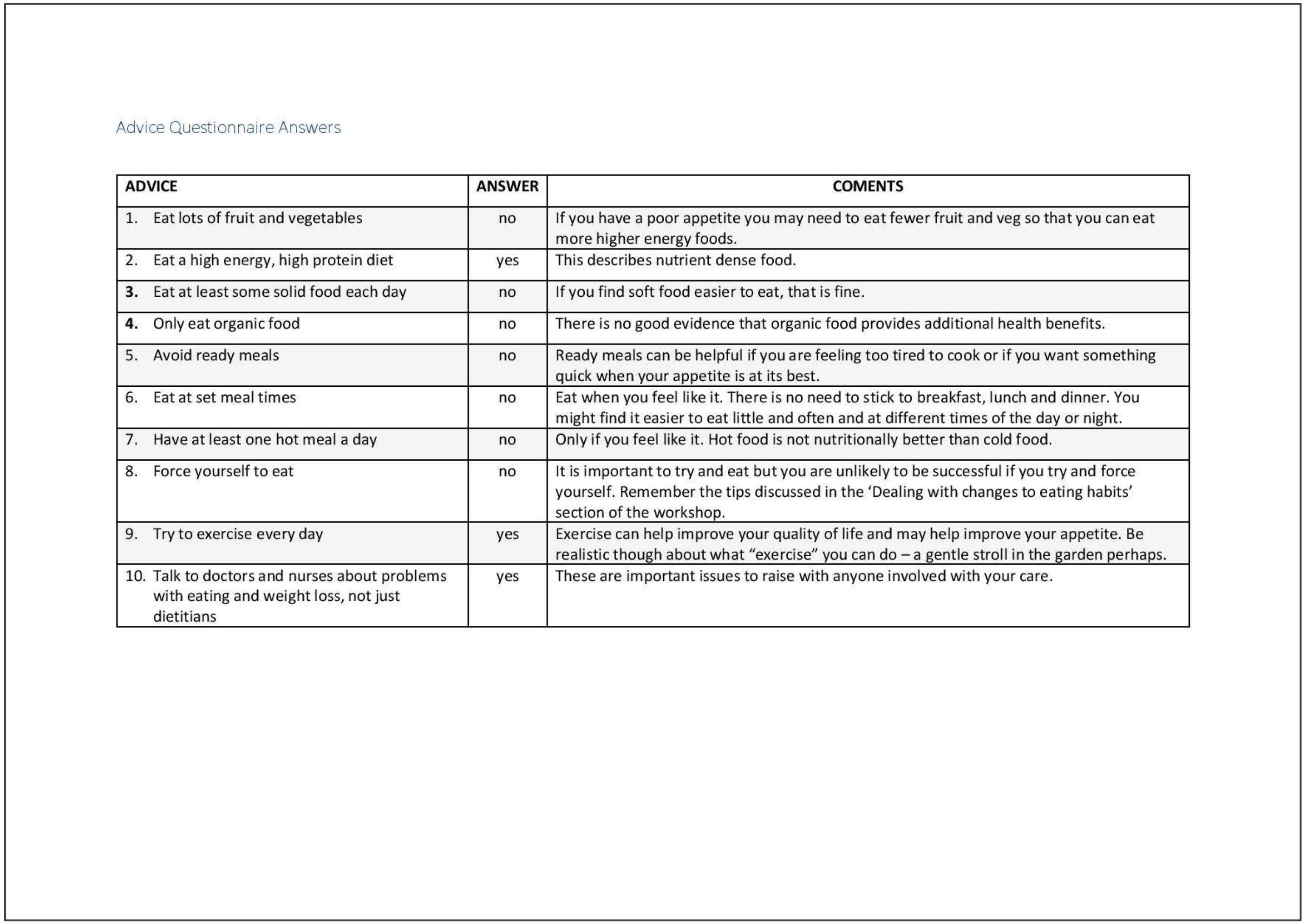
Finally you came up with lots of ideas about how to deal with changes to eating.

I am now going to invite you to complete the Advice Questionnaire again now. Have any of your answers changed?

Run through answers (see next page)

Outcomes

Reminded of the topics covered by the workshop.



