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Evaluation of a specialist weight management service for patients with severe obesity in Liverpool

Dissertation submitted in accordance with the University of Chester for the degree of Public Health Nutrition MSc

Department of Clinical Sciences

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Abstract

Objective: To evaluate a specialist weight management treatment service for patients with severe obesity and follow up at 3 months, monitoring changes in weight, BMI and clinical outcome variables. Changes in food intake, self esteem and health related quality of life (HRQL) were also compared to pre- and post- intervention.

Design: Step by step is a new obesity service which specifically targets obese patients at greater risk of further ill health. Only patients who are referred by their G.P or health professional have been included in the evaluation. After an assessment appointment all patients chose one of two treatment options: group programme, individual dietetic care or both. The group programme offered weekly contact over twelve weeks and monthly follow up thereafter in a community setting. One-to-one care offered monthly appointments with the Dietitian over a three month period.

Subjects: A total of 50 patients with a BMI>30kg/m^2 , mean age 59 years, mean weight for males 113.5kg, BMI 39,3kg/m^2 and females 92.7kg, BMI 36.5kg/m^2.

Main outcome measures: Weight, BMI, Total cholesterol, LDL, TG, HDL, FBG, HbA1C, Blood Pressure, Food Intake, Self esteem and quality of life were measured pre and post intervention

Results: Patients who attended the group programme showed a significant weight loss 1.99kg (P<0.05) and BMI 0.66kg/m^2 at three months. Male patients lost more weight (3.9kg) during the three month period compared to females (1.4kg). Data was not available for individual dietetic care. Patients significantly reduced intake of negative marker foods (P<0.00). No changes were observed between self esteem pre

and post programme however quality of life score increased considerably, 44.83 (S.D. 34.26) to 70.37 (S.D.15.86) P<0.001.

Conclusion: patients attending a 12 week weight management programme run by community dietitians and foodworkers achieve clinically worth while reductions in weight and BMI, improvements in food choice and choice and improved HRQL

Declaration

I hereby declare that work contained herewith is original and entirely my own work (unless indicated otherwise). It has not been previously submitted in support of a degree, qualification or other course.

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Dianne Mullarkey   Date …………………………………..

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Abbreviations

BMI =Body Mass Index

CVD =Cardiovascular disease

DNA =Did not attend

DSE =Diabetes support and education

FBG =Fasting blood glucose

FIQ =Food Intake questionnaire

EQ5D =Euroqol 5 Dimensions

HbA1C =glycosylated haemoglobin

ILI =Intensive lifestyle Intervention

IWMC =Intensive weight management clinic

METS =Metabolic equivalent tasks

PAL =Physical activity level

RSE =Rosenburg self esteem

S.D =Standard deviation

VLCD =Vey low calorie diet

Chapter 1

1.0 Introduction

Obesity is a not a new a phenomenon however the recent increase in the prevalence of overweight and obesity in virtually every country in the industrialised world is alarming (Haslam, 2007). The latest projections from the WHO (2006) estimates that approximately 1.2 billion people in the world are overweight, of which at least 300 million are obese. In some countries, including the USA and the UK, the rates of obesity have more than doubled in the last 25 years, and being overweight has become the norm for adults (Foresight, 2007).

1.1 Classification of obesity

The National Institute for Clinical Excellence (NICE, 2006) report classifies obesity using the body mass index.

This is defined as:

$$BMI = \frac{weight\ (Kg)}{Height^2\ (m)}$$

The NICE classification of obesity is shown in table 1.1a. Though BMI should be used as a measure of overweight in adults, the use of this in the general population needs to be interpreted with caution because it is not a direct measure of adiposity, thus individuals with a particularly well developed musculature may be classified as obese. Some other population groups such as Asians and older people have comorbidity risk factors that would be of concern at different BMI cut off points which are lower for Asian adults and higher for older people (NICE, 2006).

Table 1.1a. The degree of overweight or obesity in adults should be defined as follows

Classification	BMI (kg/m^2)
Healthy weight	18.5–24.9
Overweight	25–29.9
Obesity I	30–34.9
Obesity II	35–39.9
Obesity III	40 or more

NICE (2006)

Waist circumference may also be used, in addition to BMI, in people with a BMI less than 35 kg/m^2 (NICE, 2006).

Table 1.1b: BMI and waist circumference

BMI classification	Waist circumference		
	Low	High	Very high
Overweight	No increased risk	Increased risk	High risk
Obesity I	Increased risk	High risk	Very high risk

For men, waist circumference of less than 94 cm is low, 94–102 cm is high and more than102 cm is very high.

For women, waist circumference of less than 80 cm is low, 80–88 cm is high and more than 88 cm

NICE (2006)

1.2 Aetiology of Obesity

At first the cause of obesity seems simple. Over a period of time, energy intake exceeds energy expenditure. But this simplistic view, which is widely held to be true, hides the intricacies inherent in how we acquire and use energy. In fact, the causes of obesity are complex and multifaceted (Foresight, 2007). This variability is an important feature in that it points to a range of different solutions. Indeed, the multifactorial condition of obesity is inherently unsuited to a 'one size fits all' approach. The concept of a family of 'obesities' is a useful way of recognising this complexity (Foresight, 2007)

The existing evidence collated from research in medicine, the life sciences, the social sciences and economics tells us a great deal about these different causes.

However most of the evidence is generally not well integrated across the different disciplines. Consequently, there is a continuing debate about the relative importance of each cause or variable. In addition, the interactions between different variables are poorly understood.

The examples from a biological perspective include the role of food as a fundamental biological necessity. The hunger drive is very powerful and compels humans to search out food. By contrast, there is limited sensitivity to abundance. The feelings of having had enough (satiety cues) are weak and easily overridden by external factors such as the sight of food or how it tastes (Bloom, 2007). A practical example is the contrast between the difficulties of skipping a meal or not eating before the next mealtime, compared to the ease of succumbing to a dessert or cheese board; even though we may already feel full after eating a main course. Other research studies focus on specific aspects of the 'systems map' (Foresight, 2007) and go far beyond the remit of this evaluation.

1.3 Prevalence and future trends of obesity in the UK

A series of annual health surveys collect information on various aspects of the nation's health throughout the UK. The health survey for England including Wales, records BMI and other measurements such as waist and hip size, making it possible to monitor the increasing prevalence of obesity in the population and its distribution across age groups, gender, socio-economic status and region (DOH, 2007).

 Though BMI needs careful interpretation on an individual basis, it provides a meaningful picture at the population level. The population median (BMI) has progressively increased among adults during the past three decades leading to almost two-thirds of adults and a third of children who are either overweight or obese (Foresight, 2007). It has been suggested that, without clear action, these figures will rise to almost nine in ten adults and two-thirds of children by year 2050 (Foresight, 2007). Today the prevalence of obesity in the UK is greater than in other parts of northern and western Europe (with the exception of Germany). Data published in the Health survey for England (2004) demonstrated nearly a quarter of men (23.6%) and women (23.8%) were obese in England, and Wales which was predicted to increase to approximately 33% in men and 28% in women by 2010. Prevalence of obesity among men in 2004 shows a marked gradient in relation to social class with the highest prevalence in social class V (28%) compared to (18%) in social class II, for women the social class disparity has been longstanding while for men it has only become pronounced in recent years. In 2007, Lobstein, Jackson and Leach found the factors underpinning this are poorly understood. Comparisons of populations internationally show that, above a basic threshold, both obesity and diabetes are linked less strongly to absolute levels of national wealth than they are to indicators of inequalities within

nations which suggests obesity is associated with the degree of relative social inequality.

1.4 Incidence of obesity

The incidence of overweight and obesity in the UK varies with age and with the highest proportion of men and women being overweight or obese aged 55-64 years. The risk of obesity is also greater within Caucasian and Bangladeshi Populations (26% of Caucasian men, 23% of Caucasian women and 24% of Bangladeshi women (DOH, 2007). Other measures that give an estimate of central or abdominal fatness, such as waist circumference and waist to-hip ratio also show this rising trend. These measures may be more accurate predictors of disease (Foresight, 2007).

1.5 Health risks of obesity

Obesity is an independent risk factor for premature death, but is also strongly associated with a number of other serious medical conditions. One of the challenges for policy makers, public health practitioners and other stakeholders is that the public and the media often focus on excess weight as an appearance issue, rather than one that concerns health. Still, obesity is known to lead to both chronic and severe medical problems, long documented through WHO reports (DOH, 2007). Not only do these medical conditions adversely affect people's quality of life, but they create serious, rising financial and social burdens. Several conditions are associated with overweight and obesity. They include type 2 diabetes, hypertension, coronary heart disease and stroke, metabolic syndrome, osteoarthritis and cancer (Kopelman, 2007).

1.6 Future disease attributable to overweight and obesity

A sense of urgency has extended beyond the healthcare sector to Government to try and understand the causes of obesity and to consider how it can be addressed. A critical step in managing what some see as an epidemic is to gain insight into the likely prevalence of overweight and obesity in the future. Mcpherson, Marsh, & Brown, 2007 assessed the impact of overweight and obesity on the incidence of disease in the future by using a microsimulation that imposed the known association between BMI and health risks from the present day on simulated populations to 2050. Predicted increases in disease incidence arise solely as a result of changes in population BMI. The analysis indicated the greatest increase in the incidence of disease would be for type 2 diabetes (alarmingly 70% increase by 2050) with increases of 30% for stroke and 20% for coronary heart disease over the same period (Mcpherson et al. 2007).

1.7 Economic costs of overweight and obesity

The costs of obesity are very likely to grow significantly in the next few decades. Apart from the personal and social costs such as morbidity, mortality, discrimination and social exclusion, there are significant health and social care costs associated with the treatment of obesity and its consequences, as well as costs to the wider economy arising from chronic ill health. The House of Commons Health Select Committee estimated that the total annual cost of obesity and overweight for England in 2002 was nearly £7 billion. This total includes direct costs of treatment, the cost of dependence

on state benefits, and indirect costs such as loss of earnings and reduced productivity (Commons, 2004).

The Committee estimated that the direct healthcare costs for the treatment of obesity alone and its consequences were between £991 million and £1,124million in 2002, equating to 2.3–2.6% of NHS expenditure (2001/2002). Other indirect costs include higher levels of sickness and absence from work, decreased household incomes, earlier retirement and higher dependence on state benefits which arise from being obese (Commons, 2004).

1.8 Obesity in Liverpool

A report devised by the (DOH, 2009) indicated the health of people in Liverpool is generally worse than the average for England and the city has seen a significant rise in obesity in recent years:

- An estimated 40% of the Liverpool adult population are overweight and 20% obese.

- In Liverpool estimates predict obesity results in over 130,000 sick days every year

- The NHS in Liverpool spends £5 million a year on treating obesity related problems, which cost the city's wider economy an additional £15m a year.

If current trends continue, up to half of all children and one third of adults in Liverpool will be overweight or obese by 2020. In April 2008 Liverpool PCT launched its healthy weight: Healthy weight: Healthy Liverpool Strategy with the objective of reducing the level of obesity in the city from 2010. The community

health department already runs a number of programmes including the Community

Food Worker programme and active city which aim to motivate people to focus on a

healthier lifestyle. Liverpool community dietetic department and community food

workers have also supported campaigns which have taken place throughout the city

including the Liverpool Challenge, devised and managed by the trusts social

marketing team which aimed to galvanise the city into thinking about healthy

lifestyles in relation to their weight and encouraging large numbers of the population

to make healthy changes as part of a city wide initiative (LPCT, 2009).

1.9 Benefits of weight loss

The benefits of weight loss in overweight and obese individuals include

improvements in most parameters: physical, metabolic, endocrinological and

psychological complications. The research of Mulvihill and Quigley (2003) indicated

intentional weight loss may also reduce obesity-related mortality. The Scottish

Intercollegiate Guidelines Network (SIGN, 1996) describes in more detail below the

many benefits that can derive from a modest weight loss.

Table 1.9a. The benefits associated with a 5-10% weight loss	
Mortality	Over 20% fall in total mortality
	Over 30% fall in diabetes-related deaths
	Over 40% fall in obesity-related cancer deaths
Blood pressure (in hypertensive people)	Fall of 10 mmHg systolic
	Fall of 20 mmHg diastolic
Diabetes (in newly diagnosed people)	Fall of 50% in fasting glucose
Lipids	Fall of 10% total cholesterol
	Fall of 15% low density lipoprotein
	Fall of 30% triglycerides
	Increase of 8% high density lipoproteins

Other benefits	Improved lung function, and reduced
	back and joint pain, breathlessness, and frequency of sleep

apnoea Improved insulin sensitivity and ovarian function when more than 5% weight loss occurs

(SIGN, 1996)

The health and economic consequences described so far make it clear that obesity is a problem that needs to be addressed, though other social and health factors make obesity a complex and interesting issue for policy makers and people who manage the treatment (Mulvihill & Quigley, 2003). The public health white paper 'Choosing Health (2004), devised following extensive consultation with the public and stakeholders, set a goverment focus for the first time ever on tackling the problem of obesity. One of the policies to implement included 'specialist obesity services with access to a dietitian and advice and support on changing behaviour' (DOH, 2009) however following this agenda, recession has created economic downturn which has impacted on many services within the NHS and only one area within Liverpool was granted a budget to address this agenda.

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1.10 Patient Centred Approach

Turning to the clinical and practice management of obesity, a patient-centred approach to treatment based on respect for and understanding of the patient and requiring the strong commitment of the patient is stressed. A structured system of care with long-term support and use of healthcare teams in primary care dedicated to obesity management and other disorders requiring similar approaches (e.g. hypertension care, smoking cessation), is proposed. However there is a lack of consistent weight management programmes within primary care settings (Mulvihill & Quigley, 2003). There is a need for consistent evaluation over a longer duration and of

publishable quality to identify a programme, which is most suited for the UK

population and adaptable for regional variation.

 In the subsequent literature review I discuss the best evidence regarding approaches

to tackling obesity in a community setting.

Chapter 2

Literature review

The Foresight project 'Tackling Obesities: Future Choices' (Foresight, 2007) has collated the existing evidence base of scientific research pertinent to obesity to give a platform from which to develop a long term vision for the public health response. This expands the more specific and focused reviews of the research evidence collated by NICE (2006). It is clear from the report there are many reasons why an individual may become obese and the current prevalence of obesity in the UK population is primarily caused by people's latent biological susceptibility interacting with a changing environment that includes a more sedentary lifestyle and increased dietary abundance. The specific causes at an individual level are many and varied and differ between population groups and across a person's life course, with the accumulation of excess fat, and therefore weight, being the end result of a variety of causal pathways (Foresight, 2007). During the course of the report a number of issues to facilitate obesity research were recurring themes for e.g. improving methodologies to measure diet and physical activity and development of detailed models to examine the future impact of obesity and its co morbidities (Foresight, 2007).

Wilding (2006) also described the state of the obesity epidemic and the profound implications for public health and emphasised 'it is essential that any strategies adopted for treatment are directed towards those at greatest risk of the medical complications associated with the condition'. Strategies which already exist include dietary, physical activity, behaviour modification, pharmacological and surgical weight loss methods with multi-component interventions being the treatment of

choice (NICE, 2006). For the purpose of this literature search, existing weight loss methods and evaluation of weight management programmes will be reviewed.

2.1 Dietary approach to weight loss

The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure (NICE, 2006). There is a wide-range of dietary interventions, shown to be effective in the treatment of obesity. Avenell, Brown and Mcgee (2004) highlight existing evidence in support of 600Kcal deficit approach, low calorie, very low calorie and low fat diets as being most likely to be effective for modest weight loss. The same review found a 600Kcal deficit approach with the aim of obese clients to lose 1-2lbs/ week (0.5-1kg), focusing on portion control, low fat, high CHO diet resulted in a mean weight loss of 5.32kg when following a calorie restricted diet (95% CI –5.86 to –4.75) with improvements in risk factors at 12 months when compared to usual care. In the same review very low calorie diets under supervision produced greater short term weight loss (420 kcal/day for 8 weeks) which was shown in one study to cause significant weight loss, resulting in a body weight change of –13.40 kg (95% CI –18.43 to –8.37) compared with usual care (Avenell et al. 2004) although the relative effectiveness of clinically prescribed VLCD in the long term has shown weight regain is common.

2.2 Measuring food intake

Food intake is hard to measure, especially in obese subjects (Seidell, 1998). Discrepancies of 22% between reported energy intakes and measured energy expenditures (using the doubly labelled water method) have been described in obese

men and women using the food frequency questionnaire methods (Kroke et al. 1999).

It is widely recognised subjects who are obese; misreport, the consequence being a complex pattern of partly inaccurate information (Winkler, 2005). Despite limitations from using FFQ and 24 hr recall methods to collect diet history; in clinical practice it is not always feasible for patients to weigh foods. Also dietary questionnaires which have been developed to measure nutrient intake via usual food consumption for use in large population studies (Kroke et al. 1999), can be subject to the effects of confounding (Margetts & Nelson, 1991). Estimates of nutrient intake are not always necessary to assess eating habits or to form the basis of sound advice, due to dietary advice being given in terms of foods, not nutrients. In 1999, Johnson, Hackett, Bibby and Cross assessed the face validity of a food intake questionnaire which is an adapted recall method collecting food-based data on the consumption of specific foods eaten on the previous day. Two hundred and twenty eight dietitians were asked to name foods they considered the most important when advising clients on four aspects of healthy eating. For example when lowering sugar intake eat less sweets and increase fruit consumption. Foods mentioned by most respondents in each category were ranked. The FIQ had face validity due to food items appearing in the list of ranked foods by more than 50% of the sample. More than half of the dietitian's considered 31 out of 56 foods where important when considering the four aspects of healthy eating. For this reason the FIQ is routinely used for assessing the eating habits of the Liverpool community and will be used during the evaluation process.

2.3 Physical Activity

The health benefits of a physically active lifestyle are well documented and large amounts of evidence suggest regular activity contributes towards weight loss and is related to a lower incidence of many chronic conditions such as type II diabetes and cardiovascular disease (Shaw, Gennat, O Rourke, & Da, 2006) however it is not usually advocated as a sole treatment option (Wilding, 2006).

NICE (2006) suggest incorporating physical activity into everyday life in the form of supervised exercise programmes or lifestyle activities including brisk walking, gardening or cycling although any physical activity should take into account a person's physical fitness and ability. The guidelines also recommend increasing activity for obese patients to double that of the general population to improve weight loss maintenance (NICE, 2006).