Advice Questionnaire Answers

ADVICE	ANSWER	COMENTS
1. Eat lots of fruit and vegetables	no	If you have a poor appetite you may need to eat fewer fruit and veg so that you can eat more higher energy foods.
2. Eat a high energy, high protein diet	yes	This describes nutrient dense food.
3. Eat at least some solid food each day	no	If you find soft food easier to eat, that is fine.
4. Only eat organic food	no	There is no good evidence that organic food provides additional health benefits.
5. Avoid ready meals	no	Ready meals can be helpful if you are feeling too tired to cook or if you want something quick when your appetite is at its best.
6. Eat at set meal times	no	Eat when you feel like it. There is no need to stick to breakfast, lunch and dinner. You might find it easier to eat little and often and at different times of the day or night.
7. Have at least one hot meal a day	no	Only if you feel like it. Hot food is not nutritionally better than cold food.
8. Force yourself to eat	no	It is important to try and eat but you are unlikely to be successful if you try and force yourself. Remember the tips discussed in the 'Dealing with changes to eating habits' section of the workshop.
9. Try to exercise every day	yes	Exercise can help improve your quality of life and may help improve your appetite. Be realistic though about what "exercise" you can do – a gentle stroll in the garden perhaps.
10. Talk to doctors and nurses about problems with eating and weight loss, not just dietitians	yes	These are important issues to raise with anyone involved with your care.

ADVICE	ANSWER	COMENTS
11. Weigh the patient regularly	no	This is unnecessary and will put pressure on you both.
12. Carefully plan meals each day	no	If you put a lot of effort into planning meals it can be very disheartening if the patient does not want them. You may begin to feel resentful. The patient's appetite may be very changeable, day to day. Try to be flexible and have quick and easy food to hand. Don't wear yourself out cooking.
13. Always eat meals with the patient	no	Some patients like company at mealtimes, some may prefer to eat alone so they don't feel under pressure. Ask the person you are looking after to tell you which they prefer. This may change from day to day.
14. Give smaller portions to the patient	yes	Smaller portions are less overwhelming. They can always have seconds if they want.
15. Check how much the patient eats at each meal	no	This can make the patient feel under pressure, potentially resulting in the patient eating less and leading to tension and arguments. Try to avoid commenting on how much the patient eats. A very relaxed atmosphere may even result in the patient eating more.
16. Be firm to ensure the patient finishes meals	no	This is unlikely to be successful and is more likely to have the opposite effect. Tension and arguments are a likely consequence of this tactic.
17. Expect the patient to mainly eat old favourites	no	Tastes can often change when someone is ill. Try not to be disappointed if they no longer enjoy something that they have always had in the past.
18. Keep plenty of snack foods available	yes	The patient may find it easier to eat snacks rather than 'proper' meals.
19. Add high fat foods like cream and butter to other food	yes	This is a good way of supplementing foods and increasing the energy content.
20. Offer meal replacement/nutritional supplement drinks	yes	Some people find this easier than eating food. Discuss this option with a health care professional.

Part 6: Planned behaviour changes

Activity: complete Changes Forms

Time: 5 minutes

Materials: PowerPoint slide 16; Changes Forms and pens

Facilitator actions

Ask everyone to complete Changes Form.

Script

Slide 16

Changes Form

Please fill out the Changes Form and take it home with you.

This form is just for you. Use it how you wish.

The final part of workshop is to fill out the Changes Form, found in the back of the Participant Pack. This asks you whether you plan to do anything differently as a result of the workshop and if so what. You may choose to share it with your partner, or you may prefer to keep it just for you.

Outcomes

Have written record of planned changes, if any, to behaviour

Part 7: Sources of help

Activity: facilitator presentation

Time: 5 minutes

Materials: PowerPoint slides 17 & 18; participant pack

Facilitator actions

Talk through sources of additional help.

Invite final questions.

Distribute participant packs.

Script

Slide 17

How to get more help

If you feel you need more support to help with weight loss and eating then Macmillan Cancer Support is a really good place to start. You can phone them or look on the website. The Royal Marsden website is another really good source of information and ideas. Also please do raise the subject with one of the professionals involved in your care. Sometimes people are concerned about "bothering" doctors and nurses with this sort of problem, but please be reassured that you are not bothering them and it is definitely something to raise. Finally, as you know, I will be following you all up with a phone call in a week or so, so that's another opportunity to ask any questions.