Table 2.3a Physical activity guidelines for the general population, prevention of obesity and people who have been obese	
Type	**Time**
General population	30 minutes per day of moderate-intensity activity on 5 or more days a week
To prevent obesity	45-60 minutes of moderate-intensity activity a day particularly if not reducing energy intake
People who have been obese and have lost weight,	60-90 minutes of activity a day to avoid regaining weight
(NICE, 2006)	

A review by Shaw et al.(2006) concluded physical activity for a minimum of 30 minutes three times a week resulted in a body weight change of –3 kg (95% CI – 4.00 to –2.18) compared with no treatment, at 12 months, this improved when

duration of physical activity was increased. A number of other interventions have shown different ways of encouraging increased physical activity for the management of obesity. A review of systematic reviews and meta analyses by Bravata et al.(2007) demonstrated how using pedometers significantly increased physical activity in women over 49 years of age by 2491 steps per day more than control participants (95% CI, 1098-3885 steps per day, P<0.001). When data from this review was combined, pedometer users significantly reduced their body mass index by 0.38 (95% CI, 0.05-0.72; P =0.03). Although the positive outcome in the intervention was associated with older age, and having a step goal, pedometers appeared to motivate individuals to take part in physical activity, however more research is needed from weight management programmes which use pedometers. There appears to be lack of understanding as to the most appropriate level of exercise intensity needed to promote reasonable weight-loss. Walking is known to metabolise a high percentage of fat and is considered safe and sensible practice. However this results in small amounts of fat being oxidised due to the low metabolic demand of the exercise (Macfarlane & Thomas, 2009). Though a light exercise regimen is likely to be appropriate for those who are overweight or sedentary individuals beginning an exercise programme, the aim should be to gradually increase the work rate to moderate levels as their capacity or ability allows providing it does not compromise health. Indeed Shaw et al. (2006) concluded that vigorous exercise is more effective in causing weight loss than either moderate or light activity, but only when diet was not restricted.

2.4 Behavioural Therapy

Behaviour strategies aim to help to reinforce changes in diet and physical activity for the treatment of adult obesity and require trained health professionals with good interpersonal skills to use the approach appropriately. A report by NICE (2006) recommends techniques using behavioural therapy, which have been developed to assist patients in conjunction with other weight loss approaches.

Behavioural Interventions for adults should include the following strategies as appropriate per person.

- Self monitoring of behaviour and progress
- Stimulus control
- Goal setting
- Slowing rate of eating
- Ensuring social support
- Problem solving
- Assertiveness
- Cognitive Restructuring (modifying thoughts)
- Reinforcement of changes
- Relapse prevention
- Strategies for dealing with weight regain

(NICE, 2006)

No single method or combination of behavioural methods, prove to be clearly superior (Wilding, 2006). Thus, various strategies may be used to modify patient behaviour over the long term and such change can be achieved on an individual basis or in group settings.

It appears from research undertaken by Douketis, Feightner, Attia, and Feldman, 1999 (as cited by Wilding, 2006) suggests combining behavioural approaches with more traditional dietary and activity advice, which may lead to improved weight loss during the initial 6-12 months and is currently the most effective lifestyle approach to managing weight. However these studies are of relatively short duration, therefore the evidence base is limited to one year.

2.5 Combined approaches: Lifestyle interventions

Despite clear guidelines being published (NICE, 2006) there are still many weight loss interventions which only offer a 'quick fix' rather than a sustainable intervention to losing weight.

Multi-component interventions are the treatment of choice and programmes should include behaviour change strategies to increase physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet and reduce energy intake (NICE, 2006). The evidence for this approach is based on large multi-component interventions which clearly demonstrate a combination of various levels of physical activity, behaviour therapy in different forms, and either a low-calorie or

calorie-deficit diet that can result in a body weight change of –4.22 kg (95% CI –4.80 to –3.64) compared with no treatment, at 12 months (Shaw et al. 2006).

 Large scale clinical trials have demonstrated the effectiveness of lifestyle interventions in specific groups of patients particularly those with impaired glucose tolerance who have achieved a modest weight loss of 5-10% from presentation weight. Weight loss mainly results in clinically worthwhile reductions in co morbidities such as type 2 diabetes, dyslipidaemia and hypertension reducing the overall risk of metabolic syndrome (Wilding, 2006). In the next section of this literature review, two european lifestyle programmes which address the benefits of weight loss to prevent type 2 diabetes and the complications associated with obesity including cardiovascular risk factors will be considered.

2.6a PREDIAS (Prevention of diabetes self management programme)

 'PREDIAS' is a lifestyle modification intervention and demonstrates the effects of weight loss for the prevention of diabetes. Inclusion criteria included adults aged 20-70 years with BMI > 26kg/m^2, with impaired glucose tolerance or impaired fasting glucose and an ability to read and understand German. Exclusion criteria were manifest diabetes or diagnosis of a serious illness e.g. cancer. Kulzer, Hermans, Gorges, Schwarz, and Haak (2009) randomised 182 male and female participants into a control or lifestyle modification programme. There were no significant baseline differences between those in the PREDIAS and the control group, 43% of the participants where female and mean age of the subjects was between 56.3+10.1 years, BMI (31.5+5.3 kg/m^2) and fasting glucose 105.7+12.8mg/dl.

The prevention program consisted of 12 lessons lasting 90 minutes each. During the first 8 weeks, eight core lessons were given with one per week; the last four lessons were bi-monthly. The program is based on self- management theory and was conducted in small groups (median size seven people) and delivered by either diabetes educators or psychologists. Each participant received an exercise book, which contained information about diabetes prevention which contained resources such as a table of caloric values and worksheets e.g. eating diaries for each lesson. PREDIAS was compared with a control group whose members received written information about diabetes prevention and patient materials from the PREDIAS lifestyle modification programme.

The aim of this study was to evaluate efficacy of PREDIAS with regard to the primary outcome variable (12 month follow up), weight reduction as well as behavioural, metabolic and psychological outcomes as secondary variables.

Physical activity was assessed by a physical activity questionnaire used in a representative federal health survey in Germany. The Three factor eating questionnaire, with three scales cognitive restraint of eating, disinhibition, and hunger was used to measure psychological determinants of eating behaviour and anxiety was measured by the State Trait Anxiety Inventory.

The WHO Five well being index (WHO-5) assessed psychological well-being (low scores indicate reduced psychological well being) and the centre for Epidemiological Studies Depression Scale (CES-D) measured depressive symptoms (high scores indicate elevated depressive symptoms).

After 12 months, there was a significant effect on body weight. Participants in the intervention group had lost mean 3.8 kg of weight, whereas members of the control group had reduced their weight by 1.4kg (P=0.001). An intention to treat analysis yielded similar results (control group -1.3+3.9kg vs. PREDIAS group -3.6+5.1kg; P <0.001). A significantly higher proportion of weight was lost by those in the PREDIAS than those in the control group (-3.8 ± 5.2 vs -1.4 ± 4.0 respectively; P = 0.001). Similar results were obtained for BMI in control (-0.5 ± 1.4) and PREDIAS (1.3 ± 1.7). A between group value of ($P = 0.002$) was obtained for BMI, however discrepancies between these results were not discussed.

Both groups increased their physical activity, but this was significantly greater in the PREDIAS than in the control group. Cognitive restraint of eating behaviour was significantly increased in the PREDIAS compared to control group, and eating disinhibition was significantly decreased in the PREDIAS than in the control group. Members of the PREDIAS group showed a significant within-group reduction on the hunger scale, but there was no significance between group difference (Kulzer et al. 2009). There were significant effects on fasting glucose; however the 2-h postprandial glucose values did not change significantly between the groups. Total cholesterol and triglycerides as well as systolic and diastolic blood pressure, were significantly reduced in the PREDIAS group whereas in the control group there was no substantial change in these risk factors

This study demonstrated significant weight loss. All measurement variables such as weight and clinical markers were clearly defined, however this could not be generalised to the UK population. The methods used for collecting data were valid

however the reliability of the hunger scale seemed ambiguous, the participants stated they were less hungry; however there was no explanation given for this finding, which suggests the sensitivity of the tool may have been reduced. There was also no explanation given for the non significant effect of weight loss on 2-h postprandial glucose values.

2.6 Look AHEAD Study

The look ahead study (Action for Health in Diabetes) conducted in the USA randomized 5,145 overweight and obese individuals with type 2 diabetes into an intensive lifestyle intervention involving group and individual meetings to achieve and maintain weight loss through decreased caloric intake and increased physical activity, this was compared with usual care diabetes support and education (Pi-Sunyer, et al. 2007). Baseline characteristics included BMI >25 kg/m^2 (>27 kg/m^2 if taking insulin) and mean age > 40 years.

The primary objective was to determine whether cardiovascular morbidity and mortality in individuals with type 2 diabetes can be reduced by long-term weight reduction, achieved by an intervention that includes diet, physical activity, and behavior modification including goal setting and maintain loss of at least 7% of initial body weight.

Although one of the main objectives was to reduce weight, the overall aim was to reduce cardiovascular risk events thus an exercise test was performed on men and women with type II diabetes. Individuals not achieving criteria for age predicted maximal heart rate were not eligible for randomization into Look AHEAD.

Sessions were led by intervention teams that included registered dietitians, behavioral psychologists, exercise specialists and lifestyle counselors. Participants were seen on

a regular basis in months 1-6 which included an individual session on the fourth week of every month. During months 7-12 participants continued to have a monthly individual meeting with their lifestyle counselor but the number of group sessions was reduced from three to two per month.

A calorie restricted diet was the primary method of achieving weight loss. The macronutrient composition of the diet was structured to enhance glycemic control and to improve CVD risk factors. Participants were prescribed portion-controlled diets, which included the use of liquid meal replacements (provided free of charge) and frozen food entrées, as well as structured meal plans (comprised of conventional foods) for those who declined the meal replacements. Monthly reviews took place at an individual session to reassess progress.The physical activity program prescribed to the intervention candidates relied heavily on home-based exercise with gradual progression toward a goal of 175 min of moderate-intensity physical activity per week. Participants assigned to the intensive lifestyle program lost considerably more weight on average 8.6% of their initial weight vs. 0.7% in control group ($P < 0.001$). A significant relationship was observed between race/ethnicity and weight loss, as shown in figure **2.6c** below.

Figure 2.6c
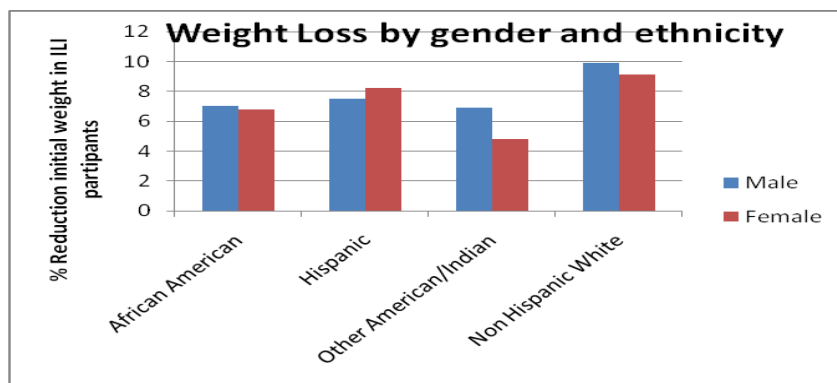
(Pi-Sunyer, et al., 2007)

Percentage reduction in initial weight (in the ILI group) based on gender and ethnicity. ILI, intensive lifestyle intervention

A one way ANOVA revealed that the four ethnic groups all differed significantly ($P < 0.001$) from each other, but there was not a statistically significant ethnicity-by-gender interaction. Weight losses achieved in this study demonstrate the wide-scale acceptability of Look AHEAD's lifestyle intervention. Smaller weight losses in groups other than Hispanic white may have been attributable to a variety of non-treatment-related factors and significant economic barriers (e.g., lack of transportation). This finding in relation to UK weight management interventions demonstrates the difficulty for programmes to achieve a 5-10% weight loss in all subsets of a demographically and ethnically diverse population,

There were greater reductions, in diabetes, hypertension, and lipid-lowering medicines when compared to control participants. Mean HbA1C dropped from 7.3% to 6.6% in Intensive LI ($P < 0.001$) vs. from 7.3 to 7.2% in DSE. Systolic and diastolic pressure, triglycerides, HDL cholesterol, and urine albumin-to-creatinine ratio improved significantly more in intensive than control participants (all $P < 0.01$)

 (Pi-Sunyer et al. 2007).

 This study's principal finding was that an ILI induced a clinically significant weight loss in all subsets of a demographically and ethnically diverse population which is more reliable than the PREDIAS study due to sheer sample size and large improvements in cardiovascular risk factors. A standard method for measuring energy expenditure was used METS (metabolic equivalent tasks). For example one MET is the energy expenditure and caloric requirement at rest, METS increase depending on level of activity which is important for reliability purposes and similar to the UK equivalent PAL (Physical activity level). However the results cannot be generalised due to the intensity of the programme and the use of liquid meal replacements. Meal

replacements are not a sustainable lifestyle change for weight loss but are useful for rapid weight loss in morbidly obese patients. Continued intervention and follow-up will determine whether changes are maintained and overall CVD risk is reduced in the same participants.

Although weight loss was solely for treatment purposes in both studies and the magnitude of these effects could not be generalised to UK population, observed metabolic change recognise that weight management does not cease at the end of the weight loss phase (6 months for most people) and ideally a structured maintenance phase should be implemented after 6 months to maintain this level of metabolic change in order to prevent diabetes and CVD.

2.7 Evaluating weight management programmes in the UK

Evaluation is particularly important in the area of UK interventions that aim to tackle the issue of overweight and obesity. The National Obesity Observatory (2009) state there is a lack of high quality evidence on effective weight management interventions in the UK, with many being of short duration, with little or no follow up.

Other studies found that whilst interventions are being commissioned by a variety of organisations, data informing the relative 'success' of the interventions, in terms of the intended health outcomes are patchy and inconsistent, (Aicken et al. 2009). In light of this finding the national obesity observatory (NOO, 2009) produced a standard evaluation framework (table **2.7b**). The aim of the framework is to support high quality, consistent evaluation of weight management interventions in order to

increase the evidence base. This should ensure core information is collected in a standardised way across the country, helping to increase our understanding of the impact of individual intervention programmes (NOO, 2009).

The essential criteria (marked x) for a successful weight management evaluation are as follows:

Table 2.7b: NOO (2009) core elements of standard evaluation framework (Criteria adapted)	
Demographics of individual participants	**Essential**
27. Age	x
28. Sex	x
29. Ethnicity	x
30. Disability	x

31. Measure of socio-economic status	x
32. Additional information including marital status, medical history.	
smoking status, parity and family make-up	x
33. Details of parental weight status (for children)	
Part three: baseline data	**x**
34. Height and weight (to calculate Body Mass Index)	**x**
35. Additional proxy measures for adiposity	
36. Measure(s) of dietary intake and behaviour	**x**
37. Measure(s) of physical activity levels and behaviour	**x**
38. Potential facilitators of, and barriers to, lifestyle change	
Part four: follow-up data Impact evaluation	**x**
39. Follow-up data: minimum of three follow-up points,	**x**
including at one year	
40. Follow-up data on key measures (height, weight, physical	
activity and diet) over a greater term than one year	**x**
41. Height and weight (to calculate Body Mass Index)	x
42. Follow-up data on additional proxy measures for adiposity	
(if collected at baseline)	
43. Dietary intake and behaviour	x
44. Physical activity levels and behaviour	

45. Follow-up measures on potential facilitators of, and barriers to, lifestyle change (if collected at baseline)	
Process evaluation	x
46. Number invited	x
47. Number recruited	x
48. Number attended each session or contact point	x
49. Number completed	x
50. Number of participants at each follow-up point	x
51. Methods of data collection and timings	
52. Reasons for opt-out (where applicable)	x
53. Details of any unexpected outcomes and/or deviations from the intended intervention design and the reasons why	
54. Participants' satisfaction with the intervention	x
55. Plans for sustainability	
Part five: analysis and interpretation	x
56. Summary of results compared to baseline	
(for primary and secondary outcomes)	x
57. Details of any further analyses and statistical methods	
58. Limitations and generalisability	

(NOO, 2009)

Though the framework is clear and consistent, clinical risk factors particularly in adults should be collected if available for e.g. lipids. If this data is available to clinicians: information can be collected at baseline with other co-interventions such as anti-hypersensitive drugs which may also influence outcome in the long term (Douketis, Macie, & Thabane, 2005). At follow up, the effects of weight loss on CVD risk factors can then be compared.

2.8 Health Related Quality of life

Another important outcome for weight loss programmes is health related quality of life, obese people suffer prejudice, discrimination and stigmatisation at all levels of social functioning with psychological distress occurring not only as a result of the negative reactions of others but failed attempts at weight loss (Ross, 1994). A study evaluating the association between quality of life (health related utility) and obesity in hospital treated people with diabetes and no diagnosed diabetes was conducted in Cardiff by postal questionnaire to 27 924 patients. Lee et al. (2005) found increasing BMI reduced utility in all three groups, BMI was significantly greater for those with type 2 diabetes (P<0.001). This study concludes obesity negatively impacts upon health related utility and thus quality of life for all patient groups, thus EQ5D is a useful tool for weight management programmes measuring changes at baseline and subsequent follow up.

2.9 Counterweight Programme

The Counterweight programme is the only fully evaluated evidence based primary care weight management programme in the UK (Counterweight, 2008). Adult patients

were offered counterweight if they had a BMI >30 kg/m2 or 28 kg/m2 with obesity related co morbidities and in the contemplative or action stages of change. (Prochaska & Diclemente, 1983).

Weight management advisers and dietitians led and facilitated implementation of counterweight, offering expertise in obesity management, providing materials and training for practice nurses from 65 UK general practices. Practice nurses delivered patient education using published materials and asked patients to commit to nine appointments in 12 months after initial screening. First-line interventions included six individual appointments (10–30 minutes each) in which a prescribed-eating plan was administered, or six group sessions (1 hour each) over a 3-month period (exclusively goal setting). Patients were then followed up at 6, 9, 12, 24 months and aimed to achieve an energy deficit of ≥500 kcal/day. The counterweight team planned 3-month reviews in session 6 of the intervention.

If weight loss of >5% was not achieved at 3 months patients were eligible for pharmacotherapy. Nurses delivered interventions to 1906 patients with the majority having severe obesity. Mean age for patients at baseline was 49.4 years (SD 13.5 years, range 18.1–76.0 years) with 77% of the intake being female. At follow up primary outcome measures include weight changes at 12 and 24 months and percentage of patients achieving and maintaining 5% loss at these time points. Secondary outcomes were changes in clinical biochemistry. There were high levels of attrition at twelve and 24 months (825 patients). For data that was available mean weight change was considerably lower (–3.0 kg (95% CI = –3.5 to –2.4 kg) and at 24 months was –2.3 kg (95% CI = –3.2 to –1.4 kg). Over a quarter of patients had maintained weight loss of 5% at 12 months and 24 months. Cardiovascular risk

factors were greatly improved at 12 months including a reduction in total-cholesterol –0.29 mmol/L ($n = 303$, $P<0.001$); low-density lipoprotein cholesterol –0.35 mmol/L ($n = 172$, $P<0.001$); HDL-cholesterol +0.03 mmol/L ($n = 234$, $P = 0.08$); systolic blood pressure –2.03 mmHg ($n =580$, $P = 0.01$); diastolic blood pressure –1.15 mmHg ($n = 580$, $P = 0.01$), and (in patients with diabetes only) HbA1c –0.19%($n = 93$, $P = 0.17$); and fasting glucose+0.08 mmol/L ($n = 28$, non-significant).

These results demonstrate Counterweight is an effective programme offering ongoing support with realistic weight loss goals. The intervention can be generalized to UK patients due to the large sample size and UK based practices. Importantly the results showed patients were monitored throughout and the effects of treatment certainly improved risk factors. The use of onscreen alerts to remind of patient appointments was useful. It was unclear why attrition rates were so high at twelve and 24 months and why there was a higher ratio of women to men (Counterweight, 2008). Other small scale studies have evaluated weight management programmes run by health visitors (Muckle, 2007) some of the recommendations for practice after conducting interviews included.

- Obesity management could mirror smoking cessation services by assessing individuals readiness to change and making services available for those who are motivated
- Education should address attitudes towards obesity; it should be managed and treated as a chronic condition.
- Specialist services should include support groups, counselling or cooking skills courses according to individual need.

- Easier access to physical activity, specifically for those who are overweight or obese because they felt too self conscious to attend mainstream services.

(Muckle, 2007)

Taking the above into consideration it is also apparent men are more reluctant to engage in weight loss programmes. Gray et al. (2009) addressed this problem by evaluating a group based weight management intervention based on the Camelon model specifically developed for men. The programme was a success as the majority of obese men 76.2% who enrolled in a weight management group completed the 12-week programme: of these, 44.3 % achieved ≥5% weight loss. The model was particularly useful at engaging hard to reach men by making them aware of health risks and being described as 'obese'. The humour, rapport with nurses, other men, positive food and exercise choices were some of the reasons why they decided to continue with the intervention (Gray et al. 2009).

2.10 Group programmes versus one to one care

In response to the obesity epidemic, the weight management field has changed dramatically over the last ten years and there is now an urgent need for the dietetic profession to consider whether current approaches meets this changing agenda and to examine how to best utilise time and expertise (DOM UK, 2007). As discussed in the literature, guidelines for weight management recommend energy restriction, combined with increase in exercise and behaviour therapy. Also disease management styles, which centre around the patient and their goals have resulted in better adherence to treatment protocols, reduced morbidity and improved (HRQL) health related quality of life (Bauman, Fardy, & Harris, 2003). Little evidence exists when

comparing one to one care to group based sessions for weight management. A study

by Ash, et al. (2005) randomised a total of 176 adults with a BMI of 27 kg/m2, (mean

age 48 years, mean BMI 34+5.5 kg/ m2) into cognitive behaviour therapy,

individualised dietetic treatment and information booklet only. The aim of this study

was to demonstrate that group therapy is more effective at reducing weight and other

weight variables, increasing activity and improving health and well being when

compared to other treatment interventions. A statistically significant difference

between groups was observed for weight change over time (P< 0.05). The change in

weight for group therapy was significantly greater than the book only group at 3 and

12 months (2.87+0.7 compared to -1.7+0.6 kg, P<0.05 and -2.9+0.9 compared to

+0.5+0.9 kg, P<0.005, respectively). Though changes in weight did not differ at any

time point except when compared to the book only intervention, the group

intervention was shown to be as effective as individualised dietetic treatment and

more cost effective as the intervention is dealing with more patients over a set time

period (Ash et al. 2005).

 A more recent evaluation by Hickson, Macqueen and Frost (2009) collected data on

consecutive obese patients, attending either and intensive weight management clinic

(IWMC) or a general dietetic outpatient clinic. The IWMC had a structured approach

with six once-a-month appointments, a signed agreement to attend, an initial

screening of readiness to change and consistent advice from one dietitian. The general

clinic was less structured, had more ad hoc follow up and did not guarantee one

dietitian. The majority of patient's refered were female with a mean age of 48 years.

Thirty-three percent (103/313) of all patients referred did not book an appointment.

Of those attending with a body mass index 32 kg m^2, 55% were seen in the general

and 45% in the intensive clinic, but only 19% and 53%, respectively, completed the

programmes. The total amount and rate of weight loss did not differ significantly between clinics. However, analysis using the last recorded weight revealed a median weight reduction of 1.8% (interquartile range = 5.6) at the median rate of 0.4 kg per month in the intensive clinic, compared to no overall weight loss in the general clinic ($P < 0.001$).In conclusion to this a more structured approach and initial screening of readiness to change is likely to achieve better weight loss results and therefore will comprise a better use of dietetic time than including obese patients in general clinics.

2.11 Evaluation aims and research questions

Aim

The aim of this evaluation was to evaluate the introduction and impact of a specialist obesity service by testing the following null hypothesis and further research questions

Null Hypotheses

Hypothesis 1: Patient's six clinical outcomes including body weight, BMI, lipids, fasting blood glucose, Hba1c (if applicable) and blood pressure did not change while taking part in the first three months of a specialist obesity treatment service.

Evaluation Questions

- Are patients reported food choice, self-esteem and HRQL improved as a result of the specialist obesity treatment service?
- Do patients attending the group programme lose more weight and improve clinical outcome when compared to 'usual one to one dietetic practice'?

Chapter 3

Methods

The design was a non-experimental pre and post evaluation of a new specialist weight management service which included usual care dietetic clinics and 12 week group programmes provided by the department of community Dietetics, Liverpool community nutrition and dietetics.

The evaluation included two phases: the intensive phase was integrated in the first 6 months of the weight management programme and follow up phase 6 months after. This was a pre and post analysis of primary data obtained from patients at baseline and 3 months including biochemical data which was ready available from G.P. routine health assessments during the intensive phase of this programme Questionnaires to measure diet, health related quality of life and self esteem were completed at baseline and 3 months in addition clinical variables were recorded if applicable.

3.1 Population and participants

This study used a convenience sampling technique, which focused on all patients routinely referred for dietetic advice for obesity by their GP or other health professional who met the inclusion criteria. The inclusion criteria included patients with a BMI of 30+ with or without comorbidities (comorbidities included high blood pressure, raised lipids or diabetes) and those treated with weight management medications including Orlistat. The principal exclusion criteria included BMI below 30; pregnancy or diagnosis of proven eating disorder: anorexia nervosa or bulimia.

The programme consisted of an intensive phase (0-6months) of which this evaluation reports (0-3 months) and a follow up phase 6-24 months. During the intensive phase patients attended an initial assessment clinic with a specialist weight management dietitian. At the assessment clinic patients chose one of two treatment options: either a 12-week group education programme and dietitian or 4 monthly individual one to one review appointments with the dietitian.

The criteria for exclusion from the data analysis included patients who did not attend their assessment clinic, did not attend their 3 monthly follow up, when data was found to be unavailable or the patient did not agree to take part in the evaluation.

3.2 Step by step group sessions

The sessions were based in Liverpool community health premises and local health centres across Liverpool. This evaluation used the existing clinic network to see patients, conduct assessments and review appointments.

Step by step is a new specialist obesity service, which specifically targets obese patients at greatest risk of further ill health due to their weight. Only patients who were referred routinely by their GP or health professional have been included in the service evaluation. Patients had the option to accept or decline treatment with the service after referral from their GP. All patients receive a service leaflet, which includes information about the dietetic service, their treatment and right to consent to be seen by a dietitian. They were informed that their agreement to attend the initial appointment with the dietitian constitutes consent for treatment. Patients are asked to consent to attend weight management groups if they agreed to take part. At their first

clinic appointment, the senior specialist dietitian completed a dietetic assessment and agreed a specific programme of treatment based on the patients needs.

The programme includes individual care or weight management group sessions. The weight management service aims to offered patient's initial assessment, group sessions, long-term support for losing weight over a two-year period and manage any other medical problems. The service evaluation will be used to enable the dietetic department to investigate and develop a range of treatment options for patients who are obese.

At present weight management groups and individualised care conducted by the community dietitian's. Referral to the multidisciplinary team is offered to patients with little or no evaluation therefore it is difficult to formalize the range of treatment options. In terms of time and cost the group education sessions allows more individuals to access a dietitian for a longer period of time, while reducing waiting lists. The evaluation will formalize the range of treatment options offered to patients with severe obesity. The design and scope of the evaluation was based on staffing levels and evidence based practice. No patients referred at this stage of care were placed at any disadvantage, and all patients meeting referral criteria had the option to be seen in the new expert weight management service model, or be seen in the usual way which enabled support based on individual choice.

3.2a Group programme

The 12-week group sessions were based on best practice, which deliver diet, behavioural approaches and incorporate physical activity for the treatment and management of obesity. The session topics include diet: fats, sugars, fibre, portion control, food combination, food labels, cooking skills and shopping skills.

From a behavioural aspect, sensible target setting and motivational support skills were included. The community food worker team (members of the dietetic team) delivered 4 practical cooking sessions as part of the group education programme, this included one session on the 'eat-well plate' and meal planning. The cook and taste sessions aimed to improve patients knowledge surrounding diet and health by cooking healthier foods which are lower in fat, sugar, salt and higher in fibre. During the community food worker session's patients were given practical tips on food portions, consumption of fruits and vegetables, water consumption, alcohol, eating out and how to eat healthier and cheaper as well as building physical activity into daily life.

Recommendations for physical activity are discussed in detail with the benefits of physical activity and common barriers explained. There is also the opportunity for patients to sign up to 'walk for health' which is a collaborative scheme run by Liverpool PCT which aims to increase physical activity levels. On joining 'walk for health' and after five supervised walks patients receive a free pedometer and gym pass for one month's period. Service information leaflets are also provided to explain and reinforce messages, which include 'Step by Step' and 'Bag a good meal' publications created by the Liverpool community dietetic department, which have been developed with local people in mind.

Patients received a baseline health assessment and were routinely weighed at the same time every week for 12 weeks. During the follow up phase (6-24 months) patients are offered a further 4 assessment clinics with a specialist dietitian at 6, 12, 18 and 24 months.

Further specialist support from the multi-disciplinary team is available when required including e.g. advice on obesity medication, physiotherapy or pyschological support will be referred as appropriate. In addition ongoing support will be available to patients who have the opportunity to access fortnightly weigh in clinics, and practical activities from members of the dietetic team through out the two- year period.

3.3 Measurements

Independent and dependant variables

In this study it was important to collect demographic information on gender (male/female), age (years) and location of health centre visited, which helped provide some characteristics of participants at baseline.

The independent variables in this evaluation included the 'one to one clinic' and '12 week weight management programme' with subsequent follow up one to one reviews.

The dependant variables included changes in weight/kg, BMI, lipid (cholesterol/mmol, LDL/mmol, HDL/mmol), fasting blood glucose/mmol, HbA1C/%, blood pressure/mgHg, food intake, self esteem (Rosenburg, 1979) and health related quality of life (Euroqol, 2010).

3.4 Clinical outcomes

The following six clinical outcomes were measured: body weight, BMI, lipid profile, fasting blood glucose, HBa1c (if appropriate) and blood pressure was extracted from patient case notes on referral and compared from baseline to 3 months to identify changes within this period. These outcomes were selected because they are objective and indicative of a reduction in obesity related risks associated with weight loss, also they represent the most common comorbidities which GP'S referred to the service. All measurement's, including weight and BMI were recorded by a registered dietitian using standardised methods. Weight was measured to the nearest 0.1kg. Patients were measured in light clothing without shoes. Height was measured in meters using a freestanding height measure (*Leicester Portable Height Measure* (SE001 by SECA). Body mass index was calculated using the formula weight (kg)/ height (m^2).

Biochemical measurements were recorded routinely by a G.P as part of the referral process, were available or could be requested with consent from the patient's from their medical records, (stored in a secure unit at Abercromby Health Centre).

Three validated questionnaires were used. The first questionnaire measured dietary intake (Johnson et al. 1999). Self esteem (Rosenburg, 1979) and quality of life (Euroqol, 2010).

3.5 Food Intake questionnaire (appendix 7.1)

The food intake questionnaire (FIQ) is an epidemiological tool for assessing eating habits. It is an adapted recall method, which collects food-based data on the consumption of specific foods eaten on the previous day. Using a food based approach to measure intake is consistent with the way messages on healthy eating are

delivered and the items included have shown to be representative of the general advice given by dietitians in terms of foods to eat more or less of to achieve a healthy diet. The FIQ provides information on food intake at the group level and was not designed to estimate nutrient intake. The FIQ asks basic questions: 'Did you at any time yesterday eat any amount of…' The question is then followed by a list of food related items. The main outcome variables are the number and proportion of adults answering yes and no to specific FIQ items (Johnson et al. 2001)

Foods can be aggregated into groups including positive and negative marker foods. A score is then given for each individual providing a mean score for groups based on gender, age and area.

3.6 Rosenburg self esteem scale (appendix 7.2)

The purpose of the 10 item RSE scale is to measure self-esteem and can been used with a variety of groups including adults. Scoring involves a method of combined ratings. Low self-esteem responses are "disagree" or "strongly disagree" on items 1, 3, 4, 7, 10, and "strongly agree" or "agree" on items 2, 5, 6, 8, 9.

The RSE demonstrates a scale coefficient of reproducibility of .92, indicating excellent internal consistency. For validity purposes the RSE is concurrent, predictive and construct validity using known groups. The RSE correlates significantly with other measures of self-esteem. In addition, the RSE correlates in the predicted direction with measures of depression and anxiety (Rosenburg, 1979).

3.7 EuroQol (appendix 7.3)

EQ-5D (2010) is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics and face-to-face interviews. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire (Euroqol, 2010).

3.8 Referral process

All patients meeting the referral criteria who have indicated that they would like to attend the programme will receive an appointment letter for the expert weight management assessment clinic. At this appointment patients will be asked to read a participant information sheet (Appendix 7.4) which, contain details of the service evaluation, attached to this is a consent form (Appendix 7.5). If a consent form has been signed questionnaires can then be administered to the patient in the first routine care clinic or first week of the group education sessions. Once the questionnaire has been completed it can be returned the lead dietitian, this process is repeated after three months in both cases for the purposes of this evaluation only.

3.9 Confidentiality

Patient's clinical records and data including questionnaires were stored in accordance with Liverpool Community Health clinical governance procedures. Only the researcher and dietitians in the direct healthcare team involved in assessment and treatment had access to personal/ clinical data. After data collection; data was anonymised using a unique reference number for each patient prior to inputting into data files to maintain confidentiality. For all subsequent analysis patient's clinical records and personal details were stored separately to data collected. All electronic data was stored on Liverpool Community Health secure network.

Information collected for analysis procedures, was stored securely on the hard drive of a HP Pavillion. The computer was ID and password protected and only available to the main researcher.

3.10 Ethics

Ethical approval was by the NHS National Research Ethics Service (Appendix 6.7). Minor adjustments were made to the participant information sheet in response to the committee which included rearranging of sentences. This was submitted and data collection commenced. A pilot study was necessary to test logistics and gather information prior to data collection for the evaluation (see appendix). Careful arrangements were in place to obtain informed consent, patients who gave consent for their data to be part of the evaluation were protected under the 'The Caldicott principles' for handling data, Data Protection act (1998) and the NHS Code of confidentiality which ensures patient information is held under legal and ethical

obligations of confidentiality in which information provided in confidence should not be used or disclosed in a form that might identify a patient without his or her consent.

The evaluation used data, which was routinely collected by health practitioners as part of their normal care of the PCT, therefore no additional measurements were taken during baseline and follow up. Patient clinical data was collected from medical records and questionnaire data was then transferred onto a secure database. There were no potential risks or burden involved when completing the questionnaire however the quality of life and self-esteem questionnaire contain questions of a sensitive nature. Such questions are routinely asked as part of the usual clinical dietetic assessment process therefore it was felt this would not affect or bias the data collected. Any potential issues arising from sensitive questions, the weight management service has access to pyschological support from Liverpool PCT's counselling service (The dietetic department became part of NHS Community Health during this evaluation).

All patients who received an appointment letter for the weight management assessment clinic received service information leaflet explaining the dietetic treatment process and could consent to or decline treatment from the service at this point. If a patient consented to attend the dietetic clinic or dietetic lead weight management group programme a separate information sheet and consent form was administered for the purposes of the evaluation. If a patient decided not to take part in the evaluation the participant would be withdrawn from the study and therefore continue with treatment as usual.

The information sheet was written in non-technical terms explaining the aims and objectives of the weight management evaluation with further contact details for the

lead researcher. It was made clear that treatment choice is not part of the evaluation; all that was required was data collection.

The questionnaires are completed by patients at their first clinic or first week of the group programme. Before the questionnaires were administered they are stapled together to ensure patients completed all three tools, furthermore the questionnaires were counted after administering to ensure patient confidentiality.

3.11 Statistical analysis

Data was analysed using SPSS version 17 (2010) All data was coded before analysis.

To test the null hypothesis mean changes in weight, BMI, lipids, fasting blood glucose, Hba1c (if available) and blood pressure at baseline and follow up (3 months) were compared using paired t-tests. A result providing a significance level of P less than or equal to 0.05 was deemed to be statistically significant.

Nominal FIQ questionnaire data is presented as percentages or frequencies. Diet data were analysed using chi-square to detect associations between intake of specific foods. Independent sample t test were performed to compare differences between mean food group score between gender at baseline and three months. A paired t test was used to evaluate changes in self esteem and HRQL at baseline and follow up

Chapter 4: RESULTS

Patient flow from initial contact through to evaluation completion is shown in fig. 4.1. A total of 50 patients were referred by their general practitioner to the specialist weight management programme, between September 2009 – February 2010 of which, 41 returned to follow up at three months (November 2009 – July 2010). The remainder (n=9) did not attend or were followed up at different time points. Anthropometric data were available for 35 patients and 33 patients completed food intake data at week 1 and week 12. In total 12 patients had clinical biochemistry compared pre and post intervention.