Slide 18

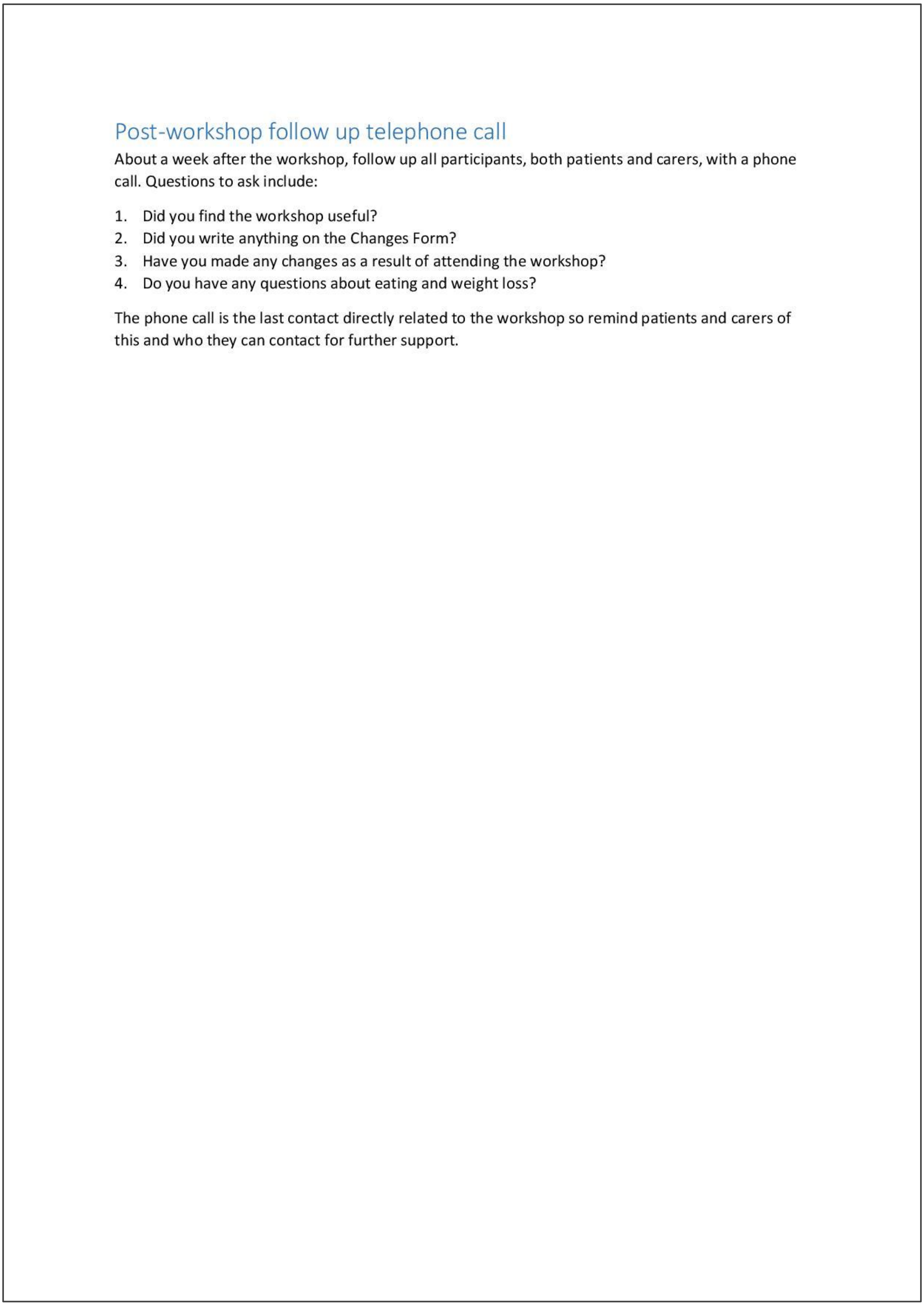
Any final questions?