Figure 4.1: Process identifying number of patients at each stage of the evaluation.

| Included in pilot n=20 September – February 2010 | **Programme Start** n= 50 Clinical Biochemistry available for n= 25 September 2009-February 2010 |

| **Programme end** **n= 41** Clinical biochemistry available for 12 January – June 2010 | No follow up at 3 months (DNA) n= 9 Or Discharged |

Follow up stage (6 months)
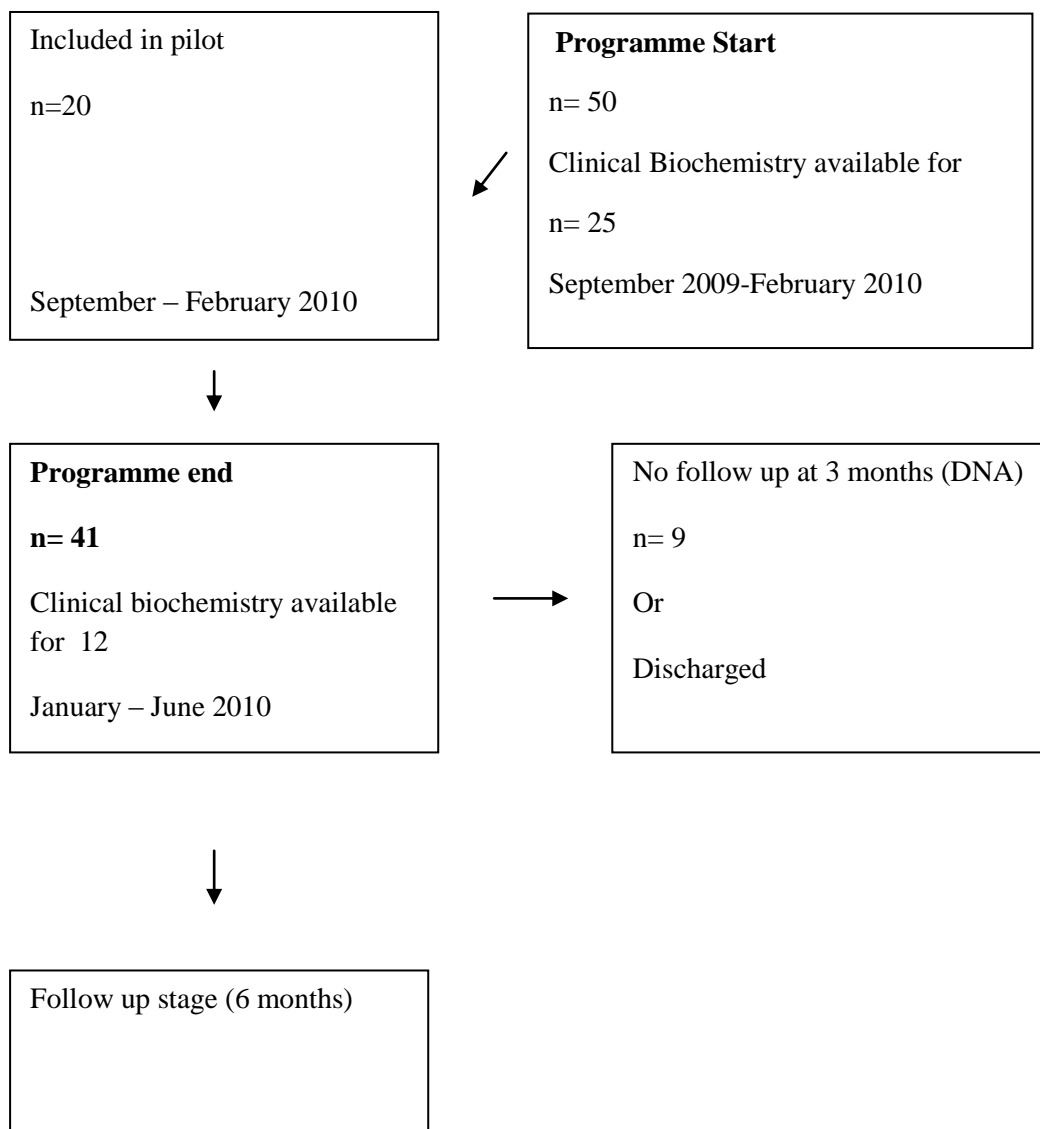
4.2 Pre intervention characteristics

Pre intervention data are presented in table 4.2. The data (male 19, and female 31) are presented as Mean ± S.D. Mean age for patients at the start of the programme was 59 years. 62 % were female and of those who took part in the programme, obesity was severe (mean weight for males 113.5 kg/m^2, BMI 39.3 kg/m^2 and mean weight for females 92.7kg/m^2, BMI 36.5 kg/m^2).

4.3 Clinical data

Clinical outcome data were available for 25 patients, who had been routinely referred by their GP. These patients were referred for weight management advice and all had additional co-morbidities. Of the 25 patients, mean values for total cholesterol were less than 5mmol/L, mean LDL (low density lipoprotein) was under <3.0mmol/l for males, and above optimal levels for females (3.17mmol/L). Mean TG was elevated in males (>2mmol/L).

Mean results for fasting blood glucose (FBG) were within the normal range for males (<5.6mmol/l), a higher mean result for females (6.58mmol/l) indicated impaired glucose tolerance (table 4.3a). In both cases, 7 patients were already diagnosed with diabetes. A high HbA1C was recorded in 1 female diabetic patient >7.5% however this result differed between all diabetic patients and would not be used to determine improved HbA1C at 12 weeks due to insufficient data. Patient blood pressure was also monitored by their G.P., mean systolic blood pressure was above 120 mmHg for 10 patients out of 13 patients (77% of patients), looking at this data in detail one patient's reading was above 170mmHg indicating some patients had severe hypertension on referral to the weight management programme.

Table 4.3a : Mean ± S.D values of anthropometry and biochemistry measures pre intervention						
	Male			*Female*		
	n 19	Mean.	S.D	*n* 31	Mean	S.D.
Height (m)	17	1.71 ±. 07	.07	17	1.6	.056
Weight (kg)	19	113.45	20.80	29	92.62	12.95
BMI (Kg/m^2)	18	39.3	6.40	26	36.5	6.20
Total Cholesterol (mmol/L)	14	4.76	1.00	9	4.92	.87
HDL (mmol/L)	13	1.13	.18	8	1.16	.31
LDL (mmol/L)	11	2.6	.89	7	3.17	.80
TG (mmol/L)	13	2.52	1.81	7	1.91	.83
FBG (mmol/L)	9	5.43 ±1.05	1.05	4	6.58	.68
HBA1C (%)	4	6.08	1.08	3	7.17	.40
SBP (mmHg)	9	140.6	16.74	4	131.8	12.28
DBP (mmHg)	9	80.8	5.16	4	73.8	4.92

4.4 Pre intervention questionnaires

In all, 46 patients completed a food intake questionnaire, 32 patients completed the

Rosenburg questionnaire and 44 patients completed the EQ5D correctly. Incomplete

questionnaires were not inputted during the evaluation period.

4.5 Post programme results (12th week of the weight management programme)

Forty one patients (82 %) returned to follow up at 12 weeks. Nine patients did not attend (DNA).

4.6 Changes in Weight and BMI

Mean weight at three months ranged from 89 kg to 136 Kg for males and 66.6kg to 128 kg for women. Table 4.6a presents mean weight changes at three months. A paired sampled t test was conducted to evaluate changes in the mean body weight for all patients. Mean weight change (chart 4.6b) was approximately 1.99 kg (95% CI 1.12- 2.86). Mean change in BMI (chart 4.6c) at three months was 0.66kg /m2 (95% CI, 0.21-1.10). Participants who attended the specialist programme showed a significant weight loss ($P<0.05$) and lower BMI ($P<.005$) during the intensive period (0-3 months). The percentage weight loss for males was higher (3.4%) than females (1.5 %).

Table 4.6a: Mean values for weight, height and BMI at the start and end of the programme for male and female

	Program Start (n=)		Programme end (n=)		Mean difference for weight and BMI	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Weight (kg)	113.44	92.62	109.54	91.25	**-3.9kg**	**-1.4kg**
BMI (kg/m^2)	39.25	36.45	37.69	36.09	-1.6	-0.35

Overall 28 patients lost weight, 5 patients stabilized and two patients gained weight at 12 weeks

4.6 b+c Paired t-test data

Compared mean values for weight and BMI at the start and end of the programme for all patients.
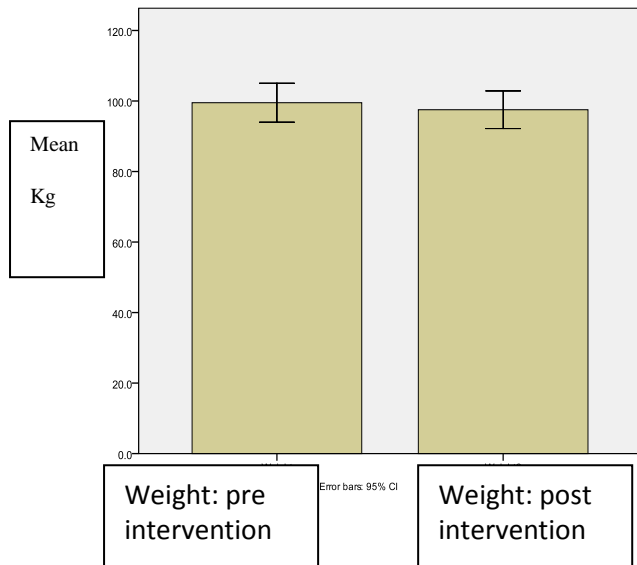
Chart 4.6b **Weight (kg)**   *Chart 4.6c* **BMI**
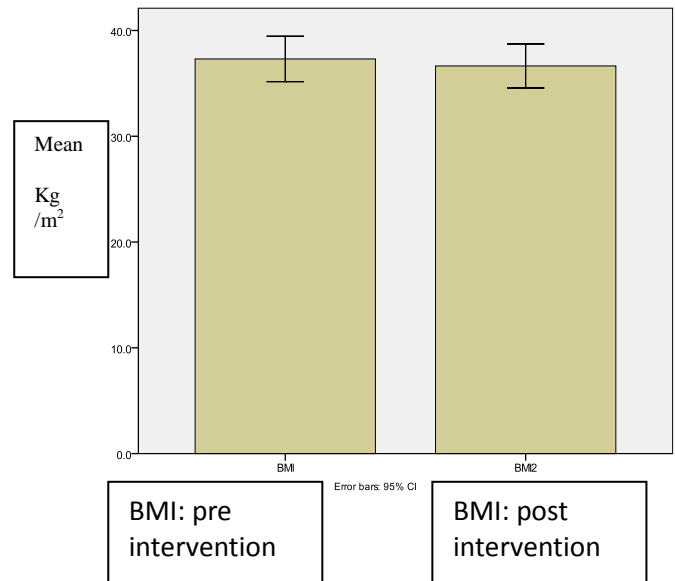
An independent samples t test was used to explore mean weight change between males and females. Male patients lost more weight during the intense phase of the programme, 2.5kg > than females (P<.001) however a significant weight loss result was observed (*P*<.005) for both males and female at twelve weeks.

4.7 Changes in blood pressure and clinical biochemistry

Table 4.7a presents patient blood pressure and biochemistry at the start and end of the programme. The changes in mean total cholesterol, HDL, LDL, TG, FBG and blood pressure were compared using paired sample t tests. Only data which was retrievable from patients who were routinely monitored by their G.P was used in the evaluation.

4.7 Paired t test data for clinical biochemistry and blood pressure

Table 4.7a: Mean values of biochemistry measures at the start and end of the programme.							
Parameter	Program Start Mean	(S.D.)	Program Finish Mean (10)	(S.D.)	95% CI Lower	Upper	P-value
Total Cholesterol	5.09	1.39	5.05	1.37	-.9097	.9897	NS
HDL	1.23	.23	1.2	.27	-.0526	.1193	NS
LDL	2.8	.92	3.06	1.45	-1.47	1.11	NS
TG	1.72	1.54	1.72	.78	-.72	.32	NS
FBG*	5.7	.96	5.96	.97	-.64	.11	NS
Hba1c	6.5	.98	X	X	X	X	NS
SBP (mmHg)	134.7	13.4	131.7	10.9	-7.63	13.63	NS
DBP (mmHg)	76.7	5.85	71.5	5.19	1.27	9.22	P<0.025

* several patients were compared to pre intervention test results

Twelve patients had clinical biochemistry and blood pressure measures to compare pre intervention. Several patients values were compared with FBG values. All values were non significant post intervention, however changes were observed at three months for blood pressure. Although non significant, SBP dropped from 134.7 to 131.7, significant changes were observed for DBP (mmHg) at twelve weeks (P<0.025).

4.8 Food Intake results

The analysis of the diet data was presented as chi^2 for all subjects, males and females could not be analysed separately due to the small sample. Thus data are presented as percentages. Mean intake of positive and negative marker food group's pre and post intervention were analysed using paired t-test (**positive and negative foods, appendix 9.2pp111**).

4.8a Mean intake of positive marker and negative foods (paired t test data)

An overall score was calculated from a list of positive and negative marker foods. Altogether there are 30 negative marker foods and 23 positive marker foods, ticking one food item from the negative or positive marker food list equates to a score of 1. Mean intake of positive marker and negative marker foods are shown in table 4.8a below.

Table 4.8a: Mean intake of positive and negative marker foods.							
Marker	1st week of programme		12 week of programme				P value
	n=		n=		95% CI		
	Mean	SD	Mean	SD			
Positive marker foods (n=20)	5.36	3.21	4.96	4.48	-.88	1.68	*P*=.539
Negative marker foods (n=23)	3.51	2.65	2.02	2.64	.60	2.37	P=0.001

Both sexes significantly reduced intake of negative marker foods (pre programme mean 3.5) after a twelve week period (post programme mean 2.02) by more than one negative marker P=<0.000 indicating a better choice of foods post programme. There appeared to be no significant change between positive marker foods and duration of programme (chart 4.8b).

Charts 4.8b/c summarise positive and negative marker food score pre and post weight management programme with 95% CI.

Chart 4.8b **Positive Marker Food**   Chart 4.8c **Negative Marker**
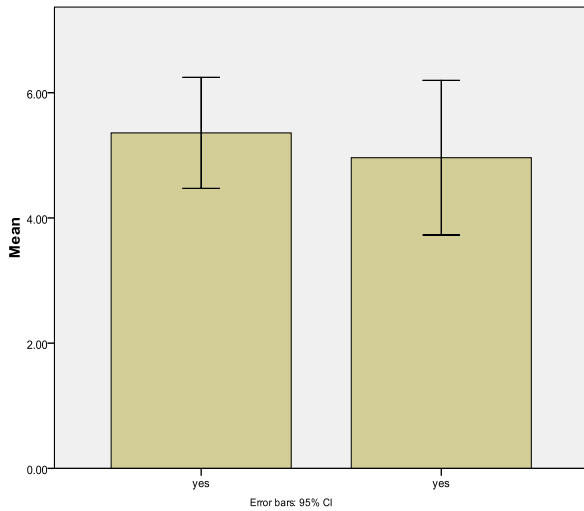
Error bars: 95% CI

Error bars: 95% CI
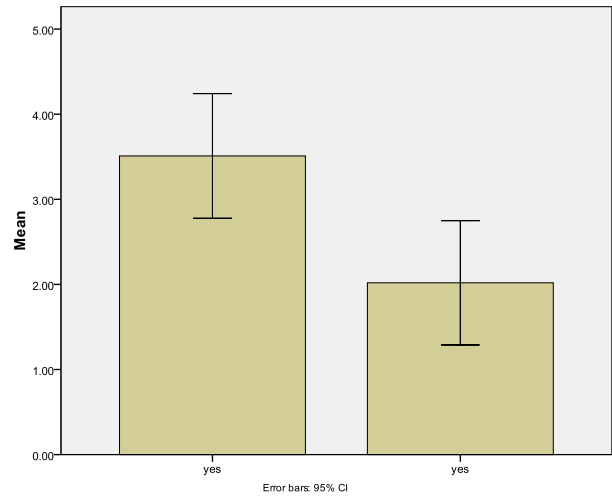
4.9 Reported intake pattern for male and female patients

Charts 4.9a and 4.9b indicate more than three quarters of males and females ate three meals
on a regular basis before and after completion of the weight management programme. There
was a higher proportion of patients who reported they ate at breakfast time after the group
programme (chi^2= 4.09, df=1, P<0.043). Reported breakfast intake in females increased by
23% at twelve weeks post programme, with lunch (8.3%) and evening meal consumption
increasing by (12.9%). The increase in males was less than females who reported a 12%
increase in lunch time eating after the programme.
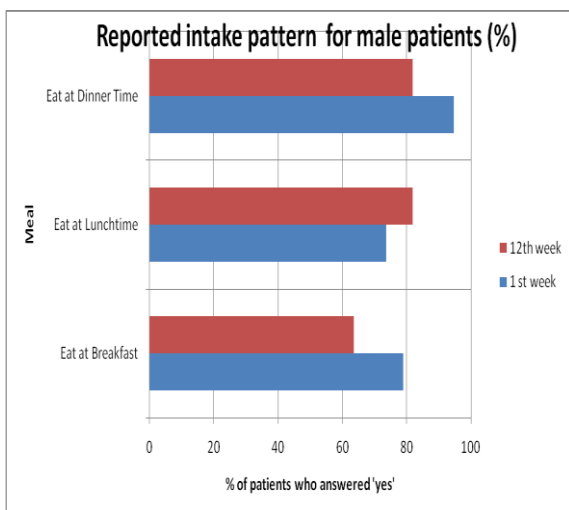
Chart 4.9a   **Chart 4.9b**
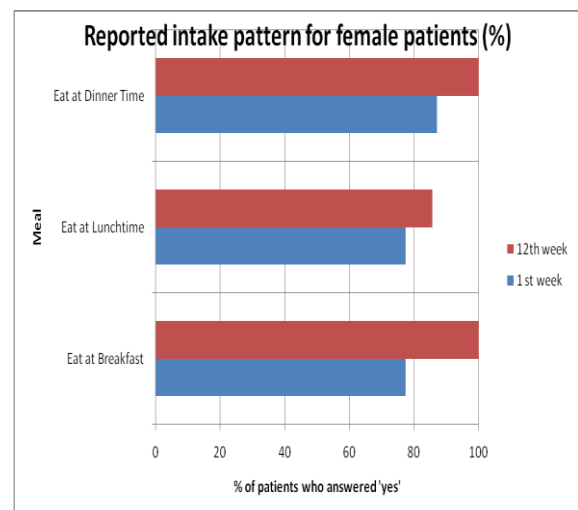
4.10 Intake of selected foods pre and post weight management programme

The following reports the proportion of patients who claimed to have eaten a food item in the previous 24 hours. The proportion of adults eating a high fibre breakfast cereal or wholegrain bread was markedly higher after the programme finished P=0.028. A significant value was observed for intake of salad vegetables P=0.021, thus more patients were eating high fibre breakfast cereal and salad vegetables post programme (chart 4.11). As summarised in charts (appendix 9.3+9.4pp112) fruit, salad vegetables and vegetables consumption increased post intervention for both sexes. Consumption of some food items stayed relatively low, though this was

expected due to changes being most apparent in common foods adults eat e.g. reported fish intake, low fat cheese and low fat yoghurt were similar to that reported on week 1 of the programme which was below 25% of patients. At twelve weeks, 90% of patients reported eating a piece of fruit 24 hours before the questionnaire was administered.