Thank you very much for all your contributions today. I hope you have found the workshop to be a useful experience. Does anyone have any final questions?

Please remember to take your pack. The pack includes a summary of the key information from today's workshop and some booklets which you may find helpful.

Outcomes

Know sources of help



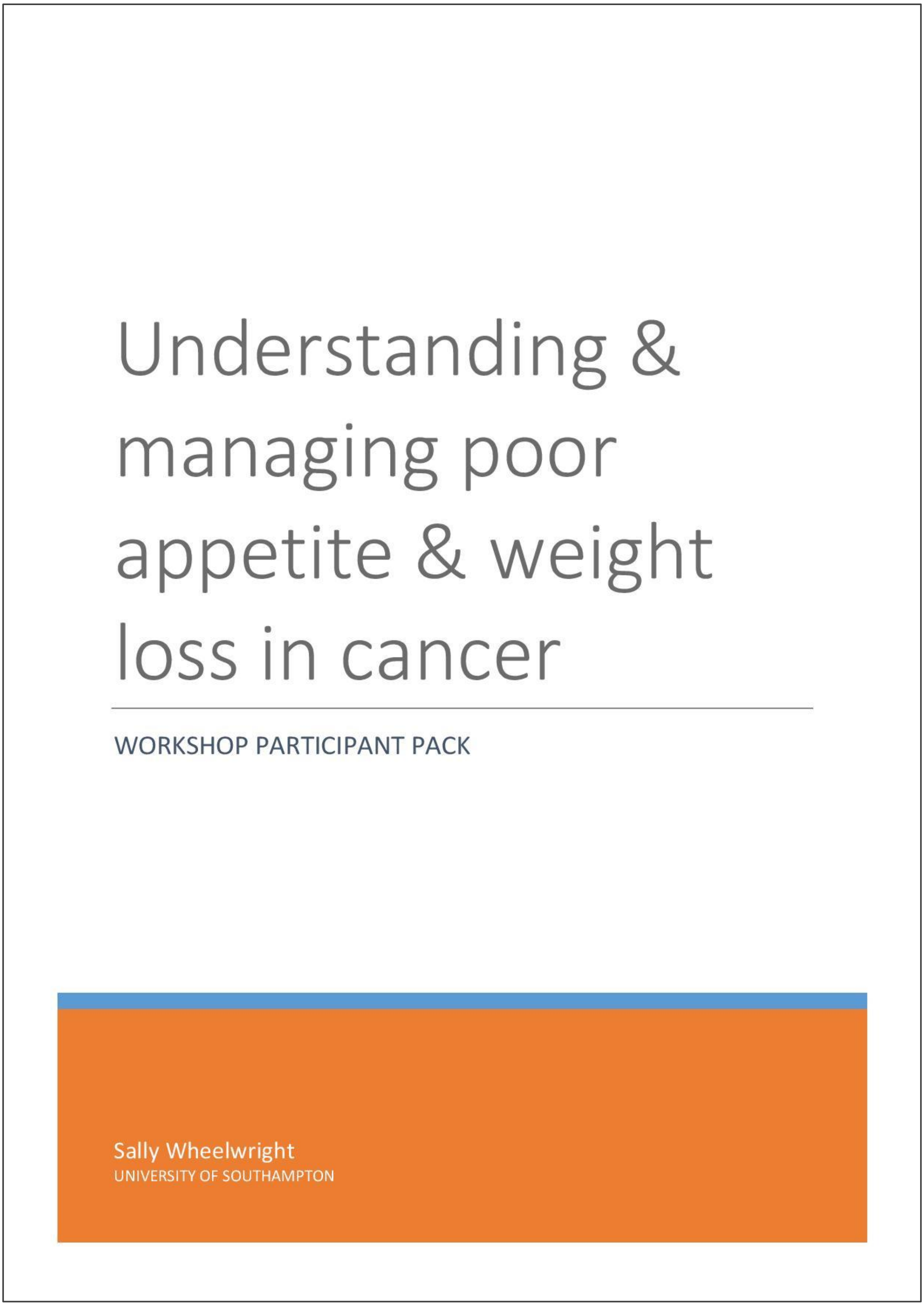
Post-workshop follow up telephone call

About a week after the workshop, follow up all participants, both patients and carers, with a phone call. Questions to ask include:

1. Did you find the workshop useful?
2. Did you write anything on the Changes Form?
3. Have you made any changes as a result of attending the workshop?
4. Do you have any questions about eating and weight loss?

The phone call is the last contact directly related to the workshop so remind patients and carers of this and who they can contact for further support.

Appendix T Participant pack



Understanding & managing poor appetite & weight loss in cancer

WORKSHOP PARTICIPANT PACK

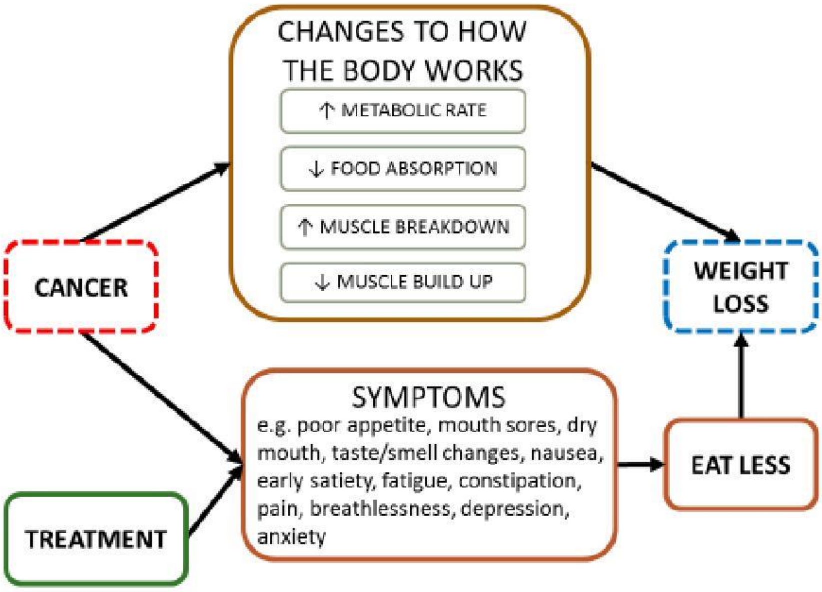
Sally Wheelwright
UNIVERSITY OF SOUTHAMPTON

Introduction

Thank you for coming to the workshop. We hope that you found it useful. This pack contains a summary of the key information that was covered in the workshop.

How can cancer lead to unintentional weight loss?

This diagram summarises current understanding on why unintentional weight loss is a common result of cancer.



Cancer can change how the body works. The rate the body uses energy, its metabolic rate, may increase. In other words, the body burns calories faster. At the same time, food absorption may not be as good as it used to be. So the body is getting less energy from food, whilst using up energy quicker.

Cancer can also affect muscle – it can make muscle breakdown more and it can make it harder for the body to build muscle up again. This can result in weakness and fatigue.

The diagram also shows how both cancer and treatment can cause lots of symptoms which means people with cancer tend to eat less. This also contributes to weight loss. As you can see, there are many symptoms which can affect the amount of food which is consumed. If any of these symptoms are a problem for you, talk to the professionals responsible for your care because they may be able to help improve things.

What should people with cancer and weight loss eat?

Although there is no evidence that any diet or food can cure or control cancer, adapting your eating habits may be helpful if you are not able to eat much food in terms of quantity. If you are struggling to eat enough food, it is a good idea to try to maximise the energy (calories) and protein content of the food you can eat. In this way, smaller portions provide more nourishment. Food which is high in energy and protein is known as **nutrient dense food**. Nutrient dense foods may not always match the usual idea of 'healthy' food but cancer changes the way the body works, so what it means to eat well changes as well.

In the workshop, there were lots of examples of nutrient dense food including:-

cheese, butter, chocolate spread, ice cream, cream, eggs, nuts, meat, chicken, fish, beans, lentils, peanut butter, jam, honey, mayonnaise, cereal bars, chocolate, pork pies, samosas, cocktail sausages

You may be able to think of some more.

Coping with changes to eating habits

The workshop also included some ideas for how to cope with changes to eating habits, listed here, and again you may be able to think of some more.