4.11 Reported intake of positive marker foods on the previous day for male and female patients pre and post intervention

Chart 4.11a reported intake of positive marker foods for all patients
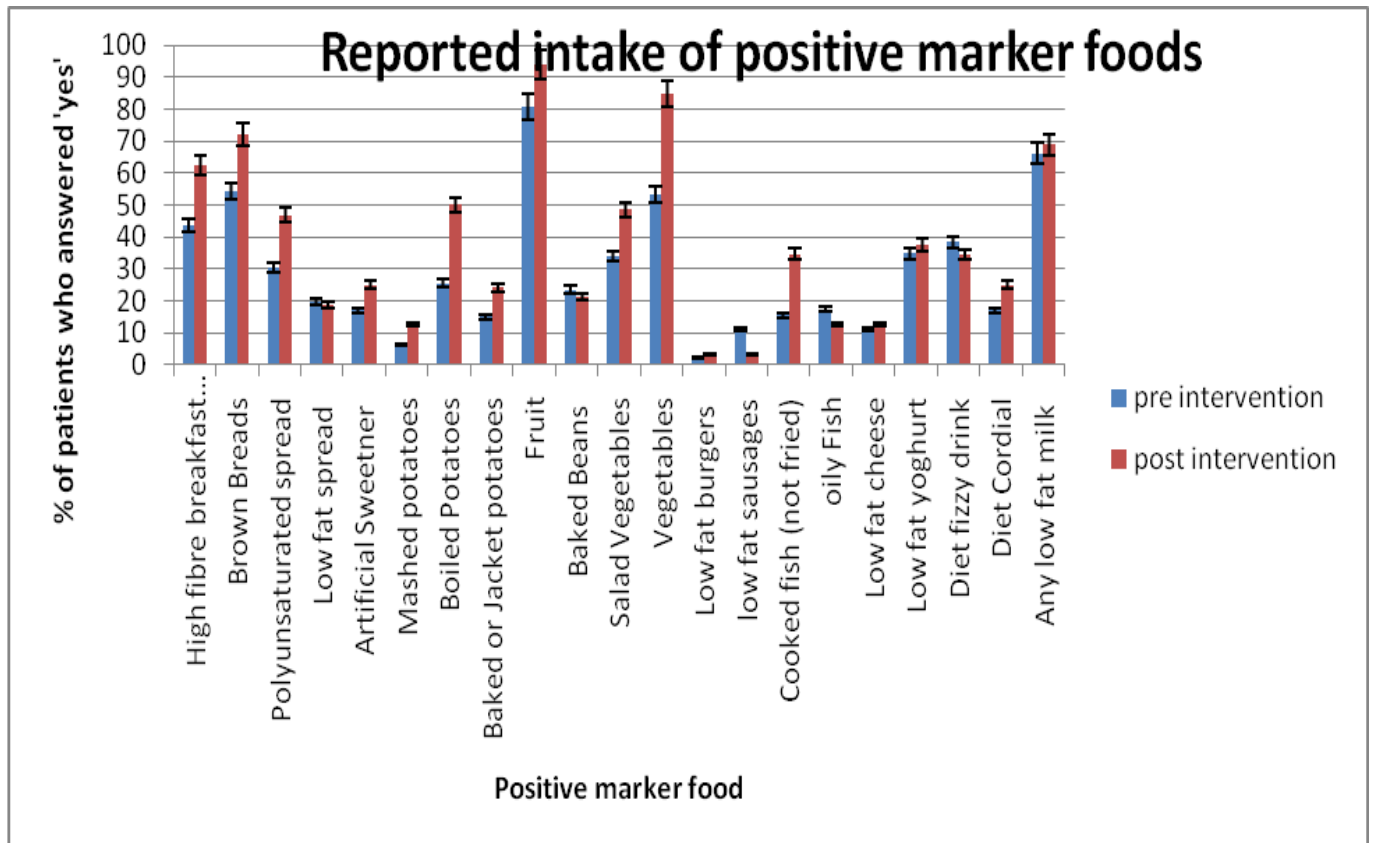
4.12 Negative marker foods

Four of the 23 negative marker foods were reported as having been eaten less by patients post intervention this included butter chi^2=17.83, df=1, P<0.000, chocolate biscuits chi^2=7.226, df=1, P=.007 and adding sugar to drinks such as tea and coffee chi^2=22.15,df=1, P<0.000 . Reported intake of negative marker foods for males and females can be seen in (appendix 9.5+9.6pp113)**.** The six most frequent negative marker foods reportedly eaten pre intervention for both males and females included plain biscuits, sweets e.g. toffees, sugar added to drinks, crisps, adding salt to food and full fat milk. Males reported eating more pre-

sugared cereals (22.2%), adding more sugar to foods (15.8%) and eating meat pies (15.8) pre intervention, this was also the case for post intervention results. Female patients reported eating more butter (28.6%), cakes and pastries (17.9%) pre intervention, however reported % intakes decreased post intervention particularly for the more common foods such as butter and chocolate confectionary. Dietary intake results were not clear for males which, makes the interpretation of the data were difficult as no statistical analysis test could be performed for both sexes to compare both sexes. Chart (4.12a) indicates the intake of negative marker foods was less post intervention.

Chart 4.12a Reported intake of negative marker foods on the previous day for all patients
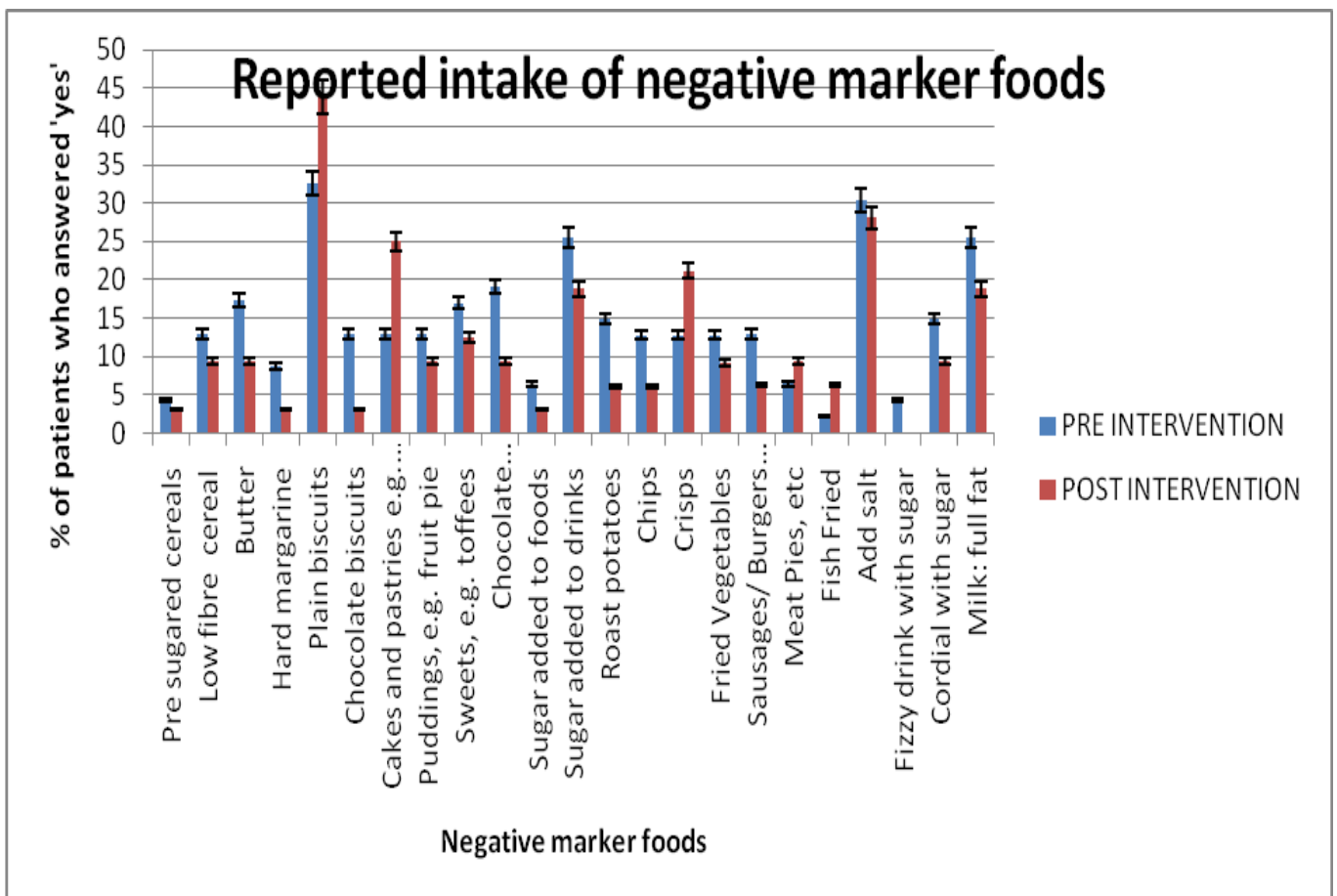
4.13 Changes in self esteem (Rosenberg questionnaire)

The first self esteem questionnaire was completed by 32 patients, comparisons between self esteem statements pre and post programme were made using chi square tests (only significant data is presented) whilst differences between mean self worth scores were evaluated using paired t test (two tailed).

4.13a Self esteem score (paired t test data)

Self esteem was calculated from the responses for the ten self worth statements, in the Rosenberg questionnaire. The possible scores ranged from 0-30. Scores between 15 and 30 are within normal range; scores below 15 suggest low self-esteem. Mean scores over the course of the 12 week programme were similar to the post programme scores (mean 19.76 S.D. 3.64). No significant results were observed when comparing mean self esteem scores pre and post intervention (P=>0.05).

Although no significant results were observed, fewer patients fell into the 'low self esteem category post twelve weeks as indicated in chart 4.13c.

4.13b **Self esteem week 1**   4.13c **Self esteem week 2**
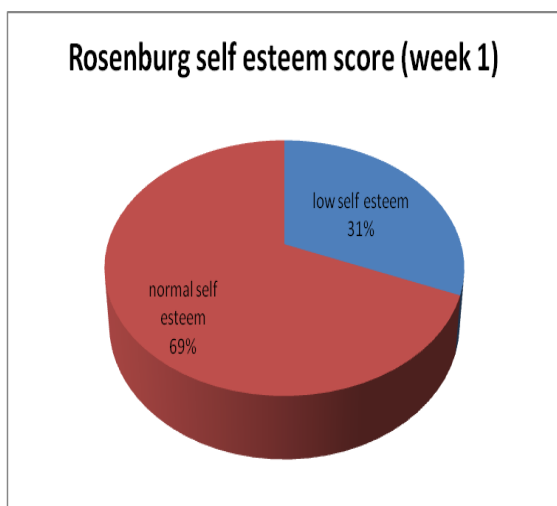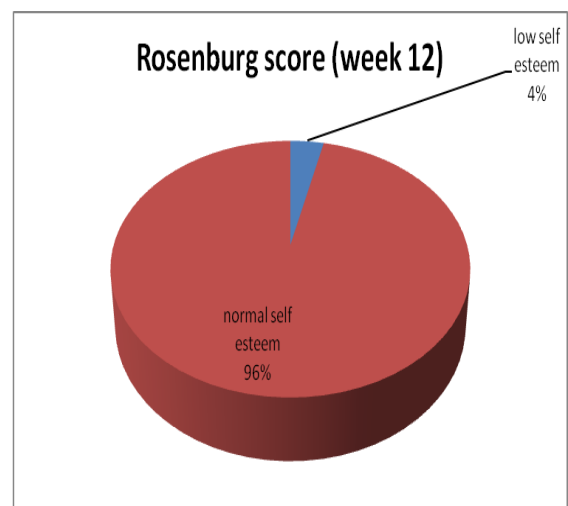
4.13d Self Esteem statements

On completion of the programme fewer patients agreed with the statement 'I wish I could have more respect for myself' (chi^2 = 14.07, df =6, P<0.029), similarly more patients disagreed with the statement 'feel that I am a failure' after twelve weeks (chi^2 = 14.97, df= 6, P=<0.020), conversely fewer patients said they take a positive attitude chi^2 = 14.79, df = 4, P=<0.005. For the remainder statements no significant results were applicable however, table 4.13e, indicated 75.8% of patients said they were 'satisfied with myself', less patients agreed with the statement 'at times no good'. A large proportion of patients agreed with the statements 'I have good qualities', do things well and a 'person of worth' post twelve weeks. The statements including 'not much to be proud off, feel useless and feel that I am a failure stayed relatively low pre and post programme.

Chart 4.13e   Reported % of patients who agree with self esteem statements pre and post specialist weight management programme
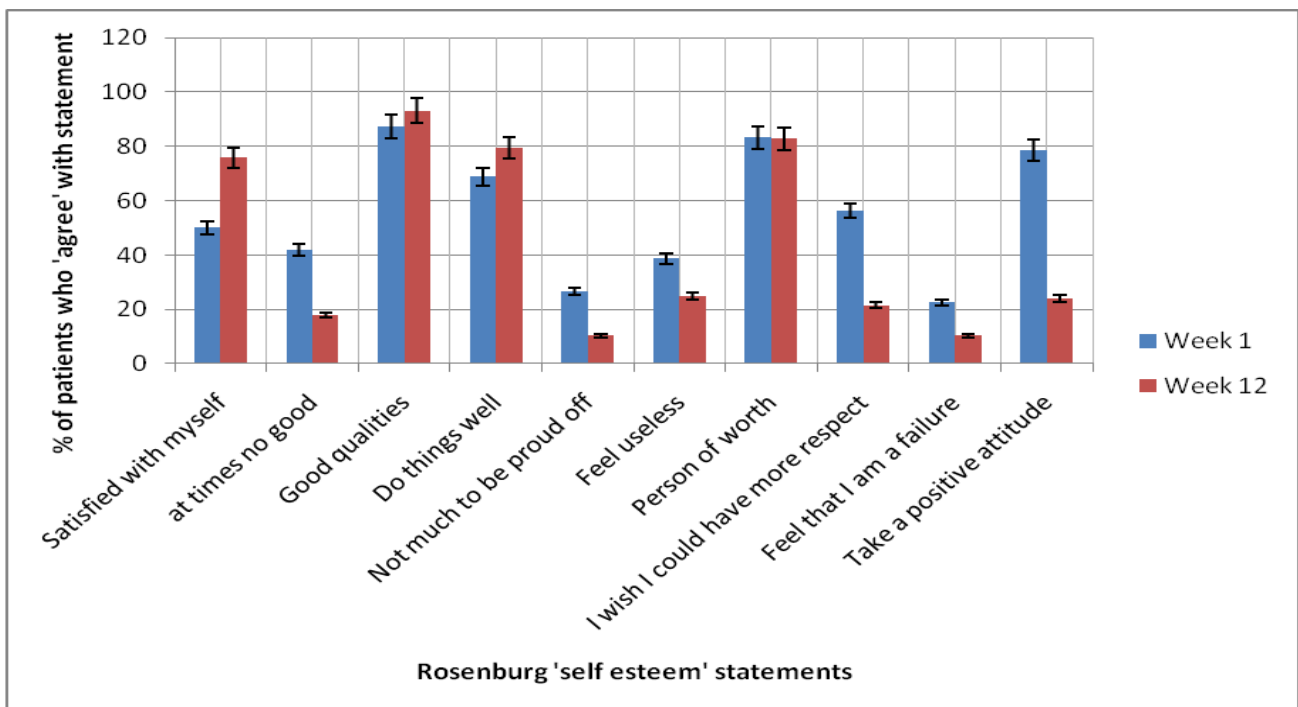
4.14 Quality of life

The EQ5D (Euroqol, 2010) assessed health related quality of life by asking the patient to consider their overall health using five dimensions. Data were available for 33 patient's pre and post intervention. The chart below includes patients who reported 'any problems' with the five dimensions before and after the specialist weight management programme.

Chart 4.14a Self reported health status profile at week 1 and week 12
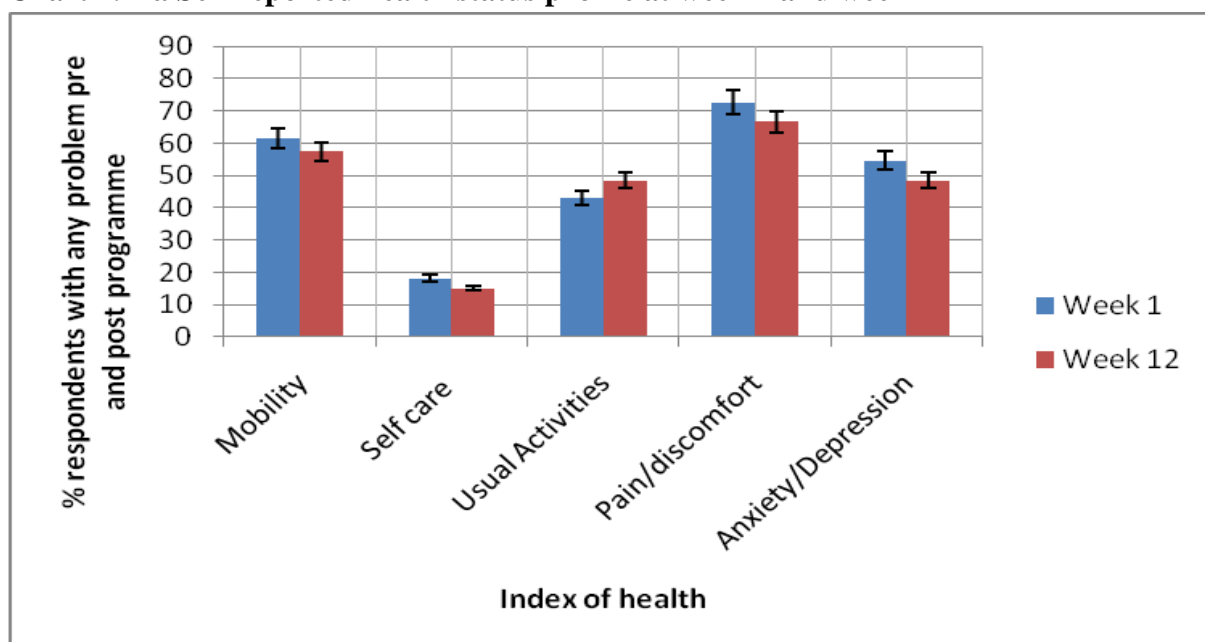
A Change in EQ5D profile for patients reporting improvement 4 dimensions post programme is apparent. The percentage of patients reporting some or extreme problems is lower in 4 out of the five domains at three months.

4.14b Mean self rated health status pre and post programme

The results of the EQ5D visual analogue (EQVAS) scores are presented as a mean score for all patients. Mean scores pre and post programme were compared using a paired t test. To provide a context for these results, mean scores pre programme were compared with scores post programme. Obese patients reported a low mean score of 44.83 (S.D. 34.26) pre programme, which falls below the normal values of similar aged groups in the UK (55-64, score 80). At three months mean scores increased considerably to 70.37, (S.D. 15.86) P=<0.001 (95%CI – 39.96-14.1).

Chart 4.14c Health related quality of life score pre and post programme

SD- Standard Deviation; 95% CI confidence interval
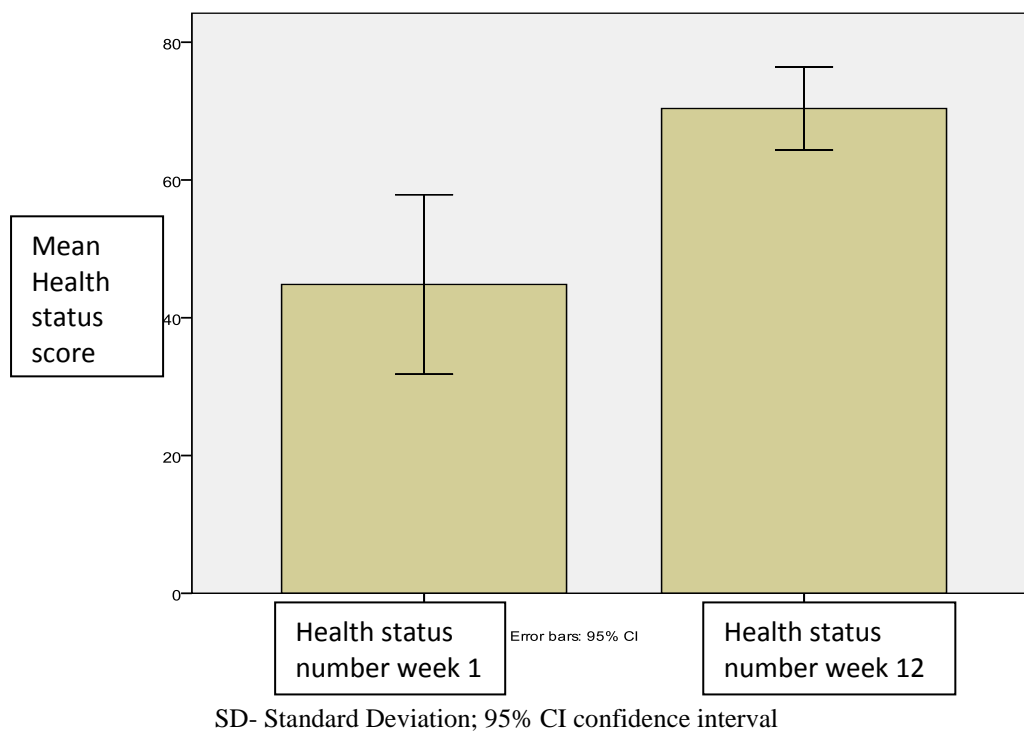
Chaper 5: Discussion

The specialist weight management programme has been shown to be an effective service model in a community NHS setting and continues to be offered to patients referred by their GP for dietetic advice on weight management despite no extra funding. The aim of the evaluation was to analyze and evaluate these findings, sharing lessons of best practice to improve the service offered to patients with a BMI > 30.

The evaluation had three main objectives.

To compare clinical outcomes including body weight, BMI, lipids, fasting blood glucose, Hba1c and blood pressure pre and post 12 weeks of the weight management group programme.

1) To evaluate reported food intake, self esteem and quality of life pre and post 12 weeks of a weight management group programme

2) To identify patients who opted for one to one dietetic intervention and compare findings to group programme patients.

5.1 Aims of obesity treatment

"To devise and deliver dietetic weight management care, based on current evidence and best practice, which helps the individual to make and maintain positive lifestyle changes that are best suited to their particular needs and expectations" (DOM, 2007). The specialist weight management programme, run by the Liverpool community dietitians and community food-workers reflects the aims of obesity treatment within a community health setting. Before the specialist service was introduced, obese patients were given one route of care which included one to one appointments with a dietitian. In 2009 patients were given the choice to attend

one to one sessions with a dietitian, a 12 week group programme or both. The group programme was developed using best evidence available in order to facilitate 5-10% weight loss, change patient eating and exercise behaviours with the expectation of clinical improvement in co-morbid conditions. Uptake of the group programme is deemed to be the most popular choice for patients and has provided a strong element of support from staff and patients. Whilst discussion will relate to the first 3 months of the programme, monitoring of patients will continue for two years.

5.2 Changes in weight and BMI

The success of treatment is affected as much by structure as by the principles and techniques used within it (Foreyt et al. 1981). For many weight management methods there are few scientific studies evaluating their effectiveness and much of this data is from long term studies outside the UK, so these results may not be generally applicable to community clinical practice (NOO, 2009). In spite of the limitations of the present evaluation, and the absence of a control group, treatment effectiveness was shown to be significant. Mean weight reduction at three months was approximately 1.9 kg (95% CI 1.12- 2.86). Though overall weight loss at three months can be improved, a sustained reduction in body weight was the main goal during the programme, not the greatest weight loss in a short time. Rapid weight loss is associated with reduced muscle mass, preservation of muscle mass is particularly important for maintenance of skeletal muscle (Berg, 2002) in obese patients.

Significant differences in weight and BMI were observed between men and women which suggests the programme is suitable for both sexes in a similar community based weight management setting, however analysis of the data indicated male patients finished the treatment most satisfactorily with mean weight loss (-3.9kg) markedly higher than females (-1.4kg) post programme P<0.001). One reason for this weight difference may be due to

female's dieting more frequently than men, successful weight loss is not easy thus such setbacks and periods of weight plateau may deflect the patient from the original goal (Drewnowski & Yee, 1987). Other studies consider that even though men are less predisposed to start weight reduction treatments they are more conscientious in their approach once they have embarked on them (Rossner, 1989). These results could be explained either because there was a higher female to male ratio in group sessions or because it may be easier to change the eating habits of male patients.

 Attrition and non attendance at clinics is a common problem in weight management, furthermore rates of attrition are not comparable among different weight management programmes because they are defined differently from one treatment to another. Despite this, treatment approaches have tried to consider reasons why patients drop out. Honas, Early, Frederickson and O Brien (2003) conducted a large clinical based weight loss programe measuring predictors of attrition. Significant risk for dropout, measured as bivariate relative risk (95% confidence interval) was found among patients who were: females, divorced and; age < 40. In the present evaluation 18% of patients who started the programme dropped out before completing at twelve weeks, which is similar to Liverpool community health department figures for other programmes (10-20%). Explanations given by patients to their dietitian for not attending group sessions included ill health, holidays, time and attending other slimming groups.

The attrition rate was considered accetable during the evaluation period, which was compared to other DNA rates within the dieteic service. Mean BMI (35) at twelve weeks was also significantly lower 0.66kg/m2 (95% CI, 0.21-1.10), a 1.7% reduction when compared with pre intervention results.

5.3 Weight maintanence

Weight loss is difficult to achieve and maintaining weight loss is an even greater challenge, thus a mean % reduction in body weight of male (3.4%) and females (1.5%) patients at three months who lost weight, demonstrated the programme is successful in the short term and aims to compare favourably with other dietary programmes shown to be effective in the treatment of obesity. During the evaluation period five patients stabilized their weight and two patients regained weight. It would be interesting to follow up such patients at six months to investigate factors which may promote weight gain. Identifying factors associated with weight loss maintenance can enhance understanding of the behaviours and prerequisites that are crucial in sustaining a lowered body weight. One study by Elfhag and Rossner (2005) described factors that may act as moderators and mediators in promoting weight maintenance or act as obstacles for long term success. Weight regain is associated with a number of factors including sedentary behaviours and a history of weight cycling, some of which can be related to patients in clinical practice. A cautionary approach should be taken with such explanations for weight loss as the majority of studies were based on behaviour modification treatment's or individual dieting efforts in samples mainly consisting of women.

5.4 Weight Loss and activity

Although patients trying to lose weight should increase their physical activity to 60 minutes per day over five days (NICE, 2006), a meta-analysis review reported 'physical activity does not appear to contribute significantly to weight loss, however it is critical for maintenance of weight loss. In this evaluation, data on physical activity was not collected due to time and ethical review. However a key factor for motivating patients to help increase activity level, was the incentive of a free pedometer which was provided to patients at the start of the

programme. The use of the pedometer created group discussion on steps per day. A review by Bravata, et al. (2007) found pedometer usage was dependant on age, users were more likely to be aged 59 years or above. Interestingly mean age of patients in the present evaluation was also 59 years. Other reasons for patients increasing physical activity included taking their dog for a walk on a regular basis, gardening and line dancing. The NOO (2009) reports such activity as mentioned is rewarding, realistic and achievable.

5.5 Comparing evaluation results to counterweight programme

 One well designed weight management programme in primary care is the counterweight model. Patients who completed the counterweight programme were more likely to achieve a greater weight loss (3.4kg at 3 months) and more likely to achieve a significant weight loss of 5% or more when compared to non compliant patients. The counterweight team also emphasised 'It has to be recognised that not all patients are appropriate for intensive management and more rigorous patient screening using the stages of change model may improve patient selection at time of referral (Counterweight, 2004).

In the present evaluation patients were referred by their G.P and suitability for treatment screened by a Dietitian before treatment commenced to ensure patients were motivated to change. Overall weight loss and BMI change was significant but less than counterweight at three months, however the results from the evaluation show a positive outcome, taking into account this is a new service being offered. Some of the differences between counterweight and the specialist programme are outlined in table 5.5a.

Table 5.5a: Differences between the specialist programme in Liverpool compared to Counterweight**.**

	Step by step	Counterweight
Number of appointments	12	6
Duration with patient	2 hours (group setting)	1 hour
Goal Setting	Similar to counterweight, included 4 practical cooking sessions	Exclusive Goal Setting

Despite the good level of awareness amongst patients in this evaluation to reduce body weight for health reasons, studies have reported subjects are not aware of the benefits a 5-10% loss of initial body weight (NICE, 2006) or why this is expected by their practitioner at least 6 months post treatment. In the present evaluation the number of individuals who lost 5% of their body weight was initially low (5.7%) post programme. At this stage in the evaluation such weight loss was not considered problematic , due to the short time scale, one aim was to support patients to go onto achieve long term sustainable weight loss over time. If weight loss was not achieved or patients had only maintained their weight at 3 months other options for treatment were discussed, with their Dietitian and further support offered.

5.6 Improving cardiovascular and metabolic risk

It is clear that significant health benefits result from a modest weight loss of 5-10% (NICE, 2006), particularly for groups of patients with impaired glucose tolerance (Wilding, 2006). A maintained weight loss of -5% is associated with substantial intrabdominal fat loss and significant prevention or amelioration of comorbidties particularly cardiovascular and metabolic risks (Counterweight, 2008). This is important as half of all patients (50%) who

were refered by their G.P for specialist support to the Liverpool weight management programme had at least one obesity related comorbidity pre intervention. This is concerning as most comorbidities known to be exacerbated by obesity are potentially preventable.

5.7 Clinical Biochemistry

The recording of individual biochemical data for the present evaluation was difficult due to extracting information from patient medical notes. Furthermore clinical biochemistry measures were only available if a practioner had requested bloods to be taken which may have underestimated the number of patients with dyslipidemia, elevated blood glucose and hypertension during the evaluation period. Severe obesity (BMI>35) was apparent in more than two thirds (66%) of the patients pre intervention which reflects the high prevalance of obesity related disease.

5.8 Cholesterol

Obesity can coexists with a variety of cardiovascular risk factors and has been related to greater cardiovacsular risk in a variety of observational studies. The risk of heart disease is doubled in patients with a BMI>25kg/m2 however it is the proportion of LDL cholesterol to HDL cholesterol which influences the degree to which atheroscelerosis is likely to develop (Calle, Thun, Petrelli, Rodriguez, & Heath, 1999).

In the present evaluation different relationships were observed between obesity and hypercholesterolemia. Firstly, mean mean total cholesterol levels of 4.7 mmol/l or above were common pre intervention. This finding was ideally below the population average of 5.7mmol/l however males and females presented different lipid profiles pre intervention. Mean LDL fractions were elevated in females (>3.17mmol/l) while mean TG were elevated

in males (>2mmol/l). High density lipoprotein cholesterol levels did not change over the 3 month time frame.

During the follow up period a small reduction, in total cholesterol was observed post programme however this was not signficant (P>0.05) and other lipid parameters were similar to pre interventions values.

 More robustly a systematic review of thirteen studies between 1966 and 2001 with a follow up of two years reported cholesterol had a significant positive linear relationship with weight change, where change in weight explains about 80% of the cholesterol difference variation (Adj R^2 = 0.80). For every 10 kg weight loss a drop of 0.23 mmol L^{-1} in cholesterol may be expected for a person suffering from obesity (Poobalan et al. 2004). The findings in the present programme are weaker in terms of changes in lipid fractions however a variety of issues should be considered. Firstly, a larger sample size and 6 month data would be required to confirm and compare to pre intervention results. In addition, a major limitation to the present evaluation was that information such as statin medication or saturated fat intake was not recorded.

5.9 Fasting Blood Glucose Level and HbA1c

Obesity is associated with an increased risk of developing insulin resistance and type 2 diabetes. In obese individuals, adipose tissue releases increased amounts of non-esterified fatty acids, glycerol, hormones, pro-inflammatory cytokines and other factors that are involved in the development of insulin resistance. When insulin resistance is accompanied by dysfunction of the pancreatic islet β-cells, insulin fails to control blood glucose levels (Kahn,

Hull, & Utzschneider, 2006). Abnormalities in β-cell function are therefore critical in defining the risk and development of type 2 diabetes.

From this analysis, 7 patients who entered the programme suffered pre-existing diabetes. Unfortunately, measurements for HbA1C were not available for the course of this evaluation. Therefore fasting blood glucose was used as determinant for newly diagnosed diabetic patients during the evaluation. On referral, mean fasting blood glucose was 5.7mmol/l (values, 4.1-7.3), this was within the impaired glucose tolerance range (5.6-7mmol/l). Similar results were found post programme (5.9mmol/l). These results were not significant however the findings reflect the relatively small sample of patients and weight loss achieved especially in women. This also suggests diabetic patients would benefit further by decreasing, 5% -10% of their total body weight before any changes in fasting blood glucose were observed. This observation is consistent with lifestyle interventions which have found risk factors to be decreased in subjects who have lost the most weight post intervention with initial impaired glucose tolerance, type 2 diabetes, or hypertension. This is because changes in risk factors are more likely in subjects with abnormal baseline levels (Douketis, Feightner, Attia, & Feldman, 1999). A limitation to such findings is that many programmes are usually intervention specific and concentrate solely on reducing the risk of one comorbidity, rather than focusing on weight loss as an overall reduction in risk factors.

5.10 Blood Pressure

In epidemiological surveys, thresholds of 140 mmHg (systolic) and 90 mmHg (diastolic) are often used when measuring the proportion of the population with hypertension (DOH, 2008). Any particular threshold used to classify blood pressure as high or low is, to some extent,

arbitrary, as any increase in blood pressure is associated with an increase in risk of cardiovascular disease (Williams, Poulter, & Brown, 2004).

On referral to the weight management programme, mean systolic blood pressure was 140mmhg for males classified as grade 1 (mild hypertension) and 131.8 mmhg (high normal) for females. When comparing the data available at twelve weeks, mean systolic blood pressure results pre intervention 134.7 (+ 13.4 S.D) was lowered post intervention (131.7 + 10.9 S.D) but not significantly different (P =.435) Also several patients were diagnosed with diabetes prior to the evaluation hence optimal B.P goals are lower for diabetic patients SBP <130mmhg and DBP <80mmhg. However positive significant results were found between diastolic blood pressure pre (76.7+ 5.85) - and post intervention (71.5+5.19) which, may indicate obesity in this group of patients is highly related to the risk of hypertension in both men and women. This improvement in blood pressure was an interesting finding considering the majority of patients had not lost 5-10% of total body weight. Other factors especially excessive alcohol consumption have been shown to increase the risk of hypertension, however the population impact is smaller because the prevalence of those factors is lower (Wallace et al. 1981). Secondly greater intake of sodium and lower consumption of calcium have also been linked to the occurrence of hypertension (Sacks, Svetky, & Vollmer, 2001) but this dietary information was not collected during the evaluation period. Advice on decreasing salt intake did form a part of the group programme and 1-1 as part of the health education for weight management.

Previous large cohort studies have shown that a variety of factors, including relative weight, heart rate, alcohol intake and levels of blood glucose, serum protein, triglyceride are related

to hypertension occurrence in one or both sexes, though excess adiposity is one of the most controllable factors (Garrison, Kannel, Stokes, & Castelli, 1987).

Furthermore one major limitation to the evaluation is that throughout the three month period a patient may have been placed on hypertensive pharmacological treatment which may have affected post intervention results.

5.11 Reported food choice

The evaluation compared choice of food not nutrient intakes. Using foods rather than nutrients to represent data has advantages when evaluating dietary intervention in patients. This is because dietary advice has to be in given in terms of foods, it is also logical to assess the diet in the same way. The methods used in this evaluation primarily compared food data pre and post weight management programme. A gold standard method for measuring dietary intake in randomised control trials includes the doubly labelled water method, however validated questionniares such as the FIQ (Johnson et al. 1999) have the potential to collect important information quickly at a lower cost. Previous studies have demonstrated, using food intake questionniares with large samples can minimize errors and improve reliability for dietary analysis (Johnson et al. 1999).

The weight management group programme included a session on the importance of breakfast consumption and included advice on suitable portion sizes of healthier cereals. The results showed that the proportions of patients who reported they ate breakfast after the group programme had significantly increased (P<0.043) when compared to the pre group numbers. 100% of female patients reported eating breakfast post programme compared to 62% of

males. The percentage of male patients reporting to eat three main meals a day was also lower than females. This observation is in agreement with other studies shows a link between obesity and skipping meals, or an inconsistent meal pattern may mean skipping meals to reduce calories. Analyses of behavioural data in men and women suggests eating breakfast is associated with reduced dietary fat intake and can minimizes impulsive snacking in weight reduction programmes (Elfhag & Rossner, 2005) . One cross sectional study (Huang, Fan, Liao, Tsai, & Hu, 2010) investigated the association between frequency of breakfast consumption and prevalence of obesity. The study revealed that the prevalence rate of obesity decreased as the frequency of breakfast consumption increased.

The present findings show that patients reported eating less negative marker foods post programme (P= 0.001) which suggests that they were making healthier food choices. Negative marker foods include foods high in saturated fat, salt and sugar, and are described in the weight management programme as foods to eat less of. There appeared to be little change or increase in positive marker foods post programme possibly indicating patients are already eating these foods but in larger portion quantities. Looking at individual foods the majority of positive marker foods increased post intervention; though this data was not significant. In particular, wholegrain bread, other starchy carbohydrate foods, fruits and vegetables increased post programme which is a positive finding. A higher percentage of patients consumed a piece of fruit or vegetable post intervervention this is a positive finding and possibly indicates patients are more aware of the importance of fruits and vegetables.

The percentage of patients eating foods such as butter and chocolate decreased post intervention, indicating patients were more aware of the association between these foods and increased risk of weight gain or cardiovascular risk. However interpreting dietary data in

terms of percentage points is extremely difficult because further data collection is needed to improve the reliability of such results. Although it maybe suggested that reported behaviour (as opposed to actual behaviour) has changed or that the patients have taken on board the advice given in the group.

Despite government recommendations to reduce saturated fat intake, trends were also identified with particular foods and drinks, one example of this was type of milk. Patients tended to report drinking full fat milk pre intervention instead of semi skimmed milk or 1% milk. The percentage of patients drinking full fat milk post weight management advice decreased, although this data was not signficant. A larger sample size at six months may indicate patients are becoming more aware of the total fat content and that calcium intake will not be reduced by changing to semi skimmed/skimmed milk.

5.12 Health Related Quality of Life

This evaluation considered the impact of obesity on health related quality of life as defined by the dimensions of the EQ5D (Euroqol, 2010) and compared VAS scores in patients who attended pre and post weight management sessions. The majority of patients rated pain and discomfort as the most reported problem. In a cross sectional study by Hitt et al. (2007), results suggested that obese adults were more likely to experience pain, when compared to healthy weight individuals. The present results indicated the percentage of patients reporting some or extreme problems is lower in 4 out of the five domains post intervention. In comparison to other studies similar proportions (>60%) of respondents with high risk for diabetes reported experiencing some pain or discomfort.

Patients rated their own health status (VAS scores) higher than at pre evaluation which resulted in a significant result. Patients' own health score has significantly increased (P<0.001) since attending the twelve week programme and confirms the importance of how patients perceive health post weight management advice. It is unclear in the present evaluation why current health status was improved so quickly in patients after three months compared to the start of the programme, because a number of factors may have contributed to this increased feeling of well being including weight loss, dietary change, decrease in energy intake and social support.

 In one study, several limitations were found when interpreting the results of patients and health related quality of life using the EQ5D (Euroqol, 2010). The present evaluation does not take into account patients who were antidepressant which may influence patients score rating. Secondly it is likely that the health state of obese patients with depression, in addition to a chronic medical disease would be significantly reduced.