- Talk to health professionals about treating symptoms which may affect appetite e.g. dry/sore mouth, nausea, diarrhoea, constipation, dehydration, pain, depression
- Choose easy to eat food e.g. soft puddings
- Use fortified milk (add 5tblsp dried milk to 1 pint full fat milk)
- Eat more fried food
- Don't fill up on fruit and veg – eat nutrient dense food
- Have high calorie snacks e.g. nuts, cheese, readily available
- Alcohol can stimulate appetite
- Food preferences may change – try new food
- Have ready meals if that's easier
- Eat what you fancy, when you want. Breakfast may be the biggest meal.
- Fortify food e.g. with cream or butter
- Eat full fat, full sugar foods (avoid low fat or diet food)
- Ask a health professional about using supplements
- Have high calorie drinks
- Try small portions on big plates
- Avoid cooking smells if off-putting (stay out of the kitchen, have cold food)
- If possible, stimulate appetite with light exercise

Relationships

In the workshop, you rated how concerned you were about the weight loss. Was it the same as your partner's or was one of you more concerned than the other? How could different levels of concern affect your relationship?

The podcast illustrated how life can be difficult for two people who care about each other, but find it difficult to explain their feelings about a situation. You can read the text from the podcast here, to remind you of the solutions that Tom and Joan came up with.

Tom and Joan's Story

When I first met Tom he was feeling helpless & frustrated. His wife Joan, who had advanced cancer, was very frail and needed help with most things. He was tired with helping her wash and dress, helping her to the toilet, helping her into bed at night. He missed her company because she was too weak to talk much. But mostly he felt angry and helpless because she would not eat. If only he could get her to eat then she would have the energy to overcome all her other problems.

Tom went to great trouble trying to find out what Joan might like to eat. He prepared proper homemade meals and presented them with great attention to detail. He would help Joan to the table, where she might just eat a single mouthful and declare herself to be full. He felt that it was not just the food that was being rejected, but that he was being rejected. He felt he was trying so hard to improve their lives yet she was trying so little and no longer loved him.

Tom was someone who cared about his wife very much, but did not understand what was happening to her.

Talking to Joan it was clear that she did still care about her husband. It was her cancer that was preventing her from eating. It caused her to have a feeling of fullness all the time that became a feeling of nausea when she ate anything. Yet she had been unable to find a way of explaining this to her husband. She had come to dread mealtimes, but not because of the nausea. She dreaded mealtimes because of the anger and frustration her husband would express. He would shout and cry because she would not eat.

Once Tom realised it was the cancer that was stopping his wife eating, he began to wonder what it may be like to have no appetite. He began to think about how he could do things differently.

He bought himself ready prepared meals from the supermarket so that he didn't need to spend a lot of time cooking and washing up. He would offer his wife a little of his own meal and found that if it took her fancy, she preferred to take one or two spoonfuls from his own plate until she felt full. He also bought yoghurts and cold puddings as Joan would enjoy a little of these, and made her Build-Up drinks that she found easier to take than meals. They enjoyed more time together. They were able to go for short walks with the aid of a wheelchair and spend time looking at photographs of times they had enjoyed in the past. But most importantly, they had freed themselves from the dinner table argument routine, as Tom had come to realise his wife was eating well given her situation.

Have you experienced any similar situations? Did you talk about how they made you feel? How did you help each other? Would you do anything differently, given the benefit of hindsight and everything you have learned about the effect of cancer on eating and weight loss?