5.13 Self esteem

Obesity is associated with alterations in psychosocial health. In addition to eating behaviour and quality of life, a UK study found nearly half of obese patients had anxiety and depressive disorders (Tuthill, Slawik, Rahilly O, & Finer, 2006). Individuals with low self esteem are often more vulnerable to depressed feelings, anxious thoughts and increased health problems.

One of the aims of this evaluation was to examine changes in patient self esteem pre and post programme. It was predicted that self esteem would improve as a result of the programme. Although it was hypothesized that there would be changes in levels of self esteem, the

average scores for all patients fell within the normal levels (scores of 15-30). This finding was consistent across the sexes. Other studies investigating the relationship between weight and psychopathology are inconsistent. Furthermore some items are interpreted differently within studies reducing the possibility of comparing the results found in the evaluation to previous studies evaluating weight management outcomes.

The present results suggest the 12 week programme did not worsen self esteem and did not increase vulnerability which is a positive finding. Wardle et al. (2006) stated that regardless of gender, socio-economic status or ethnicity, reports of depressive symptoms were not significantly higher in obese individuals when compared to normal weight groups (Wardle et al. 2006). In some clinical populations, patients with comorbidities reported a higher number of depressive symptoms. In the present evaluation, obesity was not associated with low self esteem however some patients scores fell below the threshold (<15) before group sessions commenced, suggesting that self esteem may be related with body satisfaction than actual weight and BMI status, however further research is needed to prove such results.

The RSES was a simple tool to administer and evaluate patient self esteem, however some of the questions were left unanswered. It was clear patients felt quite sensitive about some of the questions being asked in the rosenburg. Two patients stated next to question five 'I have plenty to be proud about!' and question eight 'I have always had respect for myself, silly question!'

5.14 Conclusion

It has been established that patients attending a 12 week weight management programme run by community dietitians and foodworkers:

- Achieved clinically beneficial reductions in weight and BMI when compared to to week one of the evaluation

- Showed improvements in food choice were reported: particularly decreases in negative marker foods at week twelve of the programme.

- Improved HRQL scores were greatly improved when compared to week one of the programme

5.15 Limitations

5.15a Comparing group session results to one to one care

- Unfortunately at the time of this evaluation comparing group sessions to one to one dietetic care was not possible due to time and caseload.

- The use of a control group would have provided exact quantification of the programmes full potential and achievement in relation to weight, weight loss and BMI change, though this was not an option due to ethical consideration.

5.15b Six Month Data

- The benefits of this programme on other clinical outcomes and self esteem need further investigation.

- Six month data would be needed to prove whether the programme is effective in the long term and whether improvements are sustained.

- The evaluation will continue at subsequent follow up stages. The next evaluation will focus on patients post six months weight management advice.

5.16 Implications for future research and intervention

This evaluation has contributed to the evidence base and revealed a number of advantages to patients who attend a 12 week group programme. Whilst this evaluation has used the most up to date evidence, there is room for improvement. Where improvements are needed future recommendations for the service and evaluation are outlined below.

5.16a Factors associated with recruitment

- Determination of patients 'readiness' for lifestyle changes should be carried out prior to enrolling them into the programme. Where lack of readiness is found, patients should be referred back to their GP before embarking on the programme

5.16b Increasing physical activity

- Most dietary interventions combined with exercise sessions e.g. gym lessons results in greater outcome and long term weight maintenance.

- Low to moderate intensity exercise class run by a instructor who will increase the confidence of the participants at initial consultation and most importantly how to enjoy exercise (incorporate FITT approach including type of activity, frequency, time and intensity)

- Development of coping strategies when faced with situations that would reduce adherence to exercise and evaluation of this.

5.16c Successful weight maintenance

- Follow up of those patients at six months of those who have achieved weight loss will enable them to maintain their weight loss

5.16d Difficulties encountered in evaluating the service

Problems were encountered with access to or missing post intervention clinical data. Therfore it is vital patients referred with blood results are followed up post intervention in a timely manner.

* Difficulties were encountered when processing questionniare data, which resulted in data being inputted by hand.This process needs suitably trained and motivated staff to do this accurately.

 * A standardised computerised database should be developed for patients attending weight management groups or one to one to care and used locally to facilitate patient monitoring and audit.

* Cost of the group sessions in comparison to one to one dietetic care was not conducted in this evaluation however this will be considered for future service evaluation.

TOTAL WORD COUNT = 16, 632

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NHS
Liverpool
Community Health

Date: _____   ID Code: _____
                                          (For office use only)

Department of Community Nutrition and Dietetics

Food Intake Questionnaire Adult 1

The questions ask about the foods you ate **YESTERDAY**. For each question please tick the **YES** box if you ate the food yesterday. If you did not eat the food yesterday tick the **NO** box. All of the information you give will be treated in confidence and not used by any third party.

About yourself:

Name

Are you: Male [   ]   Female [   ]

Date of Birth   _____

What is your postcode?)_____

What did *YOU* eat and drink yesterday?

	Yes
Yesterday, did you:	
Eat at breakfast	[ ]
Eat at Lunchtime	[ ]
Eat an evening meal	[ ]
Do any physical exercise e.g. walking, jogging, cycling	[ ]

Did you at any time yesterday eat any amount of any of the following:

Breakfast cereals:

Branflakes, Shredded wheat, Weetabix, Allbran, Fruit 'n' fibre?	[ ]
Rice Krispies or Cornflakes?	[ ]
Frosties or Sugar Puffs, Ricicles, Coco Pops?	[ ]

Bread:

White bread (slices or buns)?	[ ]
Brown or wholemeal bread any type (slices or buns)?	[ ]

Butter or margarine

Butter:	[ ]
Hard margarine: e.g. Stork, Echo?	[ ]
Ordinary soft margarine: e.g. Blue Band, Summer County?	[ ]
Polyunsaturated spread: e.g. Vitalite or Flora?	[ ]
Low fat spread: e.g. Outline, Gold, Freeway, Hi-life or Delight?	[ ]
Other spreads e.g. Benecol, ProActive?	[ ]

Biscuits:

Plain biscuits e.g. malted milk, Digestives, Rich Tea etc?	[ ]
Any Biscuits which were covered all over in chocolate:	
e.g. Kit-Kat, Penguin?	[ ]

Cakes and puddings:

Swiss roll (plain or chocolate), doughnuts, scones, individual pies,

jam tarts, custard tarts etc?   [ ]

Fruit pie, sponge pudding, tinned fruit, jelly, trifle, lemon meringue,

cheesecake, milk pudding like rice, semolina, tapioca, custard etc?   [ ]

Sweets & chocolates:

Boiled sweets, fruit gums or pastilles, liquorice, jelly sweets, chews,

toffees, chewing gum etc?   [ ]

Chocolates or chocolate bars like: Mars Bar, Twix, Quality Street,?   [ ]

Ice cream, choc-ices, ice lollies, ice-pops?   [ ]

Did you at any time yesterday eat any amount of any of the following:

Sugar: Yes

Sugar (white or brown) in any drink such as tea, coffee, cocoa etc   [ ]

Sugar (white or brown) on any food such as cornflakes or pancakes?   [ ]

 An artificial sweetener (like saccharin, sweetex, canderel etc)?   [ ]

Starchy Foods

Boiled potatoes?   [ ]

Mashed potatoes?   [ ]

Baked or jacket potatoes?   [ ]

Roast potatoes?   [ ]

Chips?   [ ]

Crisps (any type or flavour)?   [ ]

Fruit:

Any fresh fruit such as apples, oranges, pears, bananas, plums etc?   [ ]

Vegetables and Salad:

Any other vegetables e.g. peas, cabbage, carrots, leeks, green beans,

parsnips, tinned tomatoes, cauliflower, leeks, turnips or sprouts etc?   [ ]

Any fried vegetables e.g. Fried onions, mushrooms or tomatoes etc?   [ ]

Any type of salad such as: celery, tomatoes, lettuce, cucumber, etc?   [ ]

Beans, Peas and pulses:

97

Baked beans?   [ ]
Tinned Peas?   [ ]

Other pulses e.g. lentils, chick peas, kidney beans?   [ ]

Meat:

Steak?   [ ]

Tinned meat e.g. corned beef, luncheon meat, tinned ham?   [ ]

Chicken   [ ]

Ordinary burger?   [ ]

Ordinary sausages?   [ ]

Low fat burger?   [ ]

Low fat sausages?   [ ]

Meat pie, Cornish pasty or sausage roll etc?   [ ]

Minced meat?   [ ]

Did you at any time yesterday eat any amount of any of the following:

	Yes:

Fish fried in batter?   [ ]

Fish cooked in other ways e.g. boiled, steamed, grilled?   [ ]

Oily fish e.g. sardines, mackerel, , pilchards, fresh tuna? [ ]

Cheese:

Cheese e.g. Cheddar, Leicester, Cheshire?   [ ]

Soft cheese e.g. Philadelphia, Dairy Lea?   [ ]

Low fat cheese e.g. Shape or Philidelphia lite?   [ ]

Yoghurt:

Full fat yoghurt?   [ ]

Low fat or diet yoghurt?   [ ]

Other types of yogurt e.g. ProActive, Benecol?   [ ]

Take-away food:

Fish and chips?   [ ]

Pizza?   [ ]

Curries?   [ ]

Chinese?   [ ]

Kebabs?   [ ]

Salt:

Did you put any salt on your food?   [ ]

Did you at any time yesterday drink any amount of the following:

Fizzy drinks

Regular or ordinary fizzy drink? (e.g. Coca-Cola, Pepsi, Fanta)   [ ]

Diet or low calorie sort of fizzy drink?(Diet Coke, Pepsi Max etc)   [ ]

Still cordials (e.g. Orange squash, Ribena, barley water etc)

Diet or low calorie sort of still drink?   [ ]

Regular or ordinary still drink?   [ ]

Milk (in tea, coffee, milkshakes, cocoa or on cereals)

Ordinary full fat milk?   [ ]

Semi-skimmed or skimmed milk?   [ ]

Alcohol

Beer,lager or cider?   [ ]

Wine   [ ]

Sprits Sherry, Port Martini   [ ]
such as whisky, vodka, gin

Self-Esteem

What to do:

Below is a list of statements dealing with your general feelings about yourself. If you strongly agree, circle **SA**. If you agree with the statement, circle **A**. If you disagree, circle **D**. If you strongly disagree, circle **SD**.

1.	On the whole, I am satisfied with myself.	SA	A	D	SD
2.*	At times, I think I am no good at all.	SA	A	D	SD
3.	I feel that I have a number of good qualities.	SA	A	D	SD
4.	I am able to do things as well as most other people.	SA	A	D	SD
5.*	I feel I do not have much to be proud of.	SA	A	D	SD
6.*	I certainly feel useless at times.	SA	A	D	SD
7.	I feel that I'm a person of worth, at least on an equal plane with others.	SA	A	D	SD
8.*	I wish I could have more respect for myself.	SA	A	D	SD
9.*	All in all, I am inclined to feel that I am a failure.	SA	A	D	SD
10.	I take a positive attitude toward myself.	SA	A	D	SD

EQ-5D

Health Questionnaire

English version for the UK
(validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

Anxiety/Depression

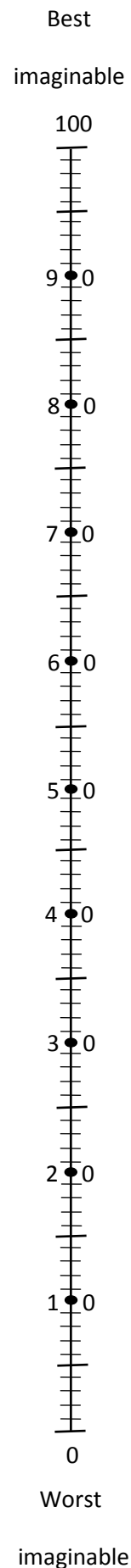|	
I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

9 0

8 0

7 0

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today

6 0

5 0

Your own

health state

4 0

3 0

2 0

1 0

0

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Participant Information Sheet

You have been referred to the weight management team, by your doctor for dietary advice and an appointment has been arranged for you to see the dietitian.

The weight management programme supports those who need to lose weight or where losing weight may help an existing medical condition such as diabetes. As part of the programme you will be offered   an appointment assessment clinic with a senior dietitian. You will then be given the option of a treatment option to meet your personal needs.

The treatment options available include:

- One to one care with a dietitian
- Weight management group sessions with the dietitian and food workers

Service evaluation of a specialist weight management programme

Your treatment is being assessed for effectiveness and quality and we ask your permission to be part of this process. It is therefore important for you to understand why the evaluation is being done and what it will involve. Please take time to read the following information. Ask the dietitian if there is anything that is not clear or if you would like more information.

 What is the purpose of this evaluation?

To review how well the weight management programme is being run and how effective it is in supporting you to lose weight and keep the weight off

It will also assess what impact it has on your medical condition and will assess if attending our service has improved your health and lifestyle. The evaluation will monitor how effective the treatment you receive is at helping you lose weight and manage any other medical problem you may have e.g. raised cholesterol. Measurements such as cholesterol that are conducted by your G.P as part of your normal treatment will be included in the data collected. To do this will be asked to complete a questionnaire which can be returned to your dietitian.

Do I have to take part?

It is completely your choice to decide whether or not to take part. If you decide that you do not want your progress monitored it will not affect your treatment or follow up with the dietitian in any way, you can inform us when you complete the consent form attached.

What will happen to me if I take part?

- You will receive an assessment and agree a treatment plan as normal with the dietitian.
- You will be asked about any other medical conditions you have and the medication you are currently taking.
- Your progress monitored to include changes in your weight and any relevant blood tests which are done routinely as part of your treatment.
- The dietitian will record the results of any other tests that have been conducted by your G.P. as part of your usual treatment e.g. blood pressure
- You will be asked to complete a questionnaire to collect information on your diet, quality of life and self-esteem, before and after your treatment

What are the possible disadvantages of taking part?

Questions of a sensitive nature regarding your medical history will be asked; however such questions are routinely asked as part of your usual assessment and treatment with the dietitian. If you have any questions please speak to your dietitian.

Will my taking part in the evaluation be kept confidential?

All of the information that is collected will remain strictly confidential. Only your dietitian will have access to your medical information.

What will happen to the results?

The data from everyone who agrees to take part will be analyzed. The results will be written up to inform our patients, the service managers and other health professionals of how best to develop services in the future. If appropriate they will be submitted for publication in relevant journals, to help inform other practitioners on ways to improve practice. You will not be identified in any reports or publications.

Who is organising and funding this research?

The research is funded and organised by Liverpool Primary Care Trust. (Department of Community Nutrition)

Who may I contact for further information?

Thank you for taking the time to read this information. If you would like more information about the evaluation before you decide whether or not you would be willing to take part please contact Dr Brian Johnson (at the address above).

NHS
Liverpool
Community Health

Patient identification Number:

Department of Community Nutrition

Abercromby Health Centre

Grove Street

Liverpool

L7 7HG

Tel: 0151-708-9370

CONSENT FORM

Title of Project

Name of Researcher

Please initial box

1. I confirm that I have read and understand the information sheet about the weight management evaluation dated………….. for the above study. I have had the opportunity to consider the information as questions and have had these answered satisfactorily.

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

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

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of patient	Date	Signature
_____	_____	_____

Dietitian	Date	Signature
	_____	_____

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes

Ethical approval

02 November 2009

Ms Dianne Mullarkey
Abercromby Health Centre
Grove Street
Liverpool
L7 7HG

Dear Ms Mullarkey

Study Title: 2-year evaluation and audit of a specialist weight management treatment service for patients with severe obesity

REC reference number: 09/H1005/59
Protocol number: 1

Thank you for your letter of 23 October 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

8 Pilot Study

A pilot study often provides the researcher with ideas, approaches and clues you may not have foreseen before conducting the pilot study. Such ideas and clues increase the chances of achieving clearer findings in the main study. Furthermore it can greatly reduce the number of unanticipated problems because you have an opportunity to redesign parts of the study and overcome difficulties that the pilot study reveals (Meriwether, 2000)**.**

8.1 Data collection for pilot study

In line with the evaluation protocol, height, body weight and biochemical data (if available) was measured at baseline and follow up. Specific sections were identified to give descriptive statistics including food intake, self esteem and quality of life. The first questionnaire (FIQ), Rosenburg and EQ5D were completed at week 1 and completed at week 12 (follow up). The questionnaires were returned to the dietitian.

8.2 Pilot -Self administration

20 patients who were actively taking part in weight management group programmes run by the community dietitians across Liverpool gave consent. The pilot study ensured the researcher that wording of questions was easy to follow to prevent ambiguity before the evaluation commenced.

8.3 Pilot study results

Response rate was high for completion of FIQ and EQ5D (100%) however only 50% of the patients completed the Rosenburg questionnaire (50% of the sample were given the incorrect version of the Rosenburg questionnaire). Firstly mean weight and BMI were compared pre and post intervention using a paired t test.

Table 8.3a Mean weight and BMI at baseline and 12 weeks					
Paired sample	Mean pre intervention	Mean post intervention	Paired differences Std. Error Mean	95% Confidence Interval of the difference Lower/Upper	Sig. (2-tailed)
Weight	101.205	98.989	.6758	.7902/3.6420	.004
BMI	38.406	37.844	.2561	.0209/1.103	.043

Table 8.3a indicates an overall mean weight loss and reduction in BMI over the pilot evaluation period for men and women. The difference in mean weight and BMI also reached statistical significance $P<0.05$.

Positive and Negative Marker Foods

Table 8.3b: Mean positive and negative marker foods score for men and women pre and post intervention					
Paired Sample	Mean pre intervention	Mean post intervention	Paired differences Std. Error Mean	Paired Differences 95% Confidence interval of the difference	Sig. (2-tailed)
Positive marker foods	6.2222	6.4444	.47524	-1.22489/ .78045	.646
Negative Marker Foods	4.0000	3.2778	.61467	-.57461/ 2.01905	.256

Table 8.3b above indicates mean positive marker foods increased by 0.2 and negative marker foods decreased by almost one marker post intervention, no gender differences were associated with a decrease in negative marker foods however large confidence intervals suggest the sample size is too small, the results did not reach any statistical significance.

8.4 Intake of selected foods during the pilot evaluation

The following reports the proportion (%) of patients who claimed to have eaten a food item 24 hours before the questionnaire was administered. The answers were compared pre intervention and post intervention

- A higher percentage of patients reported eating a high fibre breakfast cereal post intervention.

- Interestingly other vegetable intake increased by more than 50% post intervention

- Fish cooked in other ways (boiled, grilled) increased by nearly 10%

- Full fat cheese intake decreased by more than 20%

- Lean meat intake increased by 30%

Though the findings did not reach any statistical significance (cross tabs indicated there was less males than females during the pilot study period to investigate differences pre and post intervention)

8.5 Rosenburg Questionnaire

The following data refers to the Rosenburg questionnaire during the pilot evaluation. An overall score was calculated from ten questions. The scale ranges from 0-30. Scores between 15 and 25 are within normal range; scores below 15 suggest low self-esteem. Mean scores were calculated both pre and post pilot, however only ten patients completed the Rosenburg

correctly due to another form of the questionnaire being circulated. This problem was

rectified before the evaluation commenced.