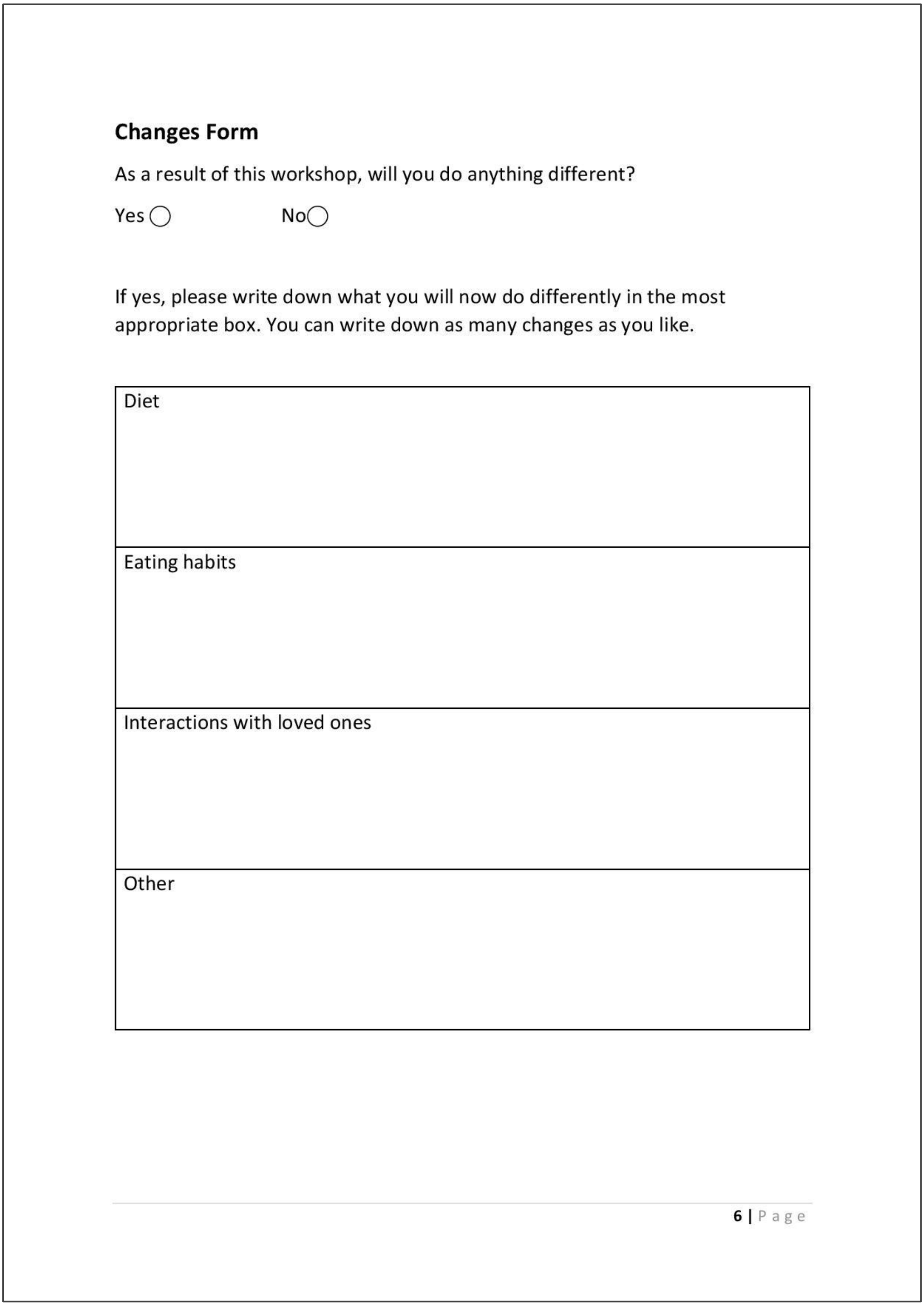
Toward the end of the workshop, you may have filled out the Changes Form, found at the back of this handout. Now that you have had some more time to think about everything the workshop covered, would you like to add some new changes to this form?

How to get more help

Talk to the professionals involved in your care. This could be a clinical nurse specialist, dietitian, oncologist, GP or anyone else who is part of your care team. Unless you tell them, they may not realise that eating and weight loss is a problem you want help with.

Macmillan Cancer Support is also a good place to find out more information and get support. You can phone on 0808 808 00 00 or look at the website at www.macmillan.org.uk.

Another good website to look at is the “Eating Well” section of the Royal Marsden NHS Foundation Trust website at https://www.royalmarsden.nhs.uk/your-care/living-and-beyond-cancer/eating-well



Changes Form

As a result of this workshop, will you do anything different?

Yes ○ No○

If yes, please write down what you will now do differently in the most appropriate box. You can write down as many changes as you like.

Diet
Eating habits
Interactions with loved ones
Other

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