Table 8.5a Pilot Rosenburg self esteem score pre and post intervention					
Paired Sample	**Mean pre intervention**	**Mean post intervention**	**Paired differences** **Std. Error Mean**	**Paired Differences** **95% Confidence interval of the difference**	**Sig. (2-tailed)**
Rosenburg Score	22.75	22	1.27825	-2.27259/ 3.77259	.576

8.6 Euroqol pilot results

Table 8.6a: The following questions obtained from EQ5D were included in the evaluation to measure quality of life				
Question	Pre intervention (reported yes to the following)	Percentage of sample	Post Intervention (reported yes to the following)	Percentage of sample
Mobility No problems Some Problems Extreme Problems	6 12	**33.3** **66.7**	5 11 1	**27.8** **61.1** **5.6**
Self Care No Problems Some Problems Extreme Problems	13 3 2	**72.2** **16.7** **11.1**	10 3 1	**55.6** **16.7** **5.6**
Activity No Problems Some Problems Extreme Problems	9 6 1	**25.7** **17.1** **2.9**	6 8	**33.3** **44.4**
Pain No Problems Some Problems Extreme Problems	9 6 2	**17.1** **25.7** **5.7**	4 11 2	**22.2** **61.1** **11.1**
Anxious No Problems Some Problems	8 8	**44.4** **44.4**	9 7	**50** **38.9**
Health status Number	Mean =67.5		72.5	

Table 5 shows a declining response percentage for patients who claimed to experience

'Extreme problems' post intervention. Though the EQ5D results do not show any statistical

significance P<0.05 a larger sample size may indicate increased health status on completion

of the weight management evaluation.

9: **Three month evaluation SPSS tables** (for questionnaires only)

Food Intake results

Table 9.2 Reported meal pattern for male and female patients								
	Start of Programme		P=value	End of programme		P=value	1ST week of programme compared with 12th week Value	P=value
Meal	Male (n=19) n (%)	Female (n=) n (%)		Male (n= 11) n (%)	Female (n=21) n (%)		Df=1	
Eat at Breakfast	15 (78.9)	24 (77.4)	NS	7 (63.6)	21 (100)	P=0.003	*4.097*	*P=0.043*
Eat at Lunchtime	14 (73.7)	24 (77.4)	NS	9 (81.8)	18 (85.7)	NS	.395	NS
Eat at Dinner Time	18 (94.7)	27 (87.1)	NS	9 (81.8)	21 (100)	P=0.044	.069	NS

Chart: 9.3 Reported positive marker food intake for female patients
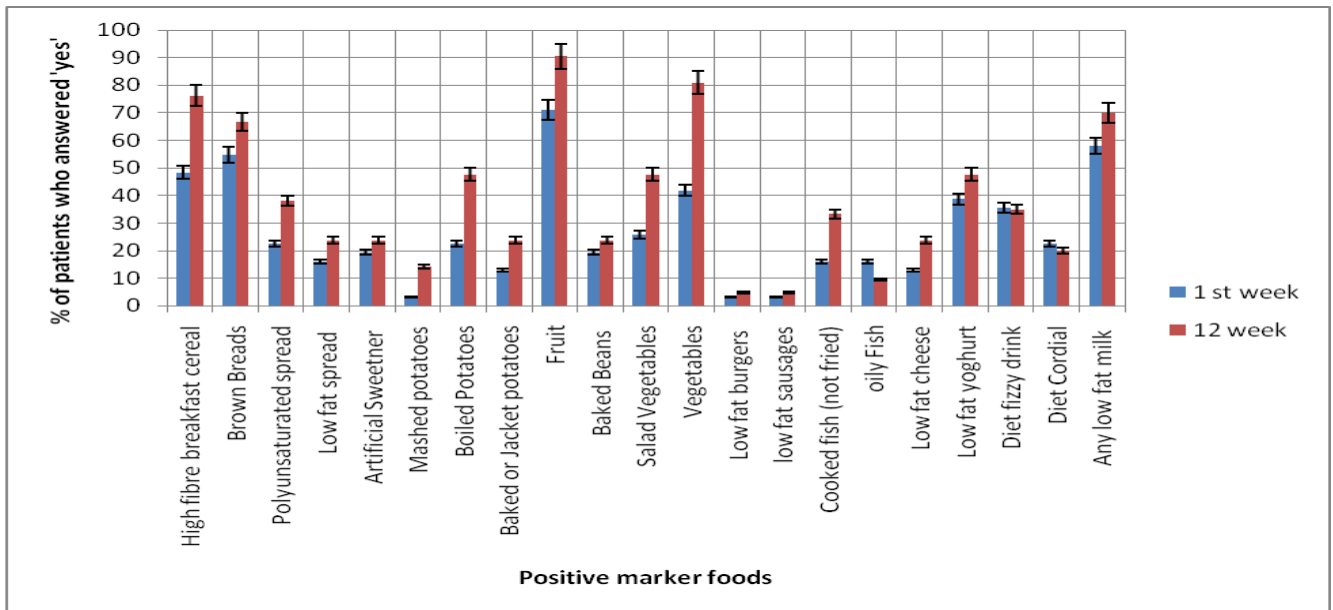
Chart: 9.4 Reported positive marker food intake for male patients
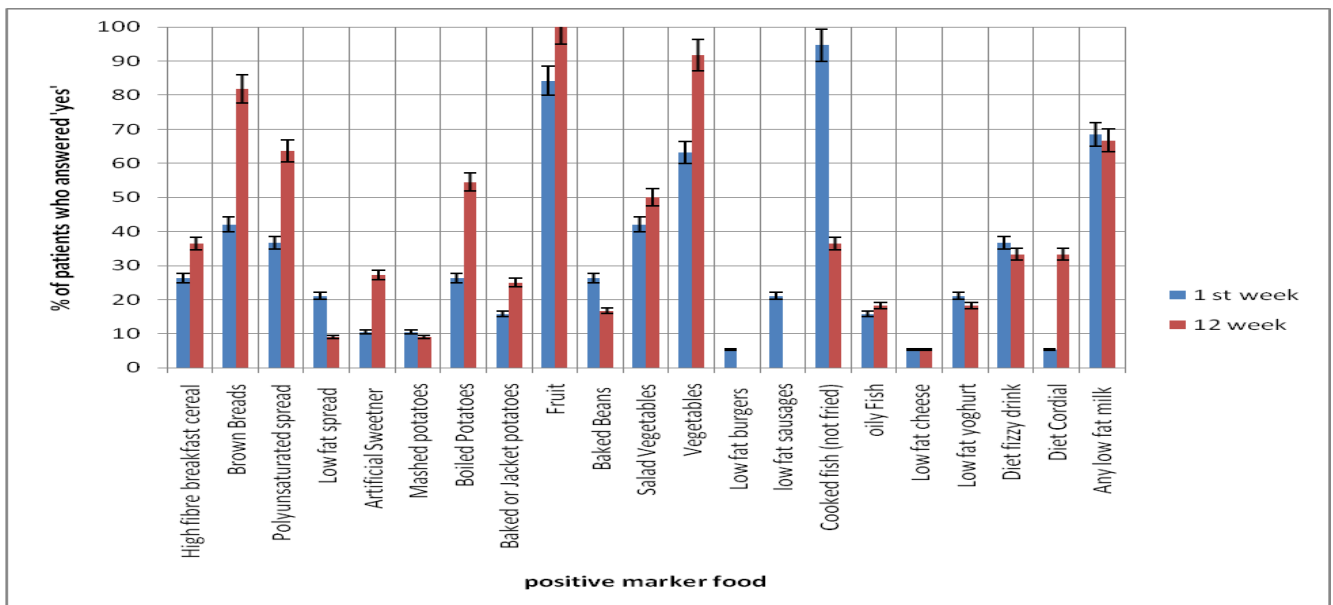
Chart 9.5 Reported negative marker food intake for female patients
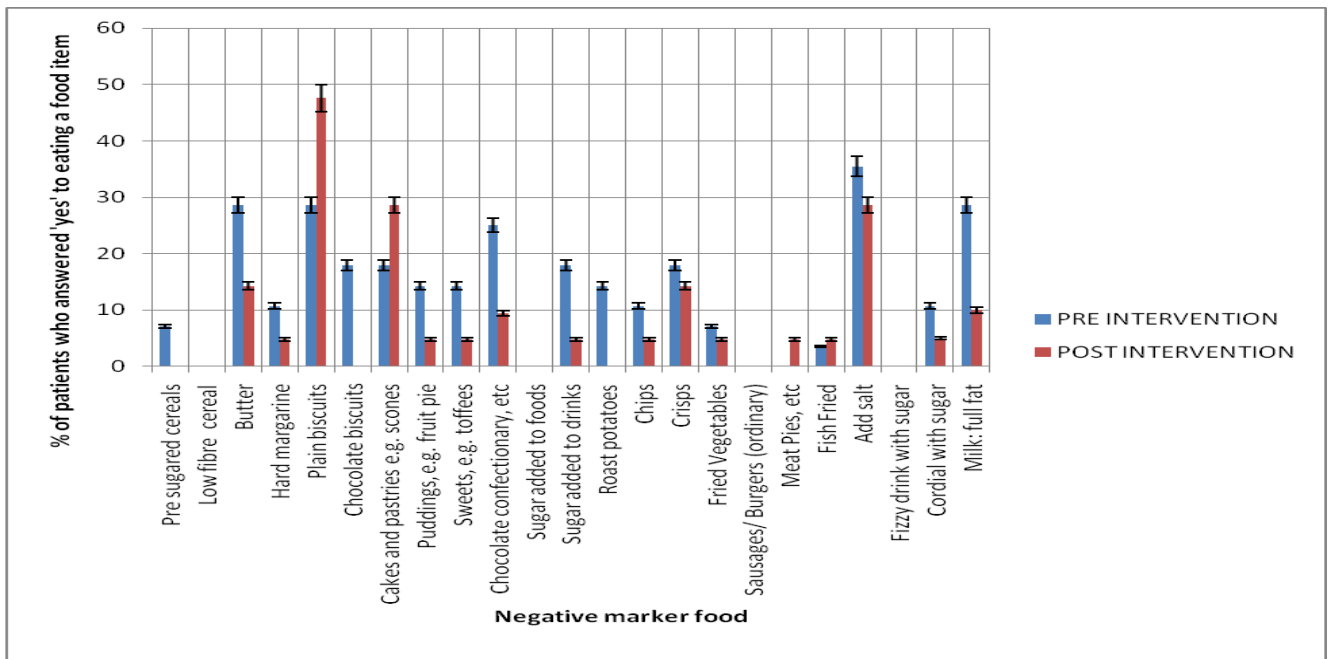

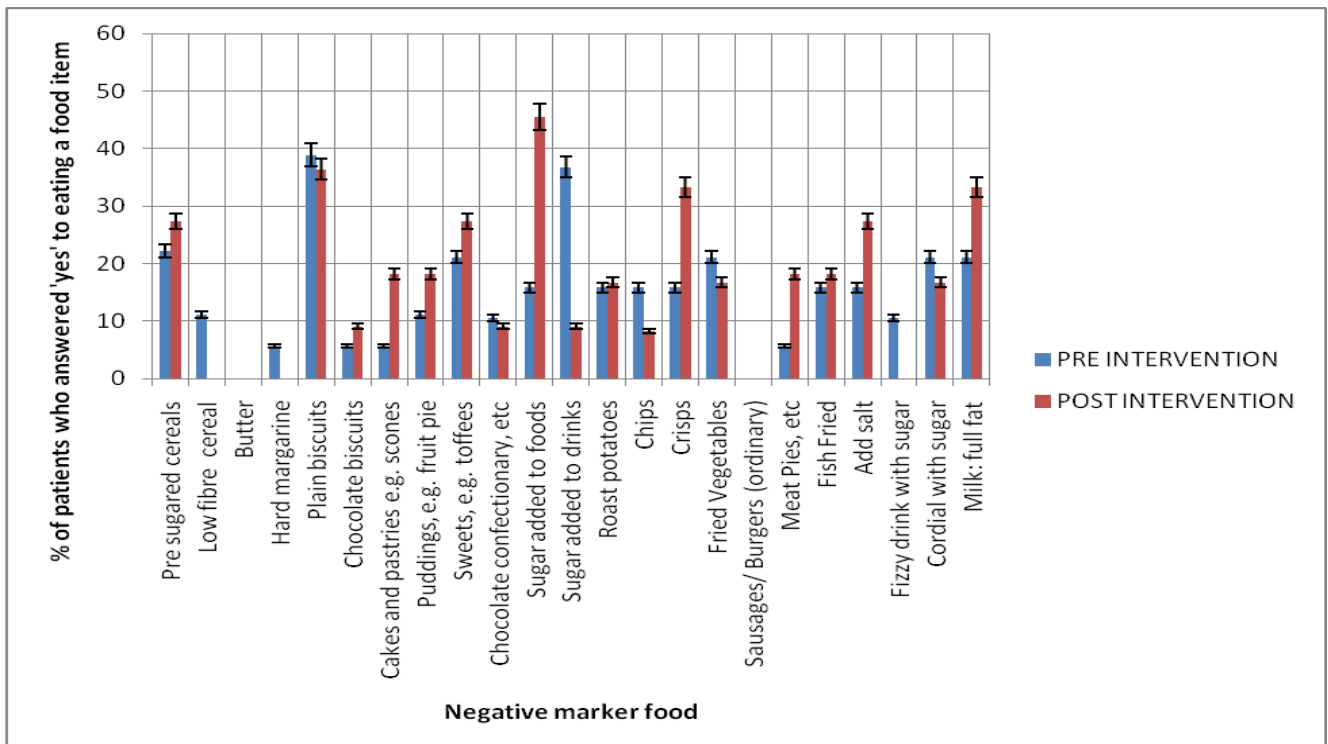**Chart 9.6 Reported negative marker food intake for male patients**

Table 9.7: Mean intake of marker foods by duration of programme (paired t test data)

Marker	1st week of programme		12 week of programme				P value
	n=		n=		95% CI		
	Mean	SD	Mean	SD			
Positive marker foods (n=20)	5.36	3.21711	4.96	4.48057	-.88906	1.68152	*P*=.539
Negative marker foods (n=23)	3.51	2.65752	2.02	2.64931	.60625	2.37488	P=0.001

Table 9.8: SPSS data for 'Rosenburg' self esteem statements

Question	Answer	Program Start	Median answer	Mean +SD	Programme Finish	Median	Mean +SD
Satisfied with myself	Strongly Agree Agree Disagree Strongly disagree	8 (25) 8 (25) 13 (40.6) 3 (9.4)	1.5	1.66 ± .97085	5 (17.2) 17 (58.6) 6 (20.7) 1 (3.4)	2	1.90 ±.72431
At times no good	Strongly Agree Agree Disagree Strongly disagree	1 (3.2) 12 (38.7) 14 (45.2) 4 (12.9)	2	1.68 ±.74776	2 (7.1) 3 (10.7) 14 (50) 8 (28.6)	2	2.11±.91649
Good qualities	Strongly Agree Agree Disagree Strongly disagree	7 (21.9) 21 (65.6) 2 (6.3) 2 (6.3)	2	2.03 ± .73985	9 (31) 18 (62.1) 2 (6.9) 0	2	2.24 ±.57664
Do things well	Strongly Agree Agree Disagree Strongly disagree	7 (21.9) 15 (46.9) 8 (25) 2 (6.3)	2	1.85 ±.84660	5(17.2) 18 (62.1) 6(20.7) 0	2	1.97±.62580
Not much to be proud off	Strongly Agree Agree Disagree Strongly disagree	1 (3.3) 7 (23.3) 15 (50) 7 (23.3)	2	1.93 ± .78492	0 3 (10.3) 14 (48.3) 12 (41.4)	2	2.31±.66027
Feel useless at times	Strongly Agree Agree Disagree Strongly disagree	1 (3.2) 11 (35.5) 15 (48.4) 4 (12.9)	2	1.71±.73908	2 (7.1) 5 (17.9) 16 (57.1) 5 (18)	2	1.89±.87514
Person of worth	Strongly Agree Agree Disagree Strongly disagree	9 (30) 16 (53.3) 3 (10) 2 (6.7)	2	2.07 ±.82768	8 (27.6) 16 (55.2) 5 (17.2) 0	2	2.10±.67320

I wish I could have more respect for myself	Strongly Agree Agree Disagree Strongly disagree	2 (6.3) 16 (50) 7 (21.9) 7 (21.9)	1	1.59 ±.91084	1(3.6) 5 (17.9) 12 (42.9) 10 (35.7)	2	2.14±.89087
Feel that I am a failure	Strongly Agree Agree Disagree Strongly disagree	2 (6.5) 5 (16.1) 16 (51.6) 8 (25.8)	2	1.97±.83602	0 3 (10.3) 12 (41.4) 14 (48.3)	2	2.45±.78314
Take a positive attitude	Strongly Agree Agree Disagree Strongly disagree	7 (21.9) 18 (56.3) 7 (21.9) 0	2	2 ± .67202	0 7 (24.1) 16 (55.2) 6 (20.7)	2 2	1.97±.68048

Table 9.8a: SPSS data for 'Rosenburg' score pre and post evaluation

Paired Sample	Start of Programme n= 21		End of Programme n=21		95% CI of the difference		P
	Mean	SD	Mean	SD	Difference		
Rosenburg Score	19.5714	4.66446	19.7619	3.64561	-1.83561	1.45465	.812

Table 9.9: SPSS 'Euroqol' dimension results

Question	Programme Start	Median Answer	Mean +SD	Programme Finish	Median answer	Mean + SD
	n= 44			n= 33		
Mobility No problems Some Problems Extreme Problems	17 (38.6) 27 (61.4) 0	2	1.6 ± .49254	13 (39.4) 18 (54.5) 1 (3)	2	1.85 ± 1.39466
Self Care No Problems Some Problems Extreme Problems	34 (77.3) 7 (15.9) 1 (2.3)	1	1.57 ± 1.70359	24 (72.7) 4 (12.1) 1 (3)	1	2.15 ± 2.62347
Activity No Problems Some Problems	23 (52.3) 18 (40.9)	1	1.81 ± 1.67433	13 (39.4) 16 (48.5)	2	2.45 ± 2.51360

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Extreme Problems	1 (2.3)			0		
Pain No Problems	11 (25)	2	2.05 ± 1.23805	10 (30.3)	2	2.0 ± 1.39194
Some Problems	26 (59.1)			19 (57.6)		
Extreme Problems	6 (13.6)			3 (9.1)		
Anxious No Problems	18 (40.9)	2	1.93 ± 1.6408	18 (54.5)	1	1.88 ± 1.89996
Some Problems	23 (52.3)			13 (39.4)		
Extreme problems	1 (2.3)			3 (9.1)		

Table 9.9a: SPSS 'Euroqol' health status results pre and post evaluation						
	1st week of programme n=29		12th week of Programme n=29		95% CI of the difference		P value
	Mean	SD	Mean	SD	Lower	Upper	
Health Status Number	44.8379	34.26125	70.3793	15.86419	-36.96965	-14.11311	P<0.001

THE